STATE OF CALIFORNIA

OFFICE OF ADMINISTRATIVE LAW

2023 OAL DETERMINATION NUMBER 1
(OAL MATTER NUMBER CTU2023-0308-01)

REQUESTED BY: **William Ray Consulting, LLC**

CONCERNING: **California Laboratory Assessment Checklist (4/29/2021), issued by the Environmental Laboratory Accreditation Program within the State Water Resources Control Board**

DETERMINATION ISSUED PURSUANT TO GOVERNMENT CODE SECTION 11340.5.

SCOPE OF REVIEW

An Office of Administrative Law (OAL) underground regulation determination evaluates whether a state agency action or enactment complies with California administrative law governing how a state agency must adopt a regulation. If a state agency's rule is a regulation and the state agency did not adopt it pursuant to the Administrative Procedure Act (APA), but should have, then the rule is an underground regulation.[1]

Nothing in this determination evaluates the advisability or the wisdom of the underlying action or enactment. OAL has neither the legal authority nor the technical expertise to evaluate the underlying policy issues involved in the subject of this determination. OAL review is limited to the sole issue of whether the challenged rule is a regulation subject to the APA.

CHALLENGED RULES

The State Water Resources Control Board through its Environmental Laboratory Accreditation Program (ELAP), issued a document entitled "California Laboratory Assessment Checklist (4/29/2021)" (Checklist).[2] ELAP, which did not adopt the Checklist pursuant to the APA, is using the Checklist in conjunction with duly adopted regulations to perform assessments of covered laboratories' Quality Manuals. An ELAP contractor suspended the petitioner, based upon ELAP's interpretations, for checking the "N/A" option in the Checklist for both challenged rules. ELAP acknowledges the Checklist

[1] Cal. Code Regs., tit.1, § 250, subd. (a)(1).
[2] The relevant pages are attached as Exhibit A.

language varies from existing regulations in the California Code of Regulations (CCR), but ELAP explains its position on the matter, saying, "ELAP's interpretation is that the requirements of our regulations need to be incorporated into **every** lab's … practices." (Emphasis added.)[3] Thus, the Checklist, referenced citations, and related correspondence operate together to govern the content of a laboratory's Quality Manual. The Checklist contains the following challenged rules:

> **Challenged Rule No. 1 (General Notification Procedure)**
> Does the Quality Manual or referenced document, identify that if an analytical result warrants a client notification, then the notification shall occur after the Technical Manager, or designee, has approved of the result?[4]
>
> **Challenged Rule No. 2 (Drinking Water Notification Procedure)**
> Does the Quality Manual, or referenced document, detail procedures when client notification is required?[5]

DETERMINATION

OAL determines Challenged Rule Nos. 1 and 2 are underground regulations because they are regulations ELAP should have adopted pursuant to the APA but did not.

FACTUAL BACKGROUND

On March 8, 2023, OAL received a petition from William Ray Consulting, LLC, specifically challenging each of the two rules identified in the Checklist as an underground regulation, including ELAP's universal application of the Checklist's challenged provisions via ELAP's related correspondence.

On May 8, 2023, OAL accepted the petition. OAL published a summary of the petition in the California Regulatory Notice Register on May 19, 2023, soliciting public comments until June 19, 2023. OAL did not receive any public comments.

On June 30, 2023, in advance of the July 3, 2023, deadline, OAL received a document entitled *CTU2023-0308-01 State Water Resources Control Board Response to Petition by William Ray* as a written response from ELAP (ELAP

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[3] Petition, at p. 3; ELAP's written response, at pp. 5-6, n. 4 (affirming its correspondence and position on the matter as stated in the petition).
[4] Checklist, at p. 12.
[5] Checklist, at p. 14.

Response). OAL received a written rebuttal from the petitioner on July 21, 2023, after the July 15, 2023, deadline.

UNDERGROUND REGULATIONS

Government Code section 11340.5(a) bars a state agency from issuing a regulation unless it does so pursuant to the APA.

