REGION 8 ADMINISTRATOR
DENVER, CO 80202

VIA EMAIL ONLY

Honorable Phil Weiser
Colorado Attorney General c/o

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RE: Colorado Department of Public Health & Environment Appeal of EPA Region 8 Laboratory Services and Applied Sciences Division Final Revocation of Certification for EPA Methods 300.0, 353.2, and 552.2

Dear Ms. Weaver and Ms. Smith,

This letter is in response to the October 3, 2024, appeal filed by the Colorado State Public Health Laboratory (the State Laboratory), through the Colorado Attorney General's Office, from the EPA Region 8 Laboratory Services and Applied Sciences Division's (LSASD) decision to revoke certification for EPA Methods 300.0, 353.2, and 552.2. For the reasons stated below, LSASD's revocation decision is affirmed.

I. Background

A. Certification Process for Principal State Laboratories

With certain exceptions not relevant here, public water systems subject to the Safe Drinking Water Act (SDWA) must submit drinking-water compliance samples to laboratories certified to use EPA-approved analytical methods. *See* 40 C.F.R. § 141.28(a). To obtain primary enforcement responsibility for public water systems, a state must establish a "program for the certification of laboratories conducting analytical measurements of drinking water contaminants." *Id.* § 142.10(b)(3)(i). Additionally, to obtain and maintain primacy, a state must establish its own laboratory facility, known as the principal state laboratory, that is "certified by the [EPA] Administrator . . . capable of performing analytical

measurements of all contaminants specified in the State primary drinking water regulations." *Id.* § 142.10(b)(4).

The EPA Administrator has delegated this certification authority to the Regional Administrators, who may in turn redelegate the authority to the division level. U.S. EPA, 9-3 Certification of Laboratories and Responsible State Officials (November 30, 2016). The Regional Administrator for EPA Region 8 has redelegated certification authority to the Director of LSASD. U.S. EPA Region 8, 9-3 Certification of Laboratories and Responsible Officials (April 29, 2019).

The EPA publishes a guidance manual specifying criteria and procedures it uses in evaluating principal state laboratories for certification.[1] "This manual is not a rule, is not legally enforceable, and does not confer legal rights or impose legal requirements upon any member of the public, States or any other Federal agency." Manual at ii.

As relevant here, the Manual defines three levels of certification:

- Certified: A laboratory that meets the regulatory performance criteria as explained in the Manual and all other applicable regulatory requirements.

- Provisionally Certified: A laboratory that has deficiencies but demonstrates its ability to consistently produce valid data within the acceptance limits specified in the [National Primary Drinking Water Regulations], and within the policy required by their certification authority…. Provisional certification may not be given if the evaluation team believes that the laboratory cannot perform an analysis within the acceptance limits specified in the regulations.

- Not Certified: A laboratory that possesses deficiencies and, in the opinion of the Certification Authority, cannot consistently produce valid data.

Id. at III-3.

The Manual further provides examples for downgrading or revoking a principal state laboratory's certification status. Among other circumstances, the Manual provides as follows:

- A laboratory should be downgraded from certified to provisionally certified status if it fails "to satisfy the [certifying authority] that the laboratory is maintaining the required standard of quality, based upon [an] EPA on-site evaluation."

[1] U.S. EPA Office of Ground Water and Drinking Water Technical Support Center, *Manual for the Certification of Laboratories Analyzing Drinking Water, Criteria and Procedures Quality Assurance* (5th eds. Jan. 2005) (Manual), *available at* https://www.epa.gov/dwlabcert/laboratory-certification-manual-drinking-water (last visited December 10, 2024).

- A provisionally certified laboratory should be downgraded to not-certified status for "failure to satisfy the [certifying authority] that the laboratory has corrected deviations identified during . . . on-site evaluations."

- Any laboratory's certification should be entirely revoked (*i.e.*, downgraded to not-certified status) for "falsification of data or other deceptive practices."

Id. at III-7 to III-8. "Once certification is revoked, a laboratory may not analyze drinking water samples for compliance until its certification has been reinstated." *Id.* at III-8. A provisionally certified laboratory, on the other hand, "may analyze drinking water samples for compliance purposes, if the said clients are notified of its downgraded status in writing, on any report." *Id.* at III-3.

