WILLIAM RAY CONSULTING, LLC

Sent via ELECTRONIC MAIL to commentletters@waterboards.ca.gov

December 20, 2019

Ms. Jeanine Townsend, Clerk to the Board
State Water Resources Control Board
1001 I Street, 24th floor
Sacramento, CA 95814

Re: Comments – Proposed Environmental Laboratory Accreditation Program Regulations

Dear Chair Esquivel:

William Ray Consulting provides comments on the proposed ELAP regulations. I have extensive knowledge of the regulatory process as I was the author of the current version of ELAP's regulations. I am also very familiar with TNI standards as both a member of several TNI committees and as a trained assessor by TNI.

Comments are provided both as general comments and section-specific detailed comments. There are three items added for reference.

This proposal is so flawed that it needs to be withdrawn immediately. I strongly suggest that ELAP quit developing these regulations in secret and work directly with the laboratory community on revising them.

Sincerely yours,

William Ray
Owner President

Appendices

A – communications received by William Ray Consulting regarding use of third-party assessors

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B – communications received by William Ray Consulting regarding A2LA's ability to conduct an onsite assessment outside of the accreditation process.

C – printout of the Excel worksheet used by William Ray Consulting and referenced in the Economic Analysis provided in the package.

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General comments

This set of regulations, although slightly better than the Draft 3 version, still contains requirements that are not defined; and alter, ignore, or exceed statutory authority. This set also alters or ignores specific TNI 2016 standards (*Management and Technical Requirements for Laboratories Performing Environmental Analyses*, The NELAC Institute (TNI), Rev 2.1, September 1, 2016). These will be elucidated under detailed comments below.

The proposed exemptions to standards

This set includes provisions allowing laboratories to delay compliance with certain sections for up to three years. The exemptions are spread throughout the language. Individual exemptions will be discussed below. Although a seemingly useful approach to weening laboratories into TNI standards, because the exemptions are handled separately in individual sections, it is possible for laboratories to follow one exemption but not another. ELAP will have to keep track of each laboratory's decision on which exemption the laboratory chose to follow. ELAP will also have to track when a laboratory decides to no longer avail itself of an exemption if it is sooner than three years.

It is noted that section 64812.00.h) is the creation of the position of Principle Analyst. The position is not in substitution of any other position listed, such as the Technical Manager. 64812.00.i) invalidates the position three years after adoption. Effectively the position of Principle Analyst is required, but only for three years – a waste of time and resources.

Creation of a system in CCR 64802.10 that bypasses the Administrative Procedures Act

CCR 64801.00.k. This definition is inadequate, conflicts with statute (H&SC 100830.(a).(9)), and matching Fields of Accreditation with Fields of Testing is inappropriate. TNI 2016 V1M2 section 3.1 defines a Field of Accreditation as follows: Matrix – Technology or Method – Analyte. The common usage is Matrix – Method – Analyte. This definition is not the same as Fields of Testing, which are groups of individual analyte/method combinations. H&SC 100830.(a).(9) states that, if ELAP writes regulations, it must include regulations dealing with Units of Accreditation. In the way this statute is arranged, Units of Accreditation would be considered members of

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Fields of Accreditation, however TNI does not recognize groupings of Fields of Accreditation.

This definition does not include any form of definition for the Matrix portion of the full definition. TNI 2016 does not define this term and uses two other definitions for Matrix. The first is under V1M1 section 3.2 where there is a matrix for the Field of Proficiency Testing. The other is under V1M2 section 3.1 where there is a definition for a Quality System Matrix. The matrix in V1M1 section 3.2 is established via decisions by the Proficiency Testing Program Executive Committee and are expressed in Field of Proficiency Testing tables available from the TNI website. The matrix definitions found under Quality System Matrix in V1M2 section 3.1 is necessary to define batch and QC requirements found in later modules. Neither of these definitions are tied to the Matrix portion of the Field of Accreditation.

In addition to the problem with the poor definition in CCR 64801 section 64802.10 contains incomplete information and creates the potential for underground regulations. This potential for underground regulations is possible because the Matrix portion of the definition is not included. ELAP may change the Matrix portion, which will require laboratories to reapply to obtain certification for something they already possessed or will lead to potential violations of CCR 64802.15.

The section also contains authority for State Board staff to determine analytical methods. In one case the Board has no authority to determine hazardous waste methods as that is under the authority of the Department of Toxic Substances Control (DTSC). Where allowed, the Board's capability is severely limited as both the Safe Drinking Water and Clean Water Acts stipulate approved methods for a large number of substances. Any restriction or addition to those approved methods constitutes an unallowed alteration of a regulation. These regulations need to reference allowed alternate test procedure approvals. They also need to stipulate where the Board, or any other agency, does have authority to stipulate methods.

<u>Excessive numbers of citations that are simply regurgitations of statute</u>

OAL standards state that regulations are not to be simple regurgitation of statutory language. This proposal contains large numbers of such repeats of statutory language that a number was not attempted. The most aggreges use of regurgitation is in section 64814 where statute provides authorities for denial, suspension, revocation, and citations that state what noncompliance actions are considered reasons for the above actions. If allowed, the statutory reference will state "and any other violation of statute or regulation." Even though the section expands on regulations each subsection invariably ends with "and any other violation of regulation."

Failures to comply with statutory limitations and creation of processes to avoid due process.

Reciprocity in CCR 64802.00.(b).

First, there is no authority for reciprocity and any agreements can only be between the Board or possibly the Governor and the other agency. Reciprocity would include recognition of ELAP certification by the other agency; which has not been the case. Statute provides for recognition only. There is significant question about the information requested for a laboratory seeking ELAP certification via reciprocity. CCR 64808.10.(b) establishes that ELAP will only recognize other programs for reciprocity if their program is at least as stringent as ELAP. The issue created here is that only 13 states are TNI Accrediting Bodies, which means the rest of the states operate a program of some other type. In many cases, other states, even those offering TNI only offer accreditation for drinking water tests. This regulation has the effect of limiting interstate commerce. Examination of ELAP's certificates issued to out-of-state labs will show that most are certified for hazardous waste testing. If another agency, under a reciprocity agreement determines a laboratory competent and issues a certificate then ELAP is not in a position to question that decision having already ceded authority to that agency via the agreement. There is no necessity to collect information relating to PTs or onsite assessments as ELAP has determined them equivalent. The only action ELAP can take is against the other agency and only if there is evidence of impropriety. Section 64808.10.d) is in violation of H&SC 100845.(a) which states certification is for 24 months.