> No state agency shall issue, utilize, enforce, or attempt to enforce any guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule, which is a regulation as defined in [Government Code] Section 11342.600, unless the guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule has been adopted as a regulation and filed with the Secretary of State pursuant to [the APA].

When an agency issues, utilizes, enforces, or attempts to enforce a rule in violation of Government Code section 11340.5, and the rule is not exempt from the APA, it creates an underground regulation as defined in CCR, title 1, section 250.

OAL may issue a determination as to whether an agency has issued, utilized, enforced, or attempted to enforce a rule that meets the definition of "regulation" as defined in Government Code section 11342.600 and should have been adopted pursuant to the APA.[6] An OAL determination is not enforceable against the agency through any formal administrative means, but it is entitled to due deference in any subsequent litigation of the issue pursuant to *Grier* v. *Kizer* (1990) 219 Cal.App.3d 422 [268 Cal.Rptr. 244].

OAL's authority to issue a determination extends only to the limited question of whether the challenged rules are "regulations" subject to the APA. This analysis will determine (1) whether the challenged rules are regulations within the meaning of Government Code section 11342.600; and (2) whether the challenged rules fall within any recognized exemption from APA requirements.

A regulation is defined in Government Code section 11342.600 as:

> . . . every rule, regulation, order, or standard of general application or the amendment, supplement, or revision of any rule, regulation, order, or standard adopted by any state agency

[6] Gov. Code, §11340, subd. (b)).

> to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure.

In *Tidewater Marine Western, Inc. v. Victoria Bradshaw* (1996) 14 Cal.4th 557, 571 [59 Cal.Rptr.2d 186], the California Supreme Court determined a regulation has two elements.

> A regulation subject to the Administrative Procedure Act (APA) (Gov. Code, §11340 et seq.) has two principal identifying characteristics. First, the agency must intend its rule to apply generally, rather than in a specific case. The rule need not, however, apply universally; a rule applies generally so long as it declares how a certain class of cases will be decided. Second, the rule must implement, interpret, or make specific the law enforced or administered by the agency, or govern the agency's procedure (Gov. Code, §11342, subd. (g)).[7]

As stated in *Tidewater*, the first element used to identify a "regulation" is whether the rule applies generally. As *Tidewater* points out, a rule need not apply to all persons in the state of California. It is sufficient if the rule applies to a clearly defined class of persons or situations.[8] The second element used to identify a "regulation" as stated in *Tidewater* is that the rule must implement, interpret, or make specific the law enforced or administered by the agency, or govern the agency's procedure.

The final issue to examine is whether the challenged rule falls within an express statutory exemption from the APA. Exemptions from the APA can be general exemptions that apply to all state rulemaking agencies. Exemptions may also be specific to a particular rulemaking agency or a specific program. Pursuant to Government Code section 11346, the procedural requirements established in the APA "shall not be superseded or modified by any subsequent legislation *except to the extent that the legislation shall do so expressly*." (Emphasis added.)

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[7] Section 11342(g) was re-numbered in 2000 to section 11342.600 without substantive change.

[8] See also *Roth v. Department of Veterans Affairs*, (1980) 110 Cal.App.3d 14, 19; 167 Cal.Rptr. 552, 557.

ANALYSIS

1. Each Challenged Rule is a Regulation.

To determine whether a rule is a regulation, the first issue is whether the challenged rule applies generally. A rule is of general application if it applies to a clearly defined class of persons or situations.[9]

ELAP accredits and has authority over environmental laboratories in California.[10] The Checklist applies to laboratories seeking or maintaining ELAP accreditation. The Checklist prefaces each page with the question, "Does the laboratory comply with this section?" Each Checklist item provides a reference citation to a regulation in the CCR and is read together with checkboxes, apparently designed to indicate whether the laboratory's Quality Manual contains necessary information or whether the Checklist item is inapplicable. ELAP acknowledges the Checklist language varies from existing regulations in the CCR, but ELAP explains its position on the matter, saying, "ELAP's interpretation is that the requirements of our regulations need to be incorporated into **every** lab's … practices." (Emphasis added.)[11]