Within 30 days of an initial decision to downgrade or revoke a laboratory's certification status, the laboratory may appeal to the Regional Administrator. *Id.* at III-8. If the Regional Administrator denies the appeal, the laboratory's certification status will remain downgraded or revoked. The laboratory may seek upgrading or reinstatement of certification "when and if the laboratory can demonstrate to the Certification Authority's satisfaction that the deficiencies which produced provisionally certified status or revocation have been corrected." *Id.* at III-9.

B. Factual Background

1. EPA Method 200.7

On April 3 and 4, 2024, LSASD performed an on-site evaluation of the State Laboratory. On April 18, 2024, LSASD issued a letter notifying the State Laboratory that it was "immediately revoking certification for EPA method 200.7 (copper, chromium, and barium) and intends to downgrade your laboratory's certification to provisionally certified for all other drinking water methods."[2] LSASD reached this decision because "laboratory management shared information with certification officers regarding an active investigation into data manipulation within the chemistry department" and had "established that a sampling of quality control [QC] data since 2021 was manipulated for EPA method 200.7."[3]

The State Laboratory subsequently "confirmed that one chemist [Chemist A] disregarded key quality control checks while performing metal analysis for EPA 200.7."[4] According to the State Laboratory, "the chemist changed the text file generated by the instrument that is used to transfer results into the Laboratory Information Management System (LIMS)" so that "the quality control result was routinely being replaced with a passing result analyzed later in the batch."[5] Chemist A also ran "multiple

[2] Letter from William Bunch, Deputy Director, EPA R8 LSASD, to Dr. Emily Travanty, Director, Colorado State Public Health Laboratory (April 18, 2024) at 1.

[3] *Id.*

[4] Letter from Emily Travanty, PhD, Director, Colorado State Public Health Laboratory, to William Bunch, Deputy Director, EPA R8 LSASD (May 17, 2024) at 1.

[5] *Id.*

analyses of one control until passing results were obtained."[6] The State Laboratory further informed LSASD of corrective actions it had taken and intended to take within the following 90 days.[7]

On May 31, 2024, LSASD issued a letter to the State Laboratory finalizing its decision to revoke certification for EPA Method 200.7 and downgrade the Laboratory's status for all other methods from certified to provisionally certified.[8] LSASD further instructed the State Laboratory to submit a Corrective Action Response by August 31, 2024, and warned that "[f]ailure to make additional corrections to those methods for which EPA has classified as Provisional within this 90-day period (August 31, 2024) may warrant EPA to further downgrade the status of these methods."[9] The State Laboratory did not appeal LSASD's decision concerning Method 200.7.

2. EPA Methods 300.0, 353.2, and 552.2

LSASD and the State Laboratory subsequently held bi-weekly meetings. Before one such meeting held on August 23, 2024, the State Laboratory informed LSASD that it had decided to recall samples for three additional methods: EPA Methods 300.0 (Inorganic Anions), 353.2 (Nitrate-Nitrite), and 552.2 (Haloacetic Acids and Dalapon).[10] For EPA Method 552.2, the State Laboratory explained that "[t]hird party review is not possible" because "accessing raw data for this method requires viewing directly on the physical instrument and requires use of instrument software that automatically re-analyses the data."[11] Therefore, "[o]ut of abundance of caution we flagged all samples tested by the chemist in question for recall."[12]

For EPA Methods 300.0 and 353.2, notes taken by an LSASD employee at the August 23, 2024, meeting indicate that LSASD asked the State Laboratory personnel to "[d]escribe data manipulation in 300.0 and 353.2."[13] In response, the State Laboratory explained: "300.0 reason for recall was CCV [Continuing Calibration Verification] failures, instance of running a control >2x, ICV [Instrument Calibration Verification] failure"; and "353.2: one CCV failure, IPC [Instrument Performance Check]

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[6] *Id.*

[7] *Id.* at 1-5.

[8] Letter from Wendy O'Brien, Director, EPA R8 LSASD, to Dr. Emily Travanty, Director, Colorado State Public Health Laboratory (May 31, 2024) at 1-4.

[9] *Id.* at 2.

[10] Email from Emily Travanty, PhD, Director, Colorado State Public Health Laboratory, to William Bunch, Deputy Director, EPA R8 LSASD (August 23, 2024).

