

Coalition of Accredited Laboratories



VIA EMAIL

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California State Water Resources Control Board
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Ms. Townsend,

The Coalition of Accredited Laboratories ("CAL") is an organization representing the community of laboratories accredited in the State of California for environmental analysis. CAL is dedicated to Safeguarding Public Health and the Environment; Bridging the gap between regulatory agencies and accredited laboratories; and Providing Education, Training and Outreach.

CAL would like to thank you for this opportunity to submit comments on the proposed amendment to the Policy for Water Quality Control for Recycled Water. CAL understands that the State Board wants to maximize its water resources of California and the use of recycled water plays an important part in achieving that objective. CAL agrees that it is essential that monitoring data produced during the course of a recycled water project needs to be of sufficient quality allow data users and decision makers to make the necessary steps to protect public health and the environment.

CAL has no opinion on the proposed Amendment to the Recycled Water Policy as a whole. CAL interest in this Amendment is as it affects laboratories. The comments below are focused on the parts of Attachment A of the proposed Amendment.

Attachment A Comments:

Attachment A outlines requirements for monitoring constituents of emerging concern for recycled water. In the preamble to Attachment A the goal is identified as follows:

"This section is to ensure laboratories conducting [Chemicals of Emerging Concern] monitoring generate data of known, consistent, and documented quality and to verify that the laboratory can meet the required reporting limits."



CAL supports this goal as public health and environmental protection agencies need consistent, accurate and precise data to make informed and useful decisions. Attachment A also proposes a mechanism to achieve this goal:

“The recycled water project proponent or recycled water producer shall develop a quality assurance project plan that is consistent with this Policy. The quality assurance project plan shall be submitted to and approved by the regional water board prior to beginning any sampling and analysis.”

CAL supports this very reasonable approach to addressing monitoring Contaminants of Emerging Concern (“CEC”). The development of a Quality Assurance Project Plan (“QAPP”) by each Recycled Water Project Proponents (“RWPP”) would ensure that each recycled water project achieves the objectives of the State Board Water Resources Control Board (“State Board”) Policy. This is important as the Environmental Laboratory Accreditation Program (“ELAP”) does not currently offer accreditation for CECs and the State Board has not yet identified a list of approved methods for the analysis of all CECs. However even without these limitations, the requirement to develop a QAPP for each RWPP would still be a positive proposal. Using QAPPs is a generally sound approach to managing environmental projects.

While CAL supports the general concepts of the Attachment A and the use of QAPPs, this approach can be improved to better achieve the objectives of the Policy.

1) International Standards Organization and The NELAC Institute

- a) Attachment A also uses the term Quality Management System (“QMS”). This is generally associated with the International Standard Organization (“ISO”) and is used for commercial and industrial application and not generally environmental compliance testing but generally covers many of the same concepts as USEPA’s QMP. The use of these two different terms is confusing and cumbersome and QMS is quite naturally a much broader and less well-defined term than QMP. **CAL recommends that the terms QAPP or QMP be used for a more clear and consistent policy. This would exclude the term QMS due to the lack of reference in State and National quality manual guidance.**
- b) Attachment A references The NELAC Institute (“TNI”) documents as part of the QMS and only as it applies to laboratories. The ISO QMS and the USEPA / State board QMP are both much larger concepts and programs than just laboratories. The State Board identified 24 elements found in each QAPP, of which only four or five apply to laboratories (B3 – B8). **CAL requests that Attachment A require all 24 quality assurance elements specified by USEPA and State Board QMP and QAPP documents to be incorporated in the regulatory process.**
- c) The inclusion of TNI laboratory documentation requirements produces additional difficulties. While ELAP had once offered laboratory accreditation TNI accreditation as an option for laboratories it ceased to make that option available several years ago. It is our understanding that ELAP has no plans to offer the TNI option for the foreseeable future. While CAL feels that laboratories should have the option of applying for TNI accreditation if it is in their best interests to do so, CAL is very much against any sort of specification that would require laboratories to obtain TNI accreditation. **CAL requests that all references to TNI be removed from Attachment A.**