ELAP issued and utilizes the Checklist to determine whether a laboratory's Quality Manual contains required content and information. The provisions at issue require a laboratory to include in its Quality Manual certain information relating to its analytical results and its testing of drinking water. ELAP's related correspondence indicates ELAP intends to apply the Checklist generally and to generally require every ELAP-accredited laboratory in a drinking water field of accreditation to include in its Quality Manual the information set forth in CCR, title 22, section 64814.00, even if the laboratory does not test drinking water or otherwise trigger a client notification requirement in the course of its actual work. ELAP's intent to generally apply each challenged rule satisfies the first *Tidewater* element of a regulation.

The second issue is whether each challenged rule implements, interprets, or makes specific the law enforced or administered by the agency, or governs its procedure. ELAP acknowledges the Checklist language differs from the CCR and that ELAP intends the Checklist to further implement or interpret two provisions governing the content of a Quality Manual: CCR, title 22, sections

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[9] *See Roth v. Dept. of Veterans Affairs*, (1980) 110 Cal.App.3d 622, 629-630.
[10] Health & Saf. Code, §§ 100829, 100830; Cal. Code Regs., tit. 22, § 64802.05, subd. (b)(1).
[11] Petition, at p. 3; ELAP Response, at pp. 5-6, n. 4 (affirming its correspondence and position on the matter as stated in the petition).

64802.05 and 64814.00.[12] This satisfies the second *Tidewater* element of a regulation as to each challenged rule.

Each challenged rule satisfies the two *Tidewater* elements of a regulation. Each challenged rule is a regulation.

2. ELAP Should Have Adopted Each Challenged Rule as a Regulation.

The final issue to examine is whether ELAP should have adopted each regulation pursuant to the APA but did not. The APA applies to a state rule unless legislation expressly supersedes or modifies the APA's requirements.[13]

ELAP suggests its interpretation of existing law requires compliance with the challenged rules, as expressed in the Checklist and its related correspondence.[14]

The APA does not apply to a regulation that embodies the only legally tenable interpretation of a provision of law.[15] This APA exception codifies the principle that if a rule is essentially a reiteration of existing law, then no duty exists to enact regulations as a reiteration. But if the rule departs from or embellishes upon existing law, then the agency must promulgate a regulation. The exception applies only in situations where the law can reasonably be read only one way, such that its application is patently compelled by, or repetitive of, the statute's plain language. To qualify for this exception, the interpretation must follow directly and inescapably from the pertinent provisions of law and be plainly ineluctable.[16]

Challenged Rule No. 1 (General Notification Procedure)

Challenged Rule No. 1 in the Checklist reads as follows:

> Does the Quality Manual or referenced document, identify that if an analytical result warrants a client notification, then the notification shall occur after the Technical Manager, or designee, has approved of the result?

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[12] *Ibid*.
[13] Gov. Code, §§ 11340.5, 11346.
[14] ELAP Response.
[15] Gov. Code, § 11340.9, subd. (f).
[16] *Morning Star Co. v. State Bd. of Equalization* (2006) 38 Cal.4th 324, 328, 336-337, 340.

The Checklist cites CCR, title 22, section 64814.00(b), as a reference. Section 64814.00(b) addresses notification requirements based upon a laboratory's analytical result, and reads as follows:

> If an analytical result warrants a Client notification, the notification shall occur after the Technical Manager or designee, set forth in the laboratory's Quality Manual, has approved of the result.

This CCR section governs a laboratory's notification requirements based upon the analytical result of its testing. By contrast, the Checklist language requires a laboratory's **incorporation of these procedures into its Quality Manual**.