[11] *Id.*

[12] *Id.*

[13] *See* August 23, 2024, Meeting Notes, attached to Email from Marcie Tidd, Laboratory Certification Program Manager, EPA R8 LSASD, to Emily Travanty, PhD, Director, Colorado State Public Health Laboratory (August 23, 2024). Upon preparing the meeting notes, LSASD sent them to the State Laboratory for review and requested any necessary corrections. *Id.* The record does not reflect that State Laboratory requested any corrections.

failure, no LFB [Laboratory Fortified Blank] with batch."[14] State Laboratory personnel also explained that the quality control failures were not "flagged on the initial data packet."[15] They further clarified: "[A]ctual reviewed data packages need to be looked at still. No answers on what happened with raw data before reviewed, needed to rapidly review raw data and recall to meet deadline."[16]

The State Laboratory submitted its Corrective Action Response on August 30, 2024.[17] The Corrective Action Response included an "Internal Data Manipulation Root Cause Analysis" the purpose of which was to "perform an investigation into why an analyst performed data manipulation and falsification and was able to do this unnoticed for four years."[18] The Internal Root Cause Analysis revealed that Chemist A had performed secondary review on samples under additional EPA methods, including Methods 300.0, 353.2, and 552.2.[19]

The State Laboratory conducted an internal data analysis on all samples reviewed by Chemist A under Methods 300.0 and 353.2 and found 250 samples that were "impacted," including 9 SDWA compliance samples.[20] The samples were "recall[ed] due to QC failure."[21] The State Laboratory also recalled all samples reviewed by Chemist A under Method 552.2, totaling 248 samples, including 234 SDWA compliance samples.[22] All samples for Method 552.2 were recalled because "[t]he laboratory has the raw data in the instrument" but "[t]he raw data would have to be reprocessed to confirm if testing integrity was impacted."[23] Chemist A also had received a "coaching form" in June 2022 from lab managers concerned about irregularities in Chemist A's quality control processes under EPA Method 552.2.[24] The managers did not take follow-up corrective action against Chemist A or notify the Laboratory Director or the EPA at that time.[25]

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[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] Corrective Action Response, First Attachment to Letter from Emily Travanty, PhD, Director, Colorado State Public Health Laboratory, to Wendy O'Brien, Director, EPA R8 LSASD (August 30, 2024) (CAR).

[18] Internal Data Manipulation Root Cause Analysis, Second Attachment to Letter from Emily Travanty, PhD, Director, Colorado State Public Health Laboratory, to Wendy O'Brien, Director, EPA R8 LSASD (August 30, 2024) at 1 (IRCA).

[19] *Id.* at 13.

[20] *Id.* at 20-22.

[21] CAR at 2-3.

[22] IRCA at 22.

[23] *Id.* at 21; *see also* CAR at 3 ("Raw data is archived on the testing instrument but instrument software does not permit re-extraction of that data without reanalysis. Additionally, third party review of the raw data is not possible because the data cannot be extracted from the instrument. For these reasons, the lab decided to flag all 552.2 data for testing performed by the analyst in question for recall.").

[24] IRCA at 16-17.

[25] *Id.*

Because Chemist A had been involved with staff training, the Internal Root Cause Analysis recommended a review of all Chemistry Program Methods.[26] Through data analysis, the State Laboratory learned that "there were other analysts who had been found with QC failures and reports had been recalled."[27] The State Laboratory "found four additional analysts with identified QC failures demonstrating that more than Chemist A's test results were included in the overall data comparison."[28] In one batch, neither the initial chemist (Chemist G) nor Chemist A acting as reviewer had caught a "failed MRL [Minimum Reporting Level]" that "should have initiated a rerun" of the sample.[29] There also was a "failed ICP that was not caught during initial review by Chemist G or secondary review by Chemist A."[30]

The State Laboratory has contracted with a third-party to conduct an independent root cause analysis, and the result of that third-party investigation remains outstanding.