2) Request for State & Federal Consistency

- a) Attachment A uses the terms QAPP and Quality Management System (“QMS”) without defining either. If the State Board would like to use QAPPs as a central part of the Recycled Water Policy, it would be best if it defined the term. The United States Environmental Protection (“USEPA”) has numerous documents which describe what a QAPP is and how to develop a QAPP. In similar situations, USEPA uses a system based upon Quality Management Plans (“QMP”) which are described in many documents but most specifically QA-G2 (guidance) and QA-R2 (requirements) where QAPPs are defined. The State Board has many of its own documents discussing the use of QAPPs such as the May 2017 for Surface Water Ambient Monitoring Program (“SWAMP”)¹, which are based on the USEPA QMP. Attachment A does not reference any of the extensive documentation available both from the State Board and from the USEPA. Attachment A appears to be “reinventing the wheel”. CAL would suggest that a more reasonable and appropriate approach would be for the State Board to use the existing terms and concepts of QAPP and QMPs currently in use by the State Board. **CAL would like to suggest that Attachment A reference USEPA and SWRCB QMP and QAPP documents.**

The QMP and QAPP include a Sampling and Analysis Plan (“SAP”) which includes laboratory requirements but has much more than that. The TNI documents do not reference any specific laboratory requirements and merely reference back to method requirements or data user requirements. **CAL requests that Attachment A require the development of an SAP as part of the QAPP and that the requirements for what is in the SAP be specified in Attachment A. CAL also requests the elimination of references to TNI & a QMS as not applicable in for this policy update.**

3) Scope of the QMP and QAPP

- a) QAPPs are part of a QMP. As such, including the requirement for both a QMP and QAPP in Attachment A would create a more robust statewide policy. **CAL requests that Attachment A include the requirement for the development of both a QMP and QAPP to strengthen environmental testing quality.**
- b) The QMP and QAPP both begin and end with the Principal Data Users (“PDU”) and Decision Makers (“DM”). The QAPP is built around the needs of the PDUs and DMs, they need to decide what degree of quality they need to accomplish the goals of this policy, in this case to maximize the safe and beneficial use of recycled water. **CAL would request that Attachment A clearly identify whom the PDUs and DMs are and what their goals are for this Policy in general and for the data generated by laboratories covered by Attachment A and this Policy in particular. The PDUs and DMs should include at least the Division of Drinking Water (“DDW”) and the RWPPs.**

1

- c) The establishment of Data Quality Objectives (“DQO”) are institutional framework of a QMS and a QAPP. Attachment A needs to set DQOs, which can then be the basis for the Project Assessment and Evaluation Plan (“PAEP”), an item within the QAPP. The DQOs need to meet the needs of both the PDUs and DMs. For example, the PDUs may decide the need for accurate results for an effective assessment of the process performance. One DQO would then be the need for accurate laboratory results. **CAL requests that Attachment A clearly identify the DQOs that the PDUs need in a PAEP.**
- d) In a QAPP, DQOs need to be quantifiable, establish a metric to assess laboratory data quality and ensure it meets the needs of the PDUs. One such metric is Data Quality Indicator (DQI), In this case, the DQI would be Accuracy (or Bias). **CAL requests that Attachment A clearly identify DQIs for each DQO listed.**
- e) For the laboratory section of the SAP, there needs to be specific metrics to make the DQIs tangible. There needs to be specific laboratory procedures identified to assess the laboratory’s ability to generate data of sufficient quality to meet the needs of the PDUs. Measurement Quality Objectives (MQOs) are how QMPs and QAPPs link the activities of the laboratory to the PDUs through the SAP. Examples of MQOs would requiring the laboratory to verify the DLR once per batch by using a Quality Control Sample prepared at the DLR concentration and requiring that the laboratory recover a fix amount, e.g. +/-30%. **CAL requests that Attachment A clearly identify MQOs for each DQO listed as part of a SAP.**

