REGION 8
DENVER, CO 80202

December 30, 2024

Ref: 8LAS-LS

Dr. Emily Travanty
Director, Colorado State Public Health Laboratory
Colorado Department of Public Health and Environment
8100 Lowry Boulevard
Denver, Colorado 80230-6928

Dr. Travanty:

The U.S. Environmental Protection Agency (EPA) appreciates the timely submittal by the Colorado Department of Public Health and Environment Laboratory (CDPHE or the Laboratory) on December 16, 2024, describing corrective actions that have been completed as well as those that are still in progress. As per the EPA's September 13, 2024 letter to CDPHE, the EPA has evaluated the information in your December 16 submittal and is herein providing you with a decision on the status of the provisionally certified Chemistry Methods upon their expiration on December 30, 2024. While the information in CDPHE's December 16, 2024 submittal was under review by the EPA, CDPHE verbally notified the EPA on December 23, 2024, that they independently suspended water testing in the Chemistry Program at the State Laboratory due to identification of manipulation of quality control data by an additional chemist.

This letter provides notice to you that the Laboratory's certification has expired for EPA Methods 200.8 (Copper, Lead, Antimony, Arsenic, Beryllium, Cadmium, Mercury, Selenium, Thallium, Total Uranium), 300.1 (Bromate, Chlorite), 504.1 (Ethylene dibromide, Dibromochloropropane), 505 (Chlordane, Polychlorinated biphenyls (as Aroclors), Toxaphene), 524.2 (Total Trihalomethanes, VOCs), 525.2 (Alachlor, Atrazine, Benzo[a]pyrene, Di(2-ethylhexyl)adipate, Di(2-ethylhexyl)phthalate, Endrin, Heptachlor, Heptachlor Epoxide, Hexachlorobenzene, Hexachlorocyclopentadiene, Lindane, Methoxychlor, Pentachlorophenol, Simazine), 531.2 (Carbofuran, Oxamyl), 547 (Glyphosate), 548.1 (Endothall), 549.2 (Diquat), and 555 (2, 4, 5-TP (Silvex), 2, 4-D, Dinoseb, Picloram) (11 Methods). This lapse is effective immediately and CDPHE is prohibited from performing future analyses under these Methods. EPA Methods 200.7, 300.0, 353.2, and 552.2 remain revoked. Through a written request, the CDPHE may seek reinstatement when the Laboratory can demonstrate that all corrective actions have been completed to the EPA's satisfaction.

This letter will further describe: 1) why certification for these 11 EPA Methods has lapsed; 2) the effect of this lapse; and 3) conditions for CDPHE to reinstate or seek new certification for any EPA drinking water chemistry methods.

1. Why Is Certification Lapsing for the 11 Provisionally-Certified Methods?

Certification for the 11 Methods is lapsing as a consequence of CDPHE's delay in completing a comprehensive data

review and fully implementing corrective actions prior to the December 30, 2024 expiration date. These 11 EPA Methods have remained in provisionally certified status for over 200 days, well exceeding the three-month timeline that is typically provided to provisionally certified laboratories to implement corrective actions and apply for full certification. Further, the scope of data impacted by deceptive quality control practices continues to expand, and CDPHE's December 16, 2024 submittal identifies a number of corrective actions that have not been completed and/or fully implemented, including:

A. Identification of the full scope of data impacted by quality control issues, including:
    - A data review that includes all samples from 2018-2024, across all analysts for each Method[1]
        - This data review should include a prioritized review of acute contaminants and contaminants with no safe thresholds (*e.g.*, lead)
    - Corrective actions that address any vulnerabilities identified during the review, including but not limited to missing raw data and any failures to follow requirements of the Laboratory's Quality Manual.
B. Implementation of an effective communication plan for notifying EPA in writing within 30 days of major changes in the Laboratory.
C. Upgrading equipment and technology, including CDPHE's Laboratory Information Management System (LIMS).
D. Increasing quality control staffing and resources.
E. Development of a crisis response protocol.
F. Unaddressed findings from CDPHE's External Root Cause Analysis.
    - Turnaround time pressure
    - Culture of urgency.

Items A-F are discussed in greater detail below.