C. LSASD's Revocation Decision for Methods 300.0, 353.2, and 552.2

Based on the information from the August 23, 2024, meeting, the Corrective Action Response, and the Internal Root Cause Analysis, LSASD sent a letter to the State Laboratory "immediately revoking certification" for EPA Methods 300.0, 353.2, and 552.2 "because you have identified these additional methods as having been impacted by known or suspected data manipulation or other deceptive quality control practices."[31] LSASD's letter explained that because Chemist A "worked on the three other methods and since data manipulation or deceptive quality control practices have either been found through [CDPHE's] internal investigation (Methods 300.0 and 353.2) or cannot be ruled out due to data retrieval issues (Method 552.2), the expanded scope of quality control issues merits similar action for these methods."[32]

LSASD acknowledged that the State Laboratory "is taking action to identify the root cause and extent of the manipulation, and that . . . analysis will take additional time," but determined that "[w]hile the review process continues and corrective actions are pending . . . it is appropriate to revoke certification for these three additional methods."[33] LSASD emphasized that "[d]ata manipulation and patterns of deceptive quality control practices are serious concerns and can carry significant implications for public

[26] IRCA at 13-14, 23, 30.

[27] *Id.* at 20.

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] Letter from Wendy O'Brien, Director, EPA R8 LSASD, to Dr. Emily Travanty, Director, Colorado State Public Health Laboratory (Sept. 3, 2024) at 1.

[32] *Id.*

[33] *Id*.

health" and some of the methods at issue "involve acute contaminants."[34] LSASD therefore decided that while the State Laboratory continued to investigate "the full scope of the quality control issues, it is critical that the certification of the four methods likely impacted by data manipulation be revoked."[35]

D. The State Laboratory's Appeal

On October 3, 2024, the State Laboratory, through the Colorado Attorney General's Office, filed a Notice of Appeal from LSASD's decision to revoke certification for EPA Methods 300.0, 353.2, and 552.2, contending that the decision was "arbitrary and capricious and an abuse of its discretion."[36] The State Laboratory argued that Chemist A's involvement had necessitated the recall of "results from less than 1% of the drinking water compliance samples over 6 years of testing due to quality control flags" and that the flags at issue "do not have evidence of data manipulation."[37] For Method 552.2, the State Laboratory stated that it recalled all of Chemist A's results "out of an abundance of caution because the recovery of raw archived data for comparison to what is stored in the lab database was not possible."[38]

The State Laboratory also argued that, until the internal and third-party consultant investigations are complete, "the EPA will not have all the facts related to the chemist's breach of quality assurance protocols before it for consideration."[39] At the time it filed its Notice of Appeal, the State Laboratory had "completed its review of approximately 80% of drinking water sampling test results affected by the chemist's deviation from quality assurance protocols and has identified no acute water quality issues related to these results."[40] The State Laboratory also noted that it had complied with all LSASD's requests for corrective action.[41]

The State Laboratory predicted it would complete an initial review of 100% of the results in October 2024 and committed to coordinate with the EPA on a "plan for drinking water system notification and resampling, where appropriate."[42] The State Laboratory estimated that the third-party would complete its investigation and deliver a report in December 2024.[43] And the State Laboratory requested that the EPA Regional Administrator "stay any decision on this appeal until January 31, 2025," because "by

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[34] *Id.* at 3.

[35] *Id*.

[36] Notice of Appeal at 3.

[37] *Id.*

[38] *Id.*

[39] *Id.* at 4.

[40] *Id.* at 3.

[41] *Id.* at 2-3.

[42] *Id.* at. 3.

[43] *Id.*

December 31, 2024, all issues related to the quality assurance breach will be identified and corrected and all testing methods will be ready for recertification."[44]

E. LSASD's Recommendation

LSASD recommends that the appeal be denied for several reasons:

1. The State Laboratory admitted at the August 23, 2024, meeting that Chemist A's deceptive practices under Methods 300.00 and 353.2 resembled the deceptive practices under Method 200.7; namely, Continuing Calibration Verification failures, or instances of running a control more than two times to get a passing result, and Instrument Calibration Failure.[45]

2. The "coaching form" showed that the State Laboratory knew of similar quality control problems with Chemist A's work under Method 552.2 as early as June 2022, but took no corrective action. And the State Laboratory kept the raw data for that method in a format that made it impossible to readily determine the integrity of Chemist A's work.[46]

3. The Internal Root Cause Analysis showed that the quality control concerns at the State Laboratory extended beyond Chemist A's work on a single EPA test method to four additional chemists and three additional EPA test methods over several years.[47]