4) Reporting Limits, Laboratory Capacity, Verification, and Accreditation

- a) Attachment A uses the term “Reporting Limits” numerous times but does not define what that term means in this context. Under the Clean Water Act, the lowest reportable value is either the Minimum Level (“ML”) or the Method Detection Limit (“MDL”) depending upon the situation. In California in the drinking water regulations, the Detection Limit for Reporting (“DLR”) or the Minimum Reporting Level (“MRL”) are used. In each case, these terms are defined. **CAL requests that the State Board use the concept of the DLR as the most appropriate approach as this is how drinking water analytes have been regulated in California for many years.**
- b) The DLR has historically been defined as the lowest concentration that at least 80% of accredited laboratories can achieve an acceptable level of accuracy. It has the advantage of being based upon both a useful and tangible DQO (accuracy) and on laboratory capacity as well as being consistent with past DDW regulations. Instituting a policy that is not achievable is antithesis of what the policy should be accomplishing. Before RWPP’s can require laboratories achieve some reporting limit, there have to be enough laboratories that are capable sufficient sensitivity. **CAL requests that the State Board first determine the DQOs and MQOs that it finds necessary to achieve the objectives of this Policy, set the DLRS on those DQOs and MQOs, and then determine if sufficient laboratory capacity exists to support those DQOs and MQOs.**
- c) Attachment A establishes the goal of having Reporting Limits that laboratories routinely verify. CAL believes that this is a very important objective and fully supports it. However, CAL believes that the State Board needs to establish a procedure for verification. It is not enough say that laboratories must verify the Reporting Limits, Attachment A needs to define

the procedures for doing his. The USEPA has a well-defined set of Reporting Limits and verification procedures that have been in use for a number of years. **CAL requests that Attachment A simply use the verification procedures found in the Disinfection By-Product Rule for the MRL as a model for DLR verification in Attachment A.**

- d) Currently ELAP does not offer accreditation for most of the tests and analytes identified in Attachment A. It would be counter-productive to implement Attachment A either as written or in some other way without an accreditation process to support it. There would be no mechanism to determine what laboratory capacity exists both in terms of the number of laboratories capable of supporting this policy and their ability to achieve DQOs and MQOs at any given Reporting Limit. **CAL requests that the State Board establish accreditation procedures for ELAP so that accreditation can be available to support the objectives of this Policy.**

5. Data Quality Assessment and the QAPP

- a. According to Attachment A, each RWPPs need to develop its own QAPP, submit it for approval to the State Board, and then require their laboratory to comply with the requirements in Attachment A. This is a good idea and consistent with the State Boards' use of QMPs and QAPPs in the past. However, for this to be an effective process, there need to be standards for the State Board to assess one QAPP as acceptable and another as not. Currently Attachment A is lacking in any set of standards for QAPPs that might be to assess QAPPs. Such standards would be a State Wide QMP for recycled water which has DQOs, DQIs, and MQOs as well as templates for QAPPs, PAEPs, and SAPs. These would be the criteria for the State Board to approve or reject a QAPP Attachment. If a QAPP meets the required elements of the State-Wide QMP, it would be acceptable or it would need to be rejected until it comes into compliance with the QMP. **CAL requests that Attachment A explicitly establish criteria for what is an acceptable QAPP and that that be based on a State-Wide QMP for Recycled Water which include template QAPPs, PAEPs, SAPs, and include DQOs, DQIs, and MQOs.**
- b. The core element of both the QMS and QAPP is Data Quality Assessment (DQA). Periodically the PDUs and DMs need to review the project holistically and assess it against the QAPP. Are the objectives of the recycled water project being met or are the objectives incorrect? This assessment would use the Policy and the QMS as the metric to answer such questions. **CAL requests that Attachment A include a requirement for a routine DQA process as part of the State-Wide QMS and each QAPP.**