A. Identification of the Scope of Quality Control Issues - Ongoing Data Review

Summary: CDPHE's December 16, 2024 submittal states that the Laboratory's comprehensive review of data is still in progress. On December 23, 2024, CDPHE provided a press release and verbally informed the EPA that the Laboratory had independently ceased operations in their Chemistry Program upon discovery of quality control data manipulation by a second chemist and that a comprehensive data review (all data, all chemistry methods, all chemists) was planned. The EPA supports CDPHE's commitment to conduct a comprehensive data review.

Supporting Information: CDPHE's December 16, 2024 submittal proposed a limited data review approach (which would have resulted in review of approximately 10-25% of data since 2018). On December 23, 2024, CDPHE verbally notified the EPA that a second employee in the Chemistry Program had been put on administrative leave after a review of recalled data demonstrated the employee had manipulated quality control data. EPA understands that this individual had been an employee of CDPHE for over 30 years, was a supervisor, and was one of the five chemists identified in CDPHE's August 30, 2024 Corrective Action Response as having data irregularities in Method 200.7. During the December 23, 2024 meeting with EPA, CDPHE committed to a comprehensive investigation (all data, all methods, all chemists) of data in the Laboratory's Chemistry Program. Given the growing scope of data quality issues and proposed data review timelines, it is no longer prudent for the EPA to offer additional extensions for provisional certification. Identifying the full extent of impacted data is important not only to enable customers to make informed decisions about their use of impacted data, but also – as CDPHE's External Root Cause Analysis points out – to ensure that the causes of the issues are remedied, that appropriate actions are taken to address individuals who have been

[1] In conversations with the EPA on December 20, 2024 and December 27, 2024, CDPHE committed to perform a full data review of all samples from 2018-2024 for all chemists. CPDHE further indicated prioritization of evaluation of lead samples and methods for nitrate/nitrite.

involved in deceptive quality control practices, and that similar quality control issues do not occur going forward.

The December 16, 2024 submittal states that the Chemistry Program Manager is responsible for overseeing the data review, however, this chemist has also been identified as having irregularities in their analytical work. Their oversight role in the data review represents a clear conflict of interest. CDPHE should assign a manager with independence to oversee the data review. Additionally, as reported in the December 16, 2024 submittal, approximately 10% more results were recalled as a result of the third-party data review catching errors missed by CDPHE's internal data review. For these reasons, the internal data review should also be paired with an external data review to further demonstrate objectivity and completeness of the review.

B. Implementation of an Effective Communication Plan for Notifying EPA in Writing, of Major Changes

Summary: CDPHE has not consistently implemented key corrective actions related to notifying the EPA of major changes related to the Laboratory. For example, the EPA discovered that in mid-November 2024, three resignations occurred within the management chain at the Laboratory, including: the Laboratory's Deputy Director, the Microbiology Program Manager, and the first line supervisor in the Microbiology Program. CDPHE did not notify the EPA of these major personnel changes as required in the Laboratory's Quality Manual and in EPA's Manual for the Certification of Laboratories Analyzing Drinking Water.

Supporting Information: As part of corrective actions submitted on August 30, 2024, CDPHE provided the following update to the Laboratory's Quality Manual to address the four-month delay in notifying the EPA of known deceptive quality control practices:

> *The laboratory must notify its regulatory body and customers impacted by major changes to include, but not limited to laboratory location; changes in personnel; personnel involved with data integrity or compliance issues within 30 days of the change* (CDPHE Quality Manual, Section 6. Organization and Responsibilities).

This addition to CDPHE's Quality Manual was needed to align CDPHE's processes with the EPA's Manual for the Certification of Laboratories Analyzing Drinking Water, which states in Section 13.4, Notification of Certifying Authority of Major Changes:

> *Certified laboratories should notify the appropriate CA (Regional Administrator or designee or the Chief, TSC-OGWDW) in writing, within 30 days of major changes in personnel, equipment, or laboratory location. A major change in personnel is defined as the loss or replacement of the laboratory supervisor or a situation in which a trained and experienced analyst is no longer available to analyze a particular parameter for which certification has been granted. The CA should discuss the situation with the laboratory supervisor and establish a schedule for the laboratory to address major changes. If the CA determines that the laboratory can no longer produce valid data, the CA should follow the procedure for revocation of certification.*