Interim certification provided for in section 64802.25.k)

In this section, ELAP state interim certification may be granted if more time is needed to complete the onsite, however, ELAP requires as part of the application package, proof of completion of the onsite (64802.00.a).5)). H&SC 100850.(c) states that interim certification can only be granted if the laboratory has filed a completed application. Failing to provide the required onsite information in the application package makes the package incomplete.

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ELAP also states that interim certification lasts until it expires (64820.k).2).C)), however, H&SC 100850.(c) states interim certificates do not have an expiration date. ELAP has failed to understand that the year timeframe in 100850.(c) is how much time ELAP had to complete the process. 100850.(c) fails to state what happens if the process is not complete within the year.

Use of Third-Party Assessors in section 64802.20

One of the major issues with this section is the requirement in CCR 64802.20.(c).(1) that laboratories with sophisticated technologies must use a third-party assessor body. Assessor Bodies are defined in statute under H&SC 100825.(c).(2) as those who execute the accreditation process (includes receiving and reviewing applications; documents; PT sample results; and onsite assessments). H&SC 100837 states those are in accordance with TNI or federal agency criteria. TNI recognizes governmental and non-governmental accrediting bodies; EPA recognizes drinking water accreditation bodies via Primacy requirements in 40CFR Part 142; and both the Departments of Defense and Energy operate accreditation programs that are, at the core, TNI based. These are the only bodies that would fit both requirements.

ELAP attempts in 64802.20.c).2).D) to add by stating anyone that ELAP contracts with, however 100837 clearly states who ELAP may contract with and those are the entities already listed in A) through C). ELAP has made that clear via communications with me, as noted in the attached (Appendix A) e-mail communications. Of note is that the current entity, namely NV5, does not meet the definition and ELAP's use of this entity to conduct onsite assessments is potentially unlawful.

TNI does recognize contract assessors for accrediting bodies, but these do not fit the requirements and ELAP itself in communications with one of these contract assessors reaffirmed this.

This means that those laboratories who are required to use assessor bodies will be required, if they can even participate, to seek a second accreditation since these bodies do not offer assessment functions outside of the full accreditation process (see attached communication with A2LA – a TNI recognized non-governmental accrediting body in Appendix B). This cost was not captured in the financial assessment. Before considering this restriction in regulation, ELAP should have amended statute to change from one that handles the full process to those who offer assessing-only services.

Use of "Withdrawal" as a means of avoiding due process

In sections 64808.00.d).2); and 64808.05.c).2) states that applications not completed by 30 days from notification of incomplete information will be withdrawn. This is contrary to H&SC 100850.(a).(5) where ELAP is required to deny based on a failure to comply with a regulation (64802.00 regarding application packages). 100855 states all denials are to include formal notification and the right to a hearing.

In section 64808.10.g), ELAP proposes to withdraw certification if under reciprocity if their certificate is denied, revoked, or suspended. ELAP cannot simply withdraw certification as statutes state they must be denied, revoked, or suspended by ELAP with all of the provisions of 100855.

Failure for fees to comply with 100847.(f).(1)

ELAP has made it clear at fee workshops that they set fees based on trial and error with a goal to generate revenue to match their budgeted allotment. However, ELAP in doing so, violated H&SC 100829.(f).(1) which requires conforming to the requirements in the California Constitution, Article XIII A, section 3. Subsection (d) requires that fees be based on actual effort called for. ELAP in using the trial and error method has not taken into account the actual effort necessary or costs associated with the activity. As example, using a flat rate for each assessment does not account for the number of staff persons, the number of days onsite, or the travel costs.

At the December 18th workshop, ELAP stated that onsite assessment fees were based on 2-3 days effort; including travel time. ELAP will likely go to remote small utility labs in such cities as El Centro or Susanville. Each of those will require two nights hotel stay and two days travel time in addition to the time at the laboratory. A similar lab in any of the metroplexes will not require the travel days or hotel stays; yet both are charged the same fee. This means that remote labs will get fewer hours onsite than a closer laboratory.

Failure in the Economic Analyses

The economic analysis is severely flawed for the following reasons

The assumed costs for hiring personnel are based on private section and unrelated job descriptions. The databased used only lists Chemical Technicians while the likely need will be for more competent persons, such as Quality Managers. The database contains information across a broad spectrum of industry types and is not specific to the environmental laboratory field. ELAP failed to account for the fact that most hires will be by governmental bodies. The salary difference is almost 2-fold based on a recent survey of laboratories who are considering hiring because of the regulations.

ELAP failed to account for the need to pay for a second accreditation for those laboratories required to seek a third-party assessor. The entities listed by ELAP do not conduct onsite assessments only but require application and fee payment for their accreditation. That cost must include annual fee payments as well.

ELAP failed to account for the resources necessary to develop the extensive recordkeeping system required by TNI standards. ELAP seems to think that all is needed are policies; procedures, and a quality system manual, however, compliance with TNI standards is measured through the records measuring conformance to those policies, procedures, and the quality system manual. There are over 170 citations where the word "Record" is used as a verb in the standard. Producing those documents is simple; estimated to be about 100 to 200 hours effort. Those who have experience in these matters, note that an additional 800 to 1000 hours are necessary to devise and refine the recordkeeping system. Those persons also recognize that it will take the first onsite assessment after accreditation to find most of the missing elements.

ELAP rejected information on the costs of bringing a laboratory into compliance because they stated the costs of approximately $117,000 was excessive. ELAP did not read the document correctly or possibly attempted to dismiss it out of hand as that cost was associate with hiring a consultant full time to do everything. The costs associated with just developing the documents ELAP focused on is more in the neighborhood of $20,000 to $30,000. A printout of the Excel spreadsheet is attached for reference (Appendix C).