CCR, title 22, section 64802.05(b)(1), governs the content of a Quality Manual and provides in part as follows:

> To ensure analytical data produced by the laboratory are of known and documented quality, and sufficient to evaluate the usability of the data for State Regulatory Agency needs, a laboratory shall:
> …
> (b) Develop and implement a quality assurance program. As evidence of such a program, the laboratory shall:
> (1) Develop and maintain a Quality Manual. The Quality Manual shall address the quality assurance and quality control practices to be employed by the laboratory and shall include at a minimum:
> (A) The quality assurance and quality control requirements specified in the test methods for which the laboratory seeks to obtain or maintain accreditation for; and
> (B) Documents, or references to documents, that contain the following elements:
> …
> (viii) Acquisition, reduction, validation and reporting of data…

Whether Challenged Rule No. 1 is an underground regulation depends upon whether the only legally tenable interpretation of CCR, title 22, section 64802.05, and more specifically, subdivision (b)(1)(B)(viii), requires an ELAP accredited laboratory that does not perform tests that would warrant client notification to still include in its Quality Manual the notification requirement in section 64814.00.

The petitioner asserts Challenged Rule No. 1, as provided in the Checklist and related correspondence, is an underground regulation that requires incorporation of an inapplicable rule into its Quality Manual. The petitioner argues the notification procedures set forth in section 64814.00 are conditioned upon a laboratory actually performing testing that would yield results warranting client notification and that no regulation adopted pursuant to the APA requires a Quality Manual to include these notification procedures when the laboratory does not perform such testing. Because the Checklist requires a laboratory that does not perform such work to include these notification procedures in its Quality Manual, the petitioner contends the Checklist is an underground regulation.

ELAP argues "[t]he requirements of [ELAP's] regulations need to be incorporated into every lab's … practices."[17] ELAP explains its reasoning, as follows:

> Laboratories who hold accreditation for Fields of Accreditation (FOAs) in a drinking water matrix are required to have policies and procedures compliant with requirements listed in § 64814.00. While the laboratory may not yet or ever perform analysis on drinking water samples, obtaining accreditation for drinking water FOAs allows the laboratory the ability to do so, and as such, requires it to have procedures specific to drinking water analysis, even if those analyses are used for testing recycled water.[18]

ELAP further contends:

> Section 64814.05, subdivision (b)(1)(B)(iii), requires a laboratory to develop and maintain a Quality Manual that must contain, at a minimum, 'documents, or references to documents, that contain [a]cquisition, reduction, validation, and reporting of data.' Cal. Code Regs., tit. 22 § 64802.05, subd. (b)(1)(B)(viii).) The 'reporting of data' provision in Section 64802.05, therefore, must include notification procedures that laboratories put in place to ensure clients are notified when analytical results warrant reporting. (ELAP's written response, at pp. 4-5)

ELAP essentially interprets the applicable regulations and challenged rules to mean a laboratory's client notification requirements depend upon its

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[17] Petition, at p. 3; ELAP Response, at pp. 5-6, n. 4 (affirming its correspondence and position on the matter as stated in the petition).
[18] *Ibid.*

potential work within a field of accreditation rather than its **actual** work within a field of accreditation. This is not the only legally tenable interpretation of section 64802.05. The parties' dispute over the very issue of interpretation is indicative. Interpreting section 64802.05 to require a laboratory to include the notification procedure in its Quality Manual pursuant to section 64814.00, based upon a laboratory's field of accreditation generally, as ELAP asserts, is tenable. But interpreting section 64802.05 to require a laboratory to include the notification procedure in its Quality Manual pursuant to section 64814.00, based upon a laboratory's actual practice, as the petitioner asserts, is also tenable.

While ELAP's interpretation may be legally tenable, existing law does not compel that result. ELAP's interpretation does not flow inescapably from existing law; it is not ineluctable. It is not the only legally tenable interpretation. Challenged Rule No. 1 is therefore an underground regulation.

Challenged Rule No. 2 (Drinking Water Notification Procedure)

Challenged Rule No. 2 in the Checklist states as follows:

> Does the Quality Manual, or referenced document, detail procedures when client notification is required?[19]

Challenged Rule No. 2 references section 64814.00(c), which provides in part as follows:

> A laboratory accredited to perform analyses on drinking water samples shall notify a water supplier's designated contact person:
> (1) Immediately within 24 hours, when the following results are confirmed:
> ….
> (2) Immediately within 48 hours, when the following results are confirmed:
> ….[20]

Like Challenged Rule No. 1, whether Challenged Rule No. 2 is an underground regulation depends on whether the only legally tenable interpretation of CCR, title 22, section 64802.05 requires a laboratory accredited to test drinking water, but that tests only recycled water, which could not trigger the notification requirements, to still include the drinking water notification requirements of section 64814.00 in its Quality Manual.