The EPA appreciates the steps that CDPHE has taken to clarify regulatory notification requirements in the Laboratory's Quality Manual; however, CDPHE has not consistently implemented these notification requirements. As an example of communication lapses despite the update described above to the Laboratory's Quality Manual, on November 22, 2024, a news article reported that the Deputy Director of the Laboratory had resigned. On December 4, 2024, CDPHE publicly posted a job advertisement for the Microbiology supervisor. During a conversation with CDPHE on December 27, 2024, the EPA confirmed that these two positions and another position (a first line supervisor in the Microbiology Program) have been vacant for more than 30 days. CDPHE did not notify the EPA of these major personnel changes within 30 days as specified in their Quality Manual. This continuing lapse in communication indicates that the corrective actions, while implemented in writing in CDPHE's Quality Manual, are not being implemented in practice and may not be fully addressing the root cause, or that additional factors might be contributing to the gaps in communication.

The EPA appreciates the immediate notification on December 23, 2024 that the Chemistry Program's first line supervisor had been placed on administrative leave, however, there are broader implications and vulnerabilities regarding vacancies in multiple management positions at the Laboratory. Within the past two months, the EPA understands that four Laboratory supervisors/managers have either resigned or have been put on administrative leave. Given the significant impacts to management oversight, CDPHE should notify EPA of these types of changes in the future and describe plans for managing the organizational structure changes.

C. Upgrading Equipment and Technology, Including CDPHE's Laboratory Information Management System (LIMS)

According to CDPHE's December 16, 2024 submittal, this corrective action remains in process. The upgrade to the new version of the LIMS system was delayed due to unanticipated issues with the vendor and delays in rebuilding the custom integration processes that exist in the current system into the new system. The LIMS vendor anticipates this development will delay the go-live date until Q1 2025.

D. Increasing Quality Control Staffing and Resources

According to CDPHE's December 16, 2024 submittal, corrective actions related to increasing quality control staffing and resources remain in process; two new Quality Assurance Officer positions are undergoing final human resource review in preparation for recruitment.

E. Development of a Crisis Response Protocol

According to CDPHE's December 16, 2024 submittal, this corrective action remains in process. The EPA recognizes that CDPHE management and senior leadership are developing a formal process and clear expectations to identify and elevate concerns early, including those that involve human resource issues, quality assurance issues, and resource needs.

F. Unaddressed Findings from CDPHE's External Root Cause Analysis

According to the CDPHE External Root Cause Analysis, the reduction in turnaround time from 28 to 14 days created additional pressure on analysts, potentially contributing to shortcuts and errors. Further, the Laboratory's time-sensitive culture and constant sense of urgency created a stressful environment that could lead to employee burnout and errors. CDPHE's December 16, 2024 submittal does not address these findings directly.

2. Effect of Lapse in Certification

As noted at the beginning of this letter, certification for the 11 Chemistry Methods that were previously in provisional status has lapsed, and the four revoked Methods remain revoked. This lapse is effective immediately and CDPHE is prohibited from performing future analyses under these Methods.

The Safe Drinking Water Act regulations require that as a condition of maintaining primacy, the Principal State Laboratory must be capable of performing analytical measurements of all contaminants specified in the State primary drinking water regulations. 40 CFR 142.10(b)(4). These laboratory facilities may be made available to the State by the operation of a State laboratory, by contracting with commercial laboratories, by making arrangements with another state (e.g. MOU), or by some combination of the above. These laboratories, collectively, represent the Principal State Laboratory (PSL) network. Based on discussions with the Laboratory, the EPA understands that CDPHE has contracted with Colorado Analytical Laboratories Inc. to provide analytical support during CDPHE's lapse in

certification. An EPA Region can recognize/certify such laboratories in several ways.[2] Accordingly, Region 8 recognizes Colorado Analytical Laboratories Inc. as part of CDPHE's Principal State Laboratory. The EPA used CDPHE's certification information to support regional recognition and has sent a letter to Colorado Analytical Laboratories Inc. indicating this recognition.