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Detailed discussion of individual sections

CCR 64801.00 Definitions

- 64801.00.b. This definition is contrary to statute. Accreditation is defined as something issued by a TNI accrediting body, which ELAP is not. H&SC 100850 states laboratories apply for ELAP certification or NELAP accreditation.
- 64801.00.c. This definition is superseded by H&SC 100825.(c).(2) where these entities are called "Assessor Bodies".
- 64801.00.e. This definition is already defined in statute (H&SC 100880) and is unnecessary.
- 64801.00.i. This definition is already defined in statute (H&SC 100850.(b))
- 64801.00.j. This is defined in statute (H&SC 100825.(c)).
- 64801.00.k. This definition is inadequate, conflicts with statute (H&SC 100830.(a).(9)), and matching Fields of Accreditation with Fields of Testing is inappropriate. Several sections in the H&SC make it clear that laboratories may gain or lose both Units and Fields of Accreditation (H&SC 100830.(b), therefore comparing Fields of Accreditation to Fields of Testing is contrary to statute. TNI 2016 V1M2 section 3.1 defines a Field of Accreditation as follows: Matrix – Technology or Method – Analyte. The common usage is Matrix – Method – Analyte. This definition is not the same as Fields of Testing, which are groups of individual analyte/method combinations. H&SC 100830.(a).(9) states that, if ELAP writes regulations, it must include regulations dealing with Units of Accreditation. In the way this statute is arranged, Units of Accreditation would be considered members of Fields of Accreditation, however TNI does not recognize groupings of Fields of Accreditation. This definition does not include any form of definition for the Matrix portion of the full definition. TNI 2016 does not define this term and uses two other definitions for Matrix. The first is under V1M1 section 3.2 where there is a matrix for the Field of Proficiency Testing. The other is under V1M2 section 3.1 where there is a definition for a Quality System Matrix. The matrix in V1M1 section 3.2 is established via decisions by the Proficiency Testing Program Executive Committee and are expressed in Field of Proficiency Testing tables available from the TNI website. The matrix definitions found under Quality System Matrix in V1M2 section 3.1 is necessary to define batch and QC requirements found in later modules. Neither of these definitions are tied to the Matrix portion of the Field of Accreditation.

- 64801.00.n. H&SC 100825.(c).(18) defines primary accrediting body in terms of TNI only. This definition would expand that definition beyond the meaning applied in statute.
- 64801.00.o. TNI establishes the Quality Manager position in V1M2 section 4.1.5.i and set duties in V1M2 section 4.1.7.1. This definition simply repeats what is in the 2016 standard. It also does not recognize that the Quality Manager and Technical Manager can be the same person (V1M2 section 4.1.7.1) and that these same duties apply to the Technical Manager as well (V1M2 section 4.1.7.2.c).
- 64801.00.q. Revocation is already defined in statute (H&SC 100825.(c).(10)
- 64801.00.r. This definition only has applicability for one section, which is slated to be non-operational three years after adoption. This definition needs to be in that section only.
- 64801.00.t. The recognition of the State Board (Board) as the State Water Resources Control Board is already stated in H&SC 100825.(c).(12).
- 64801.00.u. This definition is already defined in H&SC 100825.(c).(13).
- 64801.00.v. Although such a relation can be made between the current position called Laboratory Director and Technical Manager, it leaves open who will take on the role of Management (including the undefined Top Management) and subsequent duties cited in TNI 2016 standards. Under current regulations (CCR 64801.(f)) the Laboratory Director is responsible for all technical and operational duties related to operating a laboratory. Technical Managers in TNI 2016 V1M2 section 4.1.7.1 are responsible for technical operations. V1M2 section 4.1.5 clearly separates management from technical and, along with V1M2 section 4.1 and others, places operational control in the hands of management. TNI 2016 V1M2 section 4.15 places review requirements on management, not Technical Managers. Other sections also provide duties to management, not to Technical Managers.
- 64801.00.w. H&SC 100825.(c).(14) already defines TNI.
- 64801.00.y. The definition is for trailers yet the section on Mobile laboratories includes vehicles, vessels, and even airplanes. Those are not defined anywhere in statute or regulation.

CCR 64802.00

This section is on the necessary information to be provided in an application. H&SC 100840 establishes authority to request information via an application and lists specific items and then grants authority to request any information necessary to determine compliance with statute or regulation. This set includes the specific items cited in statute but include items not necessary to determine compliance or are without definition.

- CCR 64802.00.(a). Although ELAP needs a full set of information when a laboratory files for its first certificate, but there is no reason for any of the same information to be constantly repeated with every subsequent application beyond those cited in H&SC 100840.(a) through (c).
- CCR 64802.00.(a).(1).(B); 64802.00.(b).(1).(B). ELAP asks for "type" without defining what is meant by this term. Does it refer to CCR 64810.00 through 64810.10 or is there another meaning. Also, within that request is the identification of regulatory agencies reported to by the laboratory. This is meaningless as laboratories are not required to report compliance data to regulatory agencies, but to the regulated community. Even though there are requirements in CCR 64814 for reporting drinking water data, that data is not for compliance testing, but to deter regulated drinking water agencies from altering laboratory data to avoid noncomplying data. Even if a laboratory takes on the role of providing information to regulatory agencies they do so under the guise of the regulated entity. Commercial laboratories have no direct reporting beyond those relating to drinking water as stated above.
- CCR 64802.00.(a).(1).(F); 64802.(b).(2).(F). There is a request for documentation supporting an Owners Agent's authority, but there are no requirements for what that documentation may be. Is it a letter, memo, proclamation, or declaration? It does not include how that might be obtained if the Owners are actually the residents of a governmental body.
- CCR 64802.00.(a).(2).(A); 64802.00.(b).(2).(A). The requirement is for a Quality Manual complying with V1M2 4.2.8.3 and 4.2.8.4. These two section establish the formatting and contents for the Quality Manual, but they do not reference any other section within the TNI 2016 standard. Therefore, the Quality Manual is without a need to meet any other 2016 TNI V1M2 the rest of section 4 or section 5; or the contents of Modules 3 through 7. This brings up a conflict with CCR 64802.05 where the quality system is defined, but is not tied to the Quality Manual.
- CCR 64802.00.(a).(2).(B) This is the first example of an allowed three-year exemption. The first issue is with the timing. If I have a certificate that expires 1 year after the adoption of these regulations and I take advantage of the

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exemption, then I only have two years to come to compliance with 64802.00.(a).(2).(A). It is only one year if my certificate is issued just before these regulations become effective. This creates a disadvantage among laboratories depending on when their certificate expires relative to the adoption date of these regulations. This disadvantage is common among all of the allowed exemptions and will simply be referred to each time.