LSASD clarified that it did not revoke the State Laboratory's certification for failure to comply with the EPA's recommendations or to satisfactorily complete or timely submit its Corrective Action Response.[48] LSASD therefore contends that the State Laboratory's compliance with LSASD's corrective action requests is irrelevant to the issue on appeal.[49]

LSASD further recommends that the stay be denied because no further information is needed to decide the appeal and the recertification process is separate from appeal of the revocation decision.[50]

F. Regional Administrator's Questions

After reviewing the record, the State Laboratory's Notice of Appeal, and LSASD's recommendation, the Regional Administrator attempted to schedule an informal meeting with the State Laboratory and LSASD in November 2024 to clarify the parties' positions. However, due to the parties' other work commitments, the Regional Administrator was unable to identify a timely date for such a meeting. The

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[44] *Id.* at 4.

[45] LSASD Recommendation at 8.

[46] *Id.* at 8-10.

[47] *Id.* at 10.

[48] *Id.* at 10-11.

[49] *Id.*

[50] *Id.* at 12.

Regional Administrator therefore instead sent the following questions to the State Laboratory and LSASD and requested written responses:

1. The State Laboratory's Notice of Appeal asserts that the quality control flags at issue for EPA Methods 300.0 and 353.2 "do not have evidence of data manipulation." Please explain the factual basis for this assertion, which appears inconsistent with the notes from the August 23, 2024, meeting. There, the State Laboratory described the quality control problems that prompted recall under Methods 300.0 and 353.2, and those problems were like the problems observed for Method 200.7. Has the State's position changed? If so, why?

2. The Notice of Appeal predicts that the State Laboratory will complete a review of 100% of the affected results in October 2024. Has the State Laboratory completed that initial review and, if so, what was the result for the recalled samples under Methods 300.0, 353.2, and 552.2? Please describe any quality control errors or indication of data manipulation or deceptive practices found in those samples.

3. Why was the State Laboratory not able to more easily verify whether the data for Method 552.2 had signs of quality control problems, data manipulation, or deceptive practices? What is the standard practice for storing data for Method 552.2 at certified laboratories and how does that standard practice compare to the State Laboratory's approach here?

4. The Internal Root Cause Analysis states that the quality control problems extended beyond Chemist A to additional chemists at the State Laboratory. Has the State Laboratory conducted any investigation into quality control problems, data manipulation, or deceptive practices by other chemists over the past 6 years for Methods 300.0, 353.2, and 552.2? What has the State Laboratory found?

LSASD and the State Laboratory submitted their answers to these questions on November 27 and 29, respectively. Pertinent portions of those answers are discussed in my analysis below.

II. Analysis

A. Standard of Review

This proceeding constitutes an informal agency adjudication. *See Neustar, Inc. v. Fed. Commc'ns Comm'n*, 857 F.3d 886, 893 (D.C. Cir. 2017) ("[A]gencies may use informal adjudications when they are not statutorily required to engage in the notice and comment process or to hold proceedings on the record."). An agency's designated appellate officer exercises de novo review over initial decisions rendered in informal adjudications. *See ITServe All., Inc. v. Dep't of Homeland Sec.*, 590 F. Supp. 3d 27, 31 (D.D.C. 2022) (explaining how the Administrative Appeals Office of the U.S. Citizenship and Immigration Services exercises de novo review of initial decisions on visa petitions, which are handled as informal adjudications); *see also* 5 U.S.C. § 557(b) (stating that, even in a *formal* adjudication, "[o]n appeal from or review of the initial decision, the agency has all the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule"). This means that the appellate officer "looks at the record anew and its decision may address new issues that were not raised or resolved in the prior decision." *ITServe All., Inc.*, 590 F. Supp. 3d at 31. I therefore review

LSASD's revocation decision de novo, although the decision I render "still must comply with the familiar APA standard banning arbitrary and capricious actions." *Id*.

B. Stay Request

The State Laboratory requests that I "stay any decision on this appeal until January 31, 2025," because "by December 31, 2024, all issues related to the quality assurance breach will be identified and corrected and all testing methods will be ready for recertification."[51] I am denying this request for several reasons. As LSASD explained in its revocation decision, potential data manipulation and deceptive or irregular quality control practices are serious concerns that carry significant implications for public health, particularly because the State Laboratory uses the analytical methods at issue to analyze samples for SDWA compliance. It therefore is in the public interest to address the State Laboratory's appeal as expeditiously as practicable.