3. Conditions for CDPHE to Seek Reinstatement or New Certification

Through a written request, the CDPHE may seek a reinstatement of certification for these lapsed or revoked Methods, or seek certification of a new Method when the Laboratory can demonstrate that CDPHE has completed all corrective actions to address the deficiencies that led to the revocation or lapse.[3] "This may include an on-site evaluation, successful analysis of unknown samples or any other measure the CA deems appropriate."[4] EPA notes that CDPHE has submitted a written request for certification for barium and chromium analysis using EPA Method 200.8. Additionally, CDPHE has informed the EPA in its December 16, 2024 Letter that the Laboratory intends to remove Method 525.2 (organics), and that the Laboratory intends to seek new certification for EPA Method 525.3 instead. *All corrective actions to address the deficiencies, including the data review for all 15 of these Chemistry Methods that CDPHE was previously certified for, must be completed regardless of whether the Laboratory will seek recertification of that same Method.*

Conclusion

CDPHE has demonstrated progress in implementing corrective actions to address findings associated with the EPA's April 3-4, 2024 on-site evaluation of the Laboratory; however, a number of significant corrective actions remain outstanding. Before CDPHE seeks reinstatement of certification for existing EPA Chemistry Methods, or certification for any new EPA Chemistry Methods, all remaining corrective actions must be satisfactorily completed. Should CDPHE's full data review reveal additional deficiencies or issues of concern, the EPA may require other corrective actions as appropriate for CDPHE to obtain reinstatement or new certification of any EPA Chemistry Method. As part of its certification submittal, CDPHE should provide a summary report of the completed data review to the EPA. This requirement is in addition to an on-site evaluation by the EPA.

Please contact William Bunch, Region 8 Deputy Director, Laboratory Services and Applied Sciences Division at (303) 312-6412 (bunch.william@epa.gov), or Wendy O'Brien, Region 8 Laboratory Services and Applied Sciences Division Director at (303) 312-6712 (obrien.wendy@epa.gov) with any questions.

Sincerely,

WENDY O BRIEN Digitally signed by WENDY O BRIEN
Date: 2024.12.30 16:59:41 -07'00'

Wendy O'Brien, Director
Laboratory Services and Applied Sciences Division

[2] See Cynthia C. Dougherty, Office of Ground Water and Drinking Water, Clarification of Regional Office Responsibilities Related to Oversight of NELAP-Recognized State Drinking Water Laboratory Programs and NELAP-Accredited Principal State Laboratories (April 29, 2009).
[3] Section 14.5 of the Manual states further that the Laboratory must demonstrated that "the deficiencies which produced … revocation have been corrected." Section 14.5, the Manual.

[4] Section 14.5, the Manual.

cc: Andrea Dakan
Quality Assurance Coordinator, Laboratory Services Division

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CDPHE Drinking Water Laboratory Test Method Certification Status
December 30, 2024 Update

Parameter	Method(s)	Certification		
		Begin Date	End Date	Status
Group: Disinfection Byproducts				
Bromate	300.1	12/31/2024	N/A	Not Certified
Chlorite	300.1	12/31/2024	N/A	Not Certified
HAA5	552.2	12/31/2024	N/A	Not Certified
TTHM	524.2	12/31/2024	N/A	Not Certified
Group: Copper & Lead				
Copper	200.7	12/31/2024	N/A	Not Certified
	200.8	12/31/2024	N/A	Not Certified
Lead	200.8	12/31/2024	N/A	Not Certified
Group: Nitrate & Nitrite				
Nitrate	300.0	12/31/2024	N/A	Not Certified
Nitrite	300.0	12/31/2024	N/A	Not Certified
Nitrate + Nitrite	353.2	12/31/2024	N/A	Not Certified
Group: Metals				
Antimony	200.8	12/31/2024	N/A	Not Certified
Arsenic	200.8	12/31/2024	N/A	Not Certified
Barium	200.7	12/31/2024	N/A	Not Certified
	200.8	In review		
Beryllium	200.8	12/31/2024	N/A	Not Certified
Cadmium	200.8	12/31/2024	N/A	Not Certified
Chromium	200.7	12/31/2024	N/A	Not Certified
	200.8	In review		
Mercury	200.8	12/31/2024	N/A	Not Certified
Selenium	200.8	12/31/2024	N/A	Not Certified
Thallium	200.8	12/31/2024	N/A	Not Certified
Group: Inorganic				
Fluoride	300.0	12/31/2024	N/A	Not Certified
Group: Radiochemical Contaminants				
Total Uranium	200.8	12/31/2024	N/A	Not Certified
Group: Synthetic Organic Contaminants				
2, 4, 5-TP (Silvex)	555	12/31/2024	N/A	Not Certified
2, 4-D	555	12/31/2024	N/A	Not Certified
Alachlor	525.2	12/31/2024	N/A	Not Certified
Atrazine	525.2	12/31/2024	N/A	Not Certified
Benzo[a]pyrene	525.2	12/31/2024	N/A	Not Certified
Carbofuran	531.2	12/31/2024	N/A	Not Certified
Chlordane	505	12/31/2024	N/A	Not Certified
Dalapon	552.2	12/31/2024	N/A	Not Certified
Di(2-ethylhexyl)adipate	525.2	12/31/2024	N/A	Not Certified
Di(2-ethylhexyl)phthalate	525.2	12/31/2024	N/A	Not Certified
Dibromochloropropane	504.1	12/31/2024	N/A	Not Certified
Dinoseb	555	12/31/2024	N/A	Not Certified
Diquat	549.2	12/31/2024	N/A	Not Certified