- CCR 64802.00.(a).(4); 64802.00.(a).(5). There is some question as to why this information has to be provide with the application. For initial application the laboratory can request that the PT provider send information to ELAP directly and ELAP already as information on the onsite especially if they are the assessors. Since these sections apply to the renewal process, the necessity is completely unnecessary as ELAP will possess all information prior to the application.
- CCR 64802.00.(b). First, there is no authority for reciprocity and any agreements can only be between the Board or possibly the Governor and the other agency. Reciprocity would include recognition of ELAP certification by the other agency; which has not been the case. Statute provides for recognition only. There is significant question about the information requested for a laboratory seeking ELAP certification via reciprocity. CCR 64808.10.(b) establishes that ELAP will only recognize other programs for reciprocity if their program is at least as stringent as ELAP. The issue created here is that only 13 states are TNI Accrediting Bodies, which means the rest of the states operate a program of some other type. In many cases, other states, even those offering TNI only offer accreditation for drinking water tests. This regulation has the effect of limiting interstate commerce. Examination of ELAP's certificates issued to out-of-state labs will show that most are certified for hazardous waste testing. If another agency, under a reciprocity agreement determines a laboratory competent and issues a certificate then ELAP is not in a position to question that decision having already ceded authority to that agency via the agreement. There is no necessity to collect information relating to PTs or onsite assessments as ELAP has determined them equivalent. The only action ELAP can take is against the other agency and only if there is evidence of impropriety.
- CCR 64802.00.(c). Why after spelling out all of the application requirements for new, renewal, and under reciprocity, does ELAP not spell out the application requirement here?

CCR 64802.05

This section deals with the Quality System, but does not tie the Quality System to the Quality Manual. This creates a separation between the Quality Manual and the Quality System.

The exemption has the same issues already discussed under CCR 64801 and 64802.00 above. The exemption requirements include the requirement for internal audits under CCR 64802.05.(b).(4) but only to the provisions in 64802.05.(b).(1) and not to the entire Quality System.

CCR 64802.10

In addition to the problem with the poor definition in CCR 64801 this section contains incomplete information and creates the potential for underground regulations. This potential for underground regulations is possible because the Matrix portion of the definition is not included. ELAP may change the Matrix portion, which will require laboratories to reapply to obtain certification for something they already possessed or will lead to potential violations of CCR 64802.15.

The section also contains authority for State Board staff to determine analytical methods. In one case the Board has no authority to determine hazardous waste methods as that is under the authority of the Department of Toxic Substances Control (DTSC). Where allowed, the Board's capability is severely limited as both the Safe Drinking Water and Clean Water Acts stipulate approved methods for a large number of substances. Any restriction or addition to those approved methods constitutes an unallowed alteration of a regulation. These regulations need to reference allowed alternate test procedure approvals. They also need to stipulate where the Board, or any other agency, does have authority to stipulate methods.

- CCR 64802.10.(a). Fields of Accreditation are not specified in any form by regulatory agencies. Regulatory agencies provide a combination of approved methods and regulated substances only and do not provide any statement on Matrix.
- CCR 64802.10.(b). The list of regulations citing approved methods is incomplete. See below for missing citations.
- CCR 64802.10.(c). The section misses citing Waste Discharge Requirements (WDR) which are not part of the Clean Water Act, but are issued by Regional

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Boards. The section fails to call out methods issued under Alternate Test Procedure requirements as allowed. These alterations are approved by US. EPA Region 9 not the Board.

- CCR 64802.10.(d). The section cannot cite SW-846, it must cite the CCR section in Title 22 where DTSC has listed its approved methods. Authority is not granted to the Board to approve alternate methods. It must also cite 40CFR Part 503 for approved method for biosolids.
- CCR 64802.10.(e). Although ELAP can post such things as lists of Fields of Accreditation, but only as constrained by these regulations. Doing so does not require a regulation, but if they do then the regulation must cite the date of the website as it is not referencing any federal or state regulation where public comment and due process is involved. Amending a website would be in effect amending a regulation and that cannot be done outside of the APA.

EPA regulations

- 40CFR Part 136.3 Tables IA-IH approved methods
- 40CFR Part 136.5 Alternate Test Procedure Approval
- 40CFR Part 136.6 Method Modifications and Analytical Requirements
- 40CFR Part 141.21.(f).(3), (5), and (6) approved methods under the prior TCR
- 40CFR Part 141.74.(a).(1) approved bacterial methods under the surface water treatment rule
- 40CFR Part 141.704.(a) and (b) approved bacterial methods under the ground water rule
- 40CFR Part 141.852.(a).(5) approved bacterial methods under the revised TCR
- 40CFR Part 141.23.(k).(1) approved inorganic methods (including lead and copper rule; pH; copper; fluoride for Secondary Drinking Water Regulations)
- 40CFR Part 141.24.(e).(1) approved organic methods
- 40CFR Part 141.25.(a) approved radiochemical methods
- 40CFR Part 141.74.(a).(2) approved disinfectants methods
- 40CFR Part 141.131.(b).(1) approved disinfectant byproducts methods
- 40CFR Part 141.704.(a) and (b) approved methods for surface waters
- 40CFR Part 143.4.(b) approved methods for Secondary Drinking Water Regulations
- 40CFR Part 141 Appendix A approved Alternate Test Procedures
- 40CFR Part 503.8 approved biosolids methods.

DDW regulations

- CCR Title 22, 64415.(a) references 40CFR 141.21 thru 141.42; 141.66; and 141.89 [note 141.66 and 141.89 do not cite methods, but refer back to other sections]
- CCR Title 22, 64426.5.(h) HPC method
- CCR Title 22, 64442.(b).(3) radium method

Statewide Plans

- Policy for Implementation of Toxic Standards for Inland Surface Waters, Enclosed Bays, and Estuaries of California, Appendix 4 Minimum Levels, references 40CFR Part 136
- California Ocean Plan, Appendix II Minimum Levels, references 40CFR Part 136

Other State Regulations

- CCR Title 22, 66260.11 References DTSC approved methods.

CCR 64802.15

This section fails to link the Fields of Performance Testing (FoPT) to the Fields of Accreditation. This is necessary as identified before, the Matrix portion of Fields of Accreditation is not defined, however, FoPTs have am identified Matrix. By not making the connection here, there is potential for underground regulations through changes in what test sample to select to demonstrate compliance with this section. It also creates confusion as to whether a performance test sample exists that matches a Field of Accreditation.