Nor is there any good reason to delay a decision here. This appeal concerns whether the State Laboratory's certification for the three analytical methods at issue should remain revoked. Although the State Laboratory's third-party contractor has not yet completed its review of all the data involved, the record contains sufficient information to formulate a reasoned decision concerning the reliability and validity of the data produced by the State Laboratory under the three analytical methods at issue. It also is not clear that the State Laboratory will know the full extent of the data manipulation and deceptive practices that may have occurred even *after* the third-party's report is available. This is because, as the State Laboratory has explained, the third-party is not specifically looking for evidence of data manipulation or other deceptive practices. State Laboratory's Response to Question 2 ("The vendor's data analysis will identify quality control values exceeding parameters defined in the method and *will not* specify which if any of those failures are attributable to data manipulation issues." (emphasis added)). Staying a decision on this appeal therefore would serve no purpose other than delay.

The State Laboratory believes it will be ready for recertification for the methods in question soon, but that is not at issue in this appeal. Recertification requires LSASD to determine whether the "laboratory can demonstrate to the Certification Authority's satisfaction that the deficiencies which produced provisionally certified status or revocation have been corrected." Manual at III-9. On that issue, the State Laboratory has not yet provided complete information to LSASD, and LSASD has not yet reached a decision. The uncertain prospect of future recertification provides no reason to delay a decision on this appeal, which exclusively concerns LSASD's decision to revoke the Laboratory's certification.

C. Revocation Decision for EPA Methods 300.0, 353.2, and 552.2

The central question here is whether the State Laboratory meets the definition of "certified," "provisionally certified," or "not certified" for EPA Methods 300.0, 353.2, and 552.2:

- "Certified" means a "laboratory that *meets the regulatory performance criteria* as explained in the Manual and all other applicable regulatory requirements."

[51] Notice of Appeal at 4.

- "Provisionally certified" means that the laboratory "has deficiencies but demonstrates its ability to *consistently produce valid data* within the acceptance limits specified in the [National Primary Drinking Water Regulations], and within the policy required by their certification authority."

- "Not certified" means that the laboratory "possesses deficiencies and, in the opinion of the Certification Authority, *cannot consistently produce valid data*."

Manual at III-3 (emphasis added). Based on a review of the documents in the record and the parties' responses to the questions, I conclude that the State Laboratory cannot "consistently produce valid data" under EPA Methods 300.0, 353.2, and/or 552.2, and does not "meet[] the regulatory performance criteria as explained in the Manual and all other applicable regulatory requirements." *Id.* The Laboratory's status for these three methods therefore must remain revoked.

1. EPA Methods 300.0 and 353.2

For EPA Methods 300.0 and 353.2, the State Laboratory recalled 250 samples "due to QC failure."[52] As LSASD's response notes, this "equates to approximately 1,000 sample results because one sample can be analyzed for multiple analytes." LSASD Response to Question 2. The notes for the August 23, 2024, meeting show that these were not just routine quality control errors, but rather included instances of running a control more than two times to gain a passing result, as had occurred for Method 200.7.[53] This qualifies as a "deceptive practice" that warrants revocation. Manual at III-8.

Additionally, Chemist A did not "flag" the sample results as containing quality control errors.[54] As LSASD's response explains, "[i]t is not uncommon to detect quality control errors or failures in laboratory sampling," but when such errors occur, "it is standard practice to flag those errors and take appropriate corrective action to address them." LSASD Response to Question 1. Here, however, despite detecting quality control errors, Chemist A did not place a flag on the impacted data, making the failed quality control tests appear that they had passed. The Laboratory then reported the samples as having passed quality control procedures, when in fact they had not passed. This too constitutes a deceptive practice warranting revocation according to the Manual.

The State Laboratory argues that revocation is inappropriate here because it recalled "results from less than 1% of the drinking water compliance samples over 6 years of testing due to quality control flags."[55] This attempt to minimize the problem is unpersuasive. The State Laboratory has reviewed only a small subset of total drinking water compliance samples for the timeframe at issue, so it is not known how many would need to be recalled if they performed a more comprehensive review. Moreover,

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[52] CAR at 2-3.