6. Laboratory Accreditation

Attachment A reads as if the Board were proposing that each RWPP would be its own accreditation body and is using the proposed QAPP as tool to achieve this goal. This reading of the text would seem to be supported by the presentation of staff at the June 19 hearing in Sacramento. Staff appeared to indicate that while there are analytical methods could have the potential to become standardized, there are not yet a well defines set of actual standardized methods for all of the CECs identified. Further, it would seem that there is no list of laboratories that are documented to be capable of using these potentially standardized methods. The proposed Amendment has a very extensive and aggressive

sampling program. It would be very concerning to picture dozens of RWPPs collecting large numbers of samples over an extended period at great expense and then having the results of little value. It would equally undesirable for there to be an insufficient number to support this program. Additionally, the Amendment specifies many reporting limits but it is unknown if there enough laboratories, or indeed any, that can achieve those reporting limits on a regular basis. These issues can only be resolved by establishing a robust laboratory accreditation program. A QAPP is not a substitute for such a program. **CAL requests that the Board identify or develop a list of standardized analytical methods for all listed CECs, have ELAP offer those methods for accreditation, and then assess the overall capacity of those laboratories that elect to become accredited to conduct the analyses to meeting DQOs and MQOs.**

An Alternative Approach: The California Quality Management Plan

An alternative approach would be for the State Board to develop a single State-Wide QMP to support the entire Recycled Water Policy. The QMP would identify the PDUs and DMs, their policy objectives, SAP, the DQOs, the DQIs, and MQOs, as well as a template for the QAPP. Each RWPP would develop a QAPP, PAEP, and SAP that would include all the elements specified in the QMP. This ensures an effective QAPP that serves the goals of the Recycled Water Policy and the needs of the PDUs and DMs while helping RWPPs develop QAPPs and implement recycled water projects.

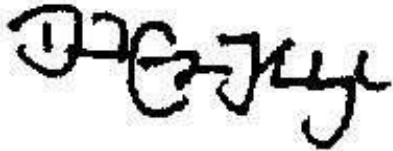
An Example of the Use of DQOs, DQIs, and MQOs

1,4-Dioxane is one of the analyte of concern specified in Attachment A. The QMP could identify that the State Board and RWPP as the PDU and DM need to monitor for 1,4-Dioxane as it is a suspected human carcinogen, is known to be a contaminant in groundwater, and is known to occur in recycled water. The QMP would then identify data quality to be a DQO to protect public health and the environment from 1,4-Dioxane, identify the DQI, which can then be incorporated into a template PAEP. The DQIs can be listed as Precision, Accuracy, Representativeness, Comparability, Completeness, and Sensitivity. Precision can be assessed by using sample replicates. Accuracy by matrix spikes and reference materials. Representativeness can be assessed through Data Quality Assessment (DQA). Comparability can be assessed by ensuring the use of appropriate methods and inter-laboratory comparisons such as Performance Testing samples. Completeness can be assessed through data verification. Sensitivity can be assessed through reporting limit verification. The PAEP and SAP can identify USEPA Method 522 or SW-846 Method 8270c as appropriate methods. In the template SAP could include the use of Field Blanks (1 per sampling event, results less than the DLR), Field duplicates (1 per sampling event, Relative Percent Difference (RPD) < 30%), calibration curve, continuing calibration checks, laboratory reagent blanks, laboratory fortified blanks, matrix spike, and matrix spike duplicate (frequency and acceptance criteria as per the method). The PDUs and DMs need to review the data, conduct DQA through verification, validation, and reconciliation. Changes to the QMP and QAPPs should be made based upon the DQA.

Summary

CAL agrees with the approach identified in Attachment A of using QAPPs which is positive, proactive, and necessary for the success of the Recycled Water Policy. However, CAL believes that a QAPP can only be useful if it is developed in the context of an entire QMP, specifically like that described by the USEPA and SWRCB, one that is detailed and specific and includes all parts of the Recycled Water Policy, not just the laboratory. The QMP should include MQOs, MQIs, MQOs, and template QAPPs that include PEAPs and SAPs. QAPPs need to be assessed within the broader context of a single state-wide QMP. A fully functioning and effective laboratory accreditation program for his effort is needed and QAPP alone will not achieve the objectives set out in the proposed Amendment.

We thank you for your attention.

A handwritten signature in black ink, appearing to read "D. Eugene Kimbrough". The signature is stylized and somewhat cursive.

David Eugene Kimbrough, Ph.D. Chair, CAL