- CCR 64802.15.(a). This section is not necessary as no TNI standard can automatically replace an existing regulation. This would include any requirements defined by another state's accreditation agency recognized under the Reciprocity section of this proposal.
- CCR 64802.15.(b).(2).(A) thru (E) This section is the alternate process provided but it is unnecessary. There is little in the way of changes in the TNI 2016 V1M1 language that have not already been adopted by laboratories. 64802.15.(2).(b) states there is to be a match between performance test samples and the Matrix portion of the Field of Accreditation, but Matrix has not been defined. It is

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interesting that this is the only attempt to link Fields of Accreditation with Fields of Performance Testing, but this section will be invalid three years after adoption of these regulations.

- CCR 64802.15.(b).(3).(A) thru (E). These sections are already covered by statute in H&SC 100850; 100870; and 100872.
- CCR 64802.15.(d). Since there is no matching of the Matrix portion between Fields of Accreditation and Fields of Proficiency Testing then it is unclear whether matching samples exists. As noted above, this creates the potential for underground regulation. Additionally, this section provides for an alternate route but fails to define what sort of "QC" data is to be submitted.
- CCR 64802.15.(g). The use of the word "reinstate" is not within any authority granted to ELAP when operating under the State program, which is the case here. It is allowed if ELAP were a TNI accrediting body. In all cases except for full denial or revocation, a laboratory will simply add in Fields of Accreditation via an amendment application. Full denial and revocation are a complete loss of accreditation and would require a new application. If the Field of Accreditation is suspended, then any conditions for lifting the suspension could include passing performance test samples and can be done on a case by case basis; including requiring multiple successive acceptable results. This section actually limits ELAP to a single process.
- CCR 64802.15.(h). The only interesting point here is that the 45-day requirement does not mean that a subsequent study be even started within the timeframe. This is important, especially if studies are farther apart, or if by the time an unacceptable score is received there is no time to sign up until after the 45-day timeframe. A check of the ERA website shows that Whole Effluent Toxicity samples are sent out only once a year. In fact, this section does not need 64802.15.(h).4).
- CCR 64802.15.(i). As noted above, the 45-day timeframe does not apply to subsequent studies as it simply states "…in a subsequent…". This is a completely unnecessary requirement.
- CCR 64802.15.(j). This section is in violation of H&SC 100910, which requires that formal notice be provided to the laboratory and the laboratory afforded a hearing. Until that process is completed, no penalties can be imposed. H&SC 100895.(c).(1) thru (3) establishes the same penalties once suspension is imposed. 64802.15.(j).(4) and (5) are unnecessary as ELAP should have received the report from the vendor and any subsequent actions taken by the laboratory can be spelled out in the suspension notice.

- CCR 64802.15.(k). As noted above, there is no authority to reinstate and ELAP restricts its actions by including them in regulation.
- CCR 64802.15.(l). This section is completely unnecessary as 64802.15.(l).(1) is already stipulated earlier and 64802.15.(l).(2) and (3) are already required by the methods.
- CCR 64802.15.(m). This section is completely unnecessary as H&SC 100870.(a) already specifies this. It should be noted that H&SC 100870.(a) requires not less than 2 and no more than 4 proficiency test samples a year for pesticide residues in food; which likely conflicts with the provisions earlier in this section.
- CCR 64802.15.(n). Although the identification of conflicts of interest is required by TNI 2016 V1M2 section 4.1, it does not specifically cite relations with providers. Even V1M1 has no similar provisions. However, the definition of a financial conflict of interest is not given and could mean to include where stock is owned via a mutual fund or other group financial investment process.

CCR 64802.20

One of the major issues with this section is the requirement in CCR 64802.20.(c).(1) that laboratories with sophisticated technologies must use a third-party assessor body. Assessor Bodies are defined in statute under H&SC 100825.(c).(2) as those who execute the accreditation process (includes receiving and reviewing applications; documents; PT sample results; and onsite assessments). H&SC 100837 states those are in accordance with TNI or federal agency criteria. TNI recognizes governmental and non-governmental accrediting bodies; EPA recognizes drinking water accreditation bodies via Primacy requirements in 40CFR Part 142; and both the Departments of Defense and Energy operate accreditation programs that are, at the core, TNI based. These are the only bodies that would fit both requirements.

TNI does recognize contract assessors for accrediting bodies, but these do not fit the requirements and ELAP itself in communications with one of these contract assessors reaffirmed this.

This means that those laboratories who are required to use assessor bodies will be required, if they can even participate, to seek a second accreditation since these bodies do not offer assessment functions outside of the full accreditation process (see attached communication with A2LA – a TNI recognized non-governmental accrediting body). Before considering this restriction in regulation, ELAP should have amended statute to change from one that handles the full process to those who offer assessing-only services.

- CCR 64802.20.(a).(4). This is unnecessary as statute already states this as a condition for issuing accreditation (H&SC 100850.(a)).
- CCR 64802.20.(b).(4). This is unnecessary as statute already allows ELAP to enter a laboratory for purposes of assessing compliance with statute and regulation (H&SC 100865.(a).(1)).
- CCR 64802.20.(c). See the discussion above about third-party assessor bodies.
- CCR 64802.20.(d). It is interesting that a laboratory has to initiate the onsite assessment even if ELAP is the assessor. They should be aware that an assessment is necessary as they have in their possession the application and they should be aware if a second-year assessment is theirs to conduct. This looks like a means of entrapment by allowing ELAP to deny an initial or renewal application simply because the lab did not call them.
- CCR 64802.20.(f). This provision does not state any restrictions or describe what might be included. Market-rate is not tied to any published fee structure. It can fluctuate for any reason.
- CCR 64802.20.(g). This seems to be a standard that expires but it is poorly written. The expiring standard is 64802.20.(g).(1) but this leaves (g).(2) and (3). There seems to be no reasoning as to why eliminating (g).(1) and TNI 2016 V1M2 is essentially the same thing.
- CCR 64802.20.(h). There is no mechanism that informs a laboratory as to why a stated corrective action is not responsive. ELAP may delay or age a response by simply stating it is non-responsive; and even attempt to deny an applicant by simply stating non-responsiveness.
- CCR 64802.20.(i). The section is completely unnecessary as several sections of statute already give authority for each of these actions based simply on a failure to comply. ELAP also has the authority to enter a laboratory at times other than regularly scheduled onsite assessments.
- CCR 64802.20.(j). This is confusing as it states approvals are by Assessing Agencies, which is those defined under CCR 64802.20.(c).(1), but then goes on to say only if ELAP commits an error. The current language was simply to prevent a laboratory from postponing the onsite indefinitely.
- CCR 64802.20.(k). Although ELAP has the authority to grant interim certification while waiting for the completion of the onsite, regulations regarding renewals in CCR 64802.00.(a).(5) requires a report on completed onsite assessments. The

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same is cited in CCR 64808.15.(h).(5). It is not possible for a laboratory to submit an application without the report and doing so would make the application incomplete.