[53] *See* August 23, 2024, Meeting Notes, attached to Email from Marcie Tidd, Laboratory Certification Program Manager, EPA R8 LSASD, to Emily Travanty, PhD, Director, Colorado State Public Health Laboratory (August 23, 2024).

[54] *Id.*

[55] Notice of Appeal at 3-4.

evidence that an employee of a state's primary laboratory has—over several years—engaged in deceptive quality control practices seriously calls into question the laboratory's ability to consistently produce valid data, even if only a small number of samples have been definitively shown to be affected. Detection of some instances of deception raises the possibility that an unknown number of additional samples may have similar problems but have escaped detection. The entire goal of deception is to conceal dishonest conduct.

The State Laboratory also argues the flags at issue for these methods "do not have evidence of data manipulation."[56] The Laboratory explained this statement in its responses to my questions. In the Laboratory's view, there is no evidence of "intentionally altered data" for these methods because Chemist A did not "select[] passing quality control values and use[] copy/paste to move those values within the run data set before submitting data packets for secondary review, thus misrepresenting the data as actual primary/raw data and intentionally concealing quality control failures," as happened with Method 200.7. State Laboratory Response to Question 1. Although the Laboratory may not yet have detected that level of "data manipulation" for Methods 300.0 and 353.2, the Laboratory's position ignores that that it did detect "other deceptive practices," as summarized above. Manual at III-8.

The Manual does not expressly define "data manipulation" or "other deceptive practices," but Supplement 1 to the Manual cites an Office of Inspector General Report (OIG Report)[57] to help explain the types of fraudulent behavior that drinking water laboratories must be prepared to detect and address. Supplement 1 to Manual at 5. The OIG Report highlights four key areas of concern:

1. **Inappropriate procedure**: A scientifically unsound or technically unjustified omission, manipulation, or alteration of procedures or data that bypasses the required quality control parameters, making the results appear acceptable.

2. **Laboratory fraud**: The deliberate falsification during reporting of analytical and quality assurance results that failed method and contractual requirements to make them appear to have passed requirements.

3. **Data quality**: The degree of acceptability or utility of data for a particular purpose – in this case, reporting public drinking water sample information.

4. **Laboratory integrity**: The laboratory's meeting general standards of objectivity, data quality, and ethical behavior, thus reporting accurate, complete, and valid information.

[56] *Id.* at 3.

[57] *Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks* (Report No. 2006-P-00036, U.S. Environmental Protection Agency (EPA), Office of Inspector General (OIG), Washington, D.C., 2006) (https://www.epaoig.gov/sites/default/files/2015-11/documents/20060921-2006-p-00036.pdf) (last visited December 10, 2024).

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Supplement 1 to Manual at 5. The State Laboratory seems to argue that the second of these concerns did not occur here because they have not found evidence of "deliberate falsification" of the results. *Id.* But Chemist A's behavior does implicate the other three areas of concern. Running samples repeatedly until getting a passing quality control result and omitting quality control flags to make the samples appear to have passed quality controls certainly constitute "[i]nappropriate procedure[s]" designed to "bypass[] the required quality control parameters, making the results appear acceptable." *Id.* And given those practices, it is hard to trust the "[d]ata quality" and "integrity" of the Laboratory's results for the methods at issue. *Id.*

Of perhaps greater concern, the reason the State Laboratory has not found evidence of data manipulation may be because it is *not looking* for such evidence. The Laboratory explains that because "discerning specific instances of data manipulation was exceptionally time and resource intensive" when reviewing data for Method 200.7, Laboratory staff "changed their review methodology to identify all quality control failures, rather than identifying specific instances of data manipulation, and used this same methodology to review Methods 300.0 and 353.2." State Laboratory Response to Question 2. The State Laboratory further explains that its third-party contractor's data analysis similarly "will identify quality control values exceeding parameters defined in the method and *will not* specify which if any of those failures are attributable to data manipulation issues." *Id.* (emphasis added). Because the State Laboratory appears not to be looking for data manipulation, it cannot rely on the absence of evidence of data manipulation to argue that it should remain provisionally certified for these methods.