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[19] Checklist, at p. 14.
[20] Cal. Code Regs., tit. 22, § 64814.00, subd. (c).

The petitioner's argument with respect to Challenged Rule No. 2 is the same as that for Challenged Rule No. 1 - the requirement to include notification procedures set forth in CCR, title 22, section 64814.00(c) is conditioned upon a laboratory performing drinking water testing and does not apply to a laboratory performing only recycled water testing. The petitioner asserts no regulation adopted pursuant to the APA requires a Quality Manual to include notification procedures set forth in section 64814.00 when the laboratory does not perform testing on drinking water, even if its field of accreditation is described as a drinking water accreditation.

In favor of its position, ELAP contends:

> Section 64814.00, subdivision (c) specifically requires laboratories accredited to perform analysis on drinking water samples to notify a water supplier's designated contact person within a confined time, if specific water analysis results warrant notification. As noted previously, Section 64802.05, subdivision (b) requires laboratories to have reporting procedures in the Quality Manual. The requirements are, therefore, not underground regulations.[21]

Just as with Challenged Rule No. 1, OAL cannot find the only legally tenable interpretation of section 64802.05 is to require a Quality Manual to include notification procedures pursuant to section 64814.00(c), when the laboratory does not perform testing on drinking water. Interpreting section 64802.05 to require a laboratory to include the notification procedure in its Quality Manual, based upon a laboratory's field of accreditation generally, as ELAP asserts, is tenable. But interpreting section 64802.05 to require a laboratory to include the notification procedure in its Quality Manual, based upon a laboratory's actual practice, as the petitioner asserts, is also tenable.

While ELAP's interpretation may be legally tenable, existing law does not compel that result. ELAP's interpretation does not flow inescapably from existing law; it is not ineluctable. It is not the only legally tenable interpretation. Challenged Rule No. 2 is therefore an underground regulation.

[21] ELAP Response, at p. 5.

CONCLUSION

OAL determines that Challenged Rules 1 and 2 are underground regulations because they are regulations ELAP should have adopted pursuant to the APA but did not.

Date: September 18, 2023

/s/
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Copy:
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Exhibit A

Reference	SOP or QM §	Does the laboratory comply with this section?	Yes	No	N/A	Observations
§ 64802.15 (b)(3)(A)		Does the laboratory identify a prohibition of sending PT study samples, in which the laboratory is participating, to another laboratory for the analysis of a FOA for which it seeks accreditation or is accredited				
§ 64802.15 (b)(3)(B)		Does the laboratory identify a prohibition of knowingly receiving or analyzing any PT samples from another laboratory for which the results are to be used for accreditation				
§ 64802.15 (b)(3)(C)		Does the laboratory identify a prohibition of communicating with any individual at another laboratory concerning the analysis of PT samples of an ongoing study				
§ 64802.15 (b)(3)(D)		Does the laboratory identify a prohibition of attempting to obtain the assigned value of any portion of a PT study from the PT provider				
§ 64802.15 (b)(3)(E)		Does the laboratory identify a prohibition of requesting the PT provider to alter any portion of the laboratory's PT report after it was issued as final				
§ 64814.00		**Notification and Reporting**				
§ 64814.00 (a)		Does the laboratory document any additional State Regulatory Agencies or federal agencies reporting requirements?				
§ 64814.00 (b)		Does the Quality Manual, or referenced document, identify that if an analytical result warrants a client notification, then the notification shall occur after the Technical Manager, or designee, has approved of the result?				
§ 64814.00 (h)(1)	TNI option	Does the laboratory report to its clients in accordance with 2016 TNI V1M2 § 5.10?				

Specific Requirements for Types of Testing

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