- CCR 64802.20.(k).(2). This is a restatement of statute. Interim certification ends when either certification is granted or denied.
- CCR 64802.20.(k).(3). This is a violation of H&SC 100850.(c) which states no expiration date. The one-year provision at the end is the time limit ELAP and the lab have to complete the process. ELAP has consistently used interim certification as a replacement of one year of full certification – not the temporary license it actually is.

CCR 64802.25

ELAP indicates these are simply placeholders and that fees will be adopted in a separate, put parallel, process. However, ELAP has made it clear at fee workshops that they set fees based on trial and error with a goal to generate revenue to match their budgeted allotment. However, ELAP in doing so, violated H&SC 100829.(f).(1) which requires conforming to the requirements in the California Constitution, Article XIII A, section 3. Subsection (d) requires that fees be based on actual effort called for. ELAP in using the trial and error method has not taken into account the actual effort necessary or costs associated with the activity. The best example is the Assessment costs in Table 2. Using a flat rate for each assessment does not account for the number of staff persons, the number of days onsite, or the travel costs. Based on the provision requiring the use of third-party assessors, ELAP will likely go to remote small utility labs in such cities as El Centro or Susanville. Each of those will require two nights hotel stay and two days travel time in addition to the time at the laboratory. A similar lab in any of the metroplexes will not require the travel days or hotel stays; yet both are charged the same fee.

- CCR 64802.25.(a).(2). The FOA fee table is without consideration for the fact that the FOA definition makes this a count of analytes, yet effort is more on the method level. There are methods that include 60 to 80 analytes each while others are for a single analyte. The effort for one is not 80 times more than the other. It is possible that some labs, although only accredited for a few methods, will exceed the 240 FOA level. They will pay essentially more money under this schedule than they did under the current Field of Testing fee structure.

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- CCR 64802.25.(b). It is unclear why a laboratory from outside California and under reciprocity has to pay a base fee, a reciprocity fee, and an FOA fee. This totals at the very least, $7,500 and more likely will average $11,000 to $13,000. It will be $5,000 more than the same lab located in California. There is no explanation as the agency under reciprocity will have done all the work to accredit the laboratory. ELAP has no additional effort and if it does conduct onsite assessments or enforcement action, can be reimbursed. This additional $5,000 can be considered a “tax” on out-of-state businesses and a restraint of interstate commerce.
- CCR 64802.25.(e). Why only $100 to amend? There are no other fees listed here.

CCR 64808

This section is listed as types of accreditation, but it is actually a second form of accreditation process and possibly in conflict with CCR 64802. Why are there two accreditation processes?

- CCR 64808.00.(a). This is a repeat of statute.
- CCR 64808.00.(b). This is an accreditation process and simply repeats with lesser detail, the contents of 64802.00.
- CCR 64808.00.(d). So, when would the review of the contents happen? 64802.00 states that the contents of an application package must meet specific requirements in other sections of 64802.00.
- CCR 64808.00.(d).(2). ELAP has no authority to simply end the processing of an application. It can only deny accreditation. This is a sneaky way to end the application process without issuing a formal denial.

- CCR 64808.05.(a). This is a repeat of statute.
- CCR 64808.05.(b). This is an accreditation process and simply repeats with lesser detail, the contents of 64802.05.
- CCR 64808.05.(c).(2). As noted above, ELAP has no authority to simply end processing an application.
- CCR 64808.05.(d). This one is a trap in that ELAP can take up to 30 days to tell a lab their application is incomplete and then charge them the late fee when the completed application comes in. Statute simply states applications are to be filed in a timely manner. The 90-day timeframe in current regulations was

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because there was an onsite assessment still to do before the certificate expired. Under this proposal, there is nothing left to do when the application is in as all document reviews, onsite assessments, and successful PTs are already done and presented with the application.

- CCR 64808.05.(e). there is no reason for this as any application for renewal cannot happen after the expiration date. By statute, the certificate is expired and the laboratory incapable of conducting business. An application after expiration would be handled as an initial application and the laboratory unable to conduct business until the process is complete. This has the potential for ELAP to sanction work after expiration.

CCR 64808.10 is not in conformance with statute and can be considered a restraint on interstate commerce. H&SC 100829.(e) allows for regulations covering recognition of other programs, but it does not allow for reciprocity. Reciprocity, by definition, requires a reciprocal action by the other entity. This would mean an agreement between government agencies in other states or the federal government. Without some form of authority, ELAP cannot enter into these agreements. They would be handled at the Board level or likely the Governor's office.

Since statutory authority is only for recognition, then ELAP will have to devise a list of recognized certification/accreditation programs.

The issue here is that most other agencies do not issue certificates/accreditations across all potential FOAs. Many states conduct these activities for drinking water, but the number of agencies fall off quickly when it comes to wastewater or hazardous wastes. There is also an issue when California requires testing that other states have not. This section effectively restricts interstate commerce since ELAP will not conduct any activities itself.

- CCR 64808.10.(d). This is in violation of H&SC 100850 where certificates are for 24 months. ELAP has to issue its own certificates so that the lab is in compliance with statutory and regulatory requirements calling for certified labs. These invariably state the lab has accreditation or certification issued under 100825, et al.

CCR 64808.25

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This is the only section that does not have an equivalent section in 64802. It should be noted that any of the items listed in this section require only a $100 fee per 64802.25.(e). CCR 654808.25 does not stipulate any other payment for actions including any assessment that is mentioned in this section.