The State Laboratory also has not addressed the finding in its own Internal Root Cause Analysis that the quality control issues for these methods extended beyond Chemist A to "four additional analysts," possibly because Chemist A had trained other staff.[58] In response to my question on this subject, the Laboratory states only that it "has not encountered any other instances of data manipulation or deceptive practices regarding these methods; however, the Laboratory is developing a data analysis plan to look back to verify no other instances of data manipulation have occurred." State Laboratory Response to Question 4. In other words, the Laboratory does not know whether and to what extent other analysts engaged in data manipulation, deceptive practices, or quality control errors for Methods 300.0 and 353.2. Based on records submitted by the State Laboratory, LSASD estimates that, for the four additional analysts identified in the Internal Root Cause Analysis, "there are 5,554 results under Method 300.0, 162 results under Method 353.2, and 644 results under Method 552.2 that CDPHE has not reviewed for QC irregularities, data manipulation, or deceptive practices that would necessitate data recalls." *See* LSASD Response to Question 4.

Given this record, I conclude that the State Laboratory "possesses deficiencies and . . . cannot consistently produce valid data" for Methods 300.0 and 353.2. Manual at III-3. I further conclude that the State Laboratory does not "meet[] the regulatory performance criteria as explained in the Manual and all other applicable regulatory requirements." *Id.* The Laboratory's certification status for those methods therefore must remain revoked. *See id.* ("Provisional certification *may not* be given if the evaluation team believes that the laboratory cannot perform an analysis within the acceptance limits specified in the regulations." (emphasis added)).

[58] IRCA at 20.

2. EPA Method 552.2

The analysis is similar for Method 552.2. The State Laboratory knows that Chemist A had contact with 248 samples, including 234 SDWA compliance samples, under Method 552.2. The Laboratory also knows that lab managers issued a "coaching form" to Chemist A in June 2022 due to irregularities in quality control processes under Method 552.2, and no follow-up corrective action was taken.[59] What the Laboratory does *not* know is whether and to what extent Chemist A or other analysts engaged in data manipulation, deceptive practices, or quality control errors for Method 552.2. This is because the Laboratory stores the raw data for this method in such a manner that it cannot be accessed for comparison to the analysts' results, which is the only way to confirm whether data manipulation or deceptive practices have occurred.[60] Nor has the Laboratory or its third-party consultant conducted a review of the data for quality control errors. State Laboratory Response to Questions 2-3 ("The data for Method 552.2 cannot be analyzed remotely and would require the third party data analysis contractor to come onsite…. [T]he review of Method 552.2 has not been completed.").

Because the State Laboratory either cannot or has not investigated the extent of data manipulation, deceptive practices, or qualtiy control errors for Method 552.2, I cannot conclude that it is capable of consistently producing valid data or that it "meets the regulatory performance criteria as explained in [the] Manual." Manual at III-3. The Manual requires that laboratories "maintain easily accessible records" including of "raw data, calculations, and quality control data." Manual at IV-9. It further specifies that "[a]dequate information should be available to allow the auditor to reconstruct the final results for compliance samples and PT samples." *Id.*

The reason for these requirements is to enable the Laboratory and its auditors to detect data manipulation and other deceptive practices, including the types of fraudulent conduct described in the OIG Report. The Laboratory admits that its records for Method 552.2 do not meet the Manual's requirements, so it does not know whether Chemist A or any other analyst manipulated data or engaged in other deceptive practices. And even though the possibility of quality control problems for Method 552.2 has been known since at least August 2024, it appears that the Laboratory has made little, if any, progress investigating the nature and extent of those errors. *See* State Laboratory Response to Questions 2-3.

Based on this record, I conclude that the State Laboratory "possesses deficiencies and . . . cannot consistently produce valid data" for Method 552.2. Manual at III-3. I further conclude that the State Laboratory does not "meet[] the regulatory performance criteria as explained in [the] Manual and all other applicable regulatory requirements." *Id.* The Laboratory's certification status for Methods 552.2 therefore must remain revoked. *Id.*

[59] IRCA at 16-17.

[60] *See* Email from Emily Travanty, PhD, Director, Colorado State Public Health Laboratory, to William Bunch, Deputy Director, EPA R8 LSASD (August 23, 2024); IRCA at 21-22; CAR at 3; State Laboratory Response to Question 3.

Sincerely,

Becker, Kathleen

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KC Becker
Regional Administrator

cc: K.C. Schefski, Regional Counsel, EPA Region 8
Wendy O'Brien, Director, LSASD, EPA Region 8