- CCR 64808.25.(c).(1). There is no requirement that laboratories notify ELAP for a simple name change. The only requirement here is when there is a change in ownership and that is handled via another section.
- CCR 64808.25.(c).(2). H&SC 100845.(b).(2) simply states lab relocation is to be provided in writing. The only penalty is if that notice is not within 30 days. There is not required consent by ELAP.
- CCR 64808.25.(c).(3). There is no requirement that a laboratory notify ELAP whenever it adds satellite or mobile facilities. The only requirement is when the lab applies for certification.
- CCR 64808.25.(d). H&SC 100840.(c) states that an applicant provides a list of Fields of Testing it is seeking. Setting aside the conflict with Fields of Accreditation, the statute does not limit this list to what is already on a certificate. Limiting additions to separate application violates the requirements in statute.
- CCR 64808.25.(e). As noted above, a laboratory only needs to provide written notification; which is not limited in form or information beyond the obvious prior and new laboratory name.
- CCR 64808.25.(f).(1). As noted above, the laboratory only provides written notice. There is no requirement that the laboratory submit any plans or other information beyond the obvious new location information. There is question as to why ELAP needs plans since they are not required to approve them.
- CCR 64808.25.(f).(2). Since ELAP has not approval authority it cannot restrict actions by the laboratory. CCR 64808.25.(f).(2).(B) restricts laboratories to moving in a single process. The provision does not allow a laboratory to move some functions now and operate at the new facility awaiting the relocation of the rest of the laboratory.
- CCR 64808.25.(f).(3). This is not supported by statute as the laboratory has no requirement to reapply. ELAP may conduct any onsite assessment it wishes after the fact or during the transition and may even request the analysis of PTs.
- CCR 64808.25.(g). There is no requirement in statute that satellite or mobile facilities that are added under the umbrella of an existing certificate apply, but be identified in an application when the lab seeks certification. Mobile and

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satellite facilities not under the umbrella of an existing certificate would be considered separate individual laboratories.

- CCR 64808.25.(i). This implies that an onsite can be waived, but the reasons are vague and dependent on opinion not evidence. There is no substitute provided, such as the inclusion of a data package.

CCR 64810

No real comments here except to state these could have been handled as definitions and, where applicable, provided with exemption or alternate requirements as appropriate.

CCR 64812

CCR 64812.00

This section covers Technical and Quality Managers but not who is assigned to perform managerial duties found in TNI 2016 V1M2 4.2 and Management Reviews in V1M2 4.15.

- CCR 64812.00.(a). There is no need for the laboratory to designate a Technical Manager in that 64800.01.(v) equates Technical Manager and Laboratory Director. Laboratories already have a Director so they have a Technical Manager. This should say that laboratories may designate more than one Technical Manager.
- CCR 64812.00.(c).(1). There were no Technical Managers in existence, except for laboratories accredited under TNI 2016 or TNI 2009. There were no requirements for a Technical Manager in TNI 2003 or the NELAP requirements prior to that. Since none existed then the grandfather clause has no meaning.
- CCR 64812.00.(f). This is not needed as it is part of TNI 2016 V1M2 4.1.7.2.(e), which is stipulated in 64812.00.(d).
- CCR 64812.00.(g). Why the three-year wait? Quality Managers have very little specified educational or experience requirements in TNI 2016. TNI 2016 also allows the Technical Manager and the Quality Manager to be the same person (V1M2. 4.1.7.1).
- CCR 64812.00.(j). Why this restriction? Note that per 64812.00.(i) that the position of Principle Analyst disappears. TNI 2016 requirements for personnel in V1M2 5.2 simply state that persons are to be trained in their functions and

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requirements in V1 Modules 3 thru 7, section 1.6 establish demonstrations of capability for each technical area. Technical Managers are considered supervisors per V1M2 4.1.7.2.a) and not analysts.

64812.05

- CCR 64812.05.(e). Why is this there except to be an inventory requirement. If a laboratory changes instrumentation, they not only take on new equipment, but they take on a new analytical method. An example would be EPA method 200.7 using Inductively Coupled Plasma (ICP) Emission versus EPA method 200.8 ICP Mass Spectrometry. Since these are changes in methods, they are different FOAs and the laboratory would comply with any amendment requirements.

CCR 64814

CCR 64814.00

This section creates vulnerabilities for laboratories by making them responsible to know the requirements placed on other entities and responsible for the work of subcontracting laboratories. It also provides a significant restriction on the ability of laboratories in selecting subcontract laboratories.

CCR 64814.00.(a). This requirement holds the laboratory to know what requirements exist even though the laboratory can't be held in non-compliance with those standards. It can make the laboratory a responsible party if the regulated agency fails to comply.
CCR 64814.00.(f). There is no reason for the alternate path in 64814.00.(f).(2). It needs to be noted that TNI 2016 V1M2 4.5.2 requires approval in writing; 4.5.3 makes the laboratory responsible for the quality of work from the subcontractor; and 4.5.5 requires work be placed with laboratories accredited to TNI 2016 standards. It is overbearing to require permission to subcontract. The second reference makes the laboratory culpable if the subcontract laboratory messes up. The third provision can't be implemented with any laboratory certified under these standards as they are not in full compliance with TNI 2016.
CCR 64814.00.(o). There is no need for the alternate pathway.

CCR 64814.05

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The section states it covers changes in Technical Managers but includes requirements in 64814.05.(a) that include Quality Managers. There are no TNI requirements that call for notification relative to Quality Managers.

CCR 64816

There is no reason for any section here as statute makes it clear what infractions qualify for these actions; even if there are provision regarding a general failure to comply with statute or regulation. The only provisions that need regulations would be the fines imposed by statute. Fines are usually listed as not to exceed so in regulation would be fines set for first offense and subsequent offenses in the same category. The goal with fines is to set an attention-getting level then rachet them up if the offender doesn't take the hint.

From: Sotelo, Christine@Waterboards
To: "WRC LLC"
Cc: Niemeyer, Kim@Waterboards
Subject: RE: Second request for clarification re Third Party Assessors
Date: Wednesday, August 7, 2019 14:56:21
Attachments: image001.png

Mr. Ray:

Although section 100837 says that the State Board may contract with approved third-party assessor bodies, if you read the definition of that term in section 100825(c)(2), that term is actually referring to accreditation bodies. The Environmental Laboratory Accreditation Act defines "assessor body" to be "the organization that actually executes the accreditation process, including receiving and reviewing applications, documents, PT sample results, and onsite assessments." ELAP therefore reads section 100837 as authorizing it to contract with organizations that "actually execute the accreditation process," such as A2LA, and who meet TNI or federal agency criteria for being an accrediting body. This would preclude you as an individual from being able to act as a third-party assessor for ELAP. ELAP would only accept a third-party assessment from one of the TNI or federal accreditation bodies.

In response to your question about what standard the laboratory would be assessed to, the assessment would be done to California standards, unless the laboratory requests that it be assessed to TNI. ELAP would accept an assessment to TNI in place of the California standard because not only is that standard at least as stringent as California's requirements, US EPA has also indicated that compliance with the 2016 TNI laboratory standard satisfies drinking water laboratory assessment requirements. I believe, however, that is what Bracewell probably was told, as section 100837 identifies, the third party "assessor body" itself has to meet TNI or a federal agency criteria.

Christine Sotelo, Chief
California Environmental Laboratory Accreditation Program
State Water Resources Control Board

From: WRC LLC <bill_ray@williamrayllc.com>
Sent: Monday, August 5, 2019 12:41 PM
To: Sotelo, Christine@Waterboards <Christine.Sotelo@waterboards.ca.gov>
Subject: Second request for clarification re Third Party Assessors

I have not heard from you regarding my questions, which need answering before I commit to my client and conduct a Third-Party assessment. I request a response be made within the next two weeks. The original request was as follows:

I have been in contact with Bracewell Engineering laboratories as they have requested my services as a third-party assessor. They have contacted you regarding using my services and have received a reply. I also submitted a form to TNI to be listed as an available assessor. Although you have agreed to allow Bracewell to use my services, your response to Bracewell and the information I have received from TNI is confusing.

Bracewell states that you requested the assessment be on A2LA letterhead. A2LA will not allow me to use letterhead for purposes other than assigned accreditation assessments. A2LA does not provide third-party assessments and only assess with application for their accreditation. Bracewell has applied to you not A2LA.

TNI states that you are using non-governmental ABs. AB stands for Accrediting Body, which would point to someone like A2LA. This seems to be conflict with H&SC 100837, which says you may contract with laboratory third-party assessor bodies – not accreditation bodies.

Bracewell tells me that you want the assessment done under TNI standards. This is not in keeping with H&SC 100850.(a) which states that certificates are issued after finding for full compliance with statute and underlying regulations. Currently your regulations do not cite TNI standards. An application to you, without requesting recognition of another program's accreditation, would require compliance with your current standards.

Please provide an explanation of what is required for use of third-party assessors by laboratories.

Thank you,

William (Bill) Ray, President/Owner

William Ray Consulting, LLC

Registered California SBE

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From: noreply@salesforce.com on behalf of Luis Zuniga
To: bill_ray@williamrayllc.com
Subject: Web Inquiry Follow Up A2LA
Date: Thursday, August 8, 2019 13:09:52

Hello William,

Looking over your request, it seems like it is not something we are able to do. We also do not preform PT. We accredit PT providers, but we do not actually preform PT.

Thank You,

Luis Zuniga
Business Development Assistant

Monday - Friday 9 a.m. - 5 p.m. EST
A2LA
2406084341

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Main Line: 301.644.3248 - Fax: 240.454.9449
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Costs associated with maintaining accreditation

Current Costs	Dollars	per	Unit time		
Annual accreditation fee	$ 3,592.00		Year		
Costs for purchasing PTs	$ 617.00		Year		
Costs to run PTs	$ 777.15		Year		
Personnel costs	$ 48,494.16		Year		
Equipment costs			Year		
Supplies costs			Year		
Assessment costs	$2,560		3 Years		
		Total annual costs		$	54,333.64

Costs added if accreditation dropped	Dollars	per	Unit time
Costs for contract lab services for additional tests	$ 16,499.60		Year
Transport costs to deliver samples to contract lab			Year
Total annual costs	$ 16,499.60		

staff burdened rate/hr $ 155.43

Consultant Costs to become TNI certified

Upgrade costs to transition to TNI standards as amended by ELAP	Hours	Hourly	100%	75%	50%	25%
Preparation of 22 separate Policies/Procedures	350	$ 90.00	$ 31,500.00	$ 23,625.00	$ 15,750.00	$ 7,875.00
Preparation of QS Manual	50	$ 90.00	$ 4,500.00	$ 3,375.00	$ 2,250.00	$ 1,125.00
Update of 4 analytial SOPs	24	$ 90.00	$ 2,160.00	$ 1,620.00	$ 1,080.00	$ 540.00
Development of recordkeeping system covering 22 P/P, QSM, analytical SOPs	800	$ 90.00	$ 72,000.00	$ 54,000.00	$ 36,000.00	$ 18,000.00
Internal Assessment	40	$ 90.00	$ 3,600.00	$ 2,700.00	$ 1,800.00	$ 900.00
Training	40	$ 90.00	$ 3,600.00	$ 2,700.00	$ 1,800.00	$ 900.00
	1304	Total	$ 117,360.00	$ 88,020.00	$ 58,680.00	$ 29,340.00

Staff Costs

	Hourly	25%	50%	75%	100%
Preparation of 22 separate Policies/Procedures	$ 155.43	$ 13,600.13	$ 27,200.25	$ 40,800.38	$ 54,400.50
Preparation of QS Manual	$ 155.43	$ 1,942.88	$ 3,885.75	$ 5,828.63	$ 7,771.50
Update of 4 analytical SOPs	$ 155.43	$ 932.58	$ 1,865.16	$ 2,797.74	$ 3,730.32
Development of recordkeeping system covering 22 P/P, QSM, analytical SOPs	$ 155.43	$ 31,086.00	$ 62,172.00	$ 93,258.00	$ 124,344.00
Internal Assessment	$ 155.43	$ 1,554.30	$ 3,108.60	$ 4,662.90	$ 6,217.20
Training	$ 155.43	$ 1,554.30	$ 3,108.60	$ 4,662.90	$ 6,217.20
Total		$ 50,670.18	$ 101,340.36	$ 152,010.54	$ 202,680.72

Grand total	$ 117,360.00	$ 138,690.18	$ 160,020.36	$ 181,350.54	$ 202,680.72

need to add training as an ongoing cost (integrity)
other on-going?