CDPHE Drinking Water Laboratory Test Method Certification Status
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Parameter	Method(s)	Certification		
		Begin Date	End Date	Status
Endothall	548.1	12/31/2024	N/A	Not Certified
Endrin	525.2	12/31/2024	N/A	Not Certified
Ethylene dibromide	504.1	12/31/2024	N/A	Not Certified
Glyphosate	547	12/31/2024	N/A	Not Certified
Heptachlor	525.2	12/31/2024	N/A	Not Certified
Heptachlor Epoxide	525.2	12/31/2024	N/A	Not Certified
Hexachlorobenzene	525.2	12/31/2024	N/A	Not Certified
Hexachlorocyclopentadiene	525.2	12/31/2024	N/A	Not Certified
Lindane	525.2	12/31/2024	N/A	Not Certified
Methoxychlor	525.2	12/31/2024	N/A	Not Certified
Oxamyl (Vydate)	531.2	12/31/2024	N/A	Not Certified
Pentachlorophenol	525.2	12/31/2024	N/A	Not Certified
Picloram	555	12/31/2024	N/A	Not Certified
Polychlorinated biphenyls (as Aroclors)	505	12/31/2024	N/A	Not Certified
Simazine	525.2	12/31/2024	N/A	Not Certified
Toxaphene	505	12/31/2024	N/A	Not Certified
Group: Volatile Organic Contaminants				
1, 1, 1-Trichloroethane	524.2	12/31/2024	N/A	Not Certified
1, 1, 2-Trichloroethane	524.2	12/31/2024	N/A	Not Certified
1, 1-Dichloroethylene	524.2	12/31/2024	N/A	Not Certified
1, 2, 4-Trichlorobenzene	524.2	12/31/2024	N/A	Not Certified
1, 2-Dichlorobenzene	524.2	12/31/2024	N/A	Not Certified
1, 2-Dichloroethane	524.2	12/31/2024	N/A	Not Certified
1, 2-Dichloropropane	524.2	12/31/2024	N/A	Not Certified
1, 4-Dichlorobenzene	524.2	12/31/2024	N/A	Not Certified
Benzene	524.2	12/31/2024	N/A	Not Certified
Carbon Tetrachloride	524.2	12/31/2024	N/A	Not Certified
Chlorobenzene	524.2	12/31/2024	N/A	Not Certified
Cis-1, 2-dichloroethylene	524.2	12/31/2024	N/A	Not Certified
Dichloromethane	524.2	12/31/2024	N/A	Not Certified
Ethylbenzene	524.2	12/31/2024	N/A	Not Certified
Styrene	524.2	12/31/2024	N/A	Not Certified
Tetrachloroethylene	524.2	12/31/2024	N/A	Not Certified
Toluene	524.2	12/31/2024	N/A	Not Certified
Trans-1, 2-dichloroethylene	524.2	12/31/2024	N/A	Not Certified
Trichloroethylene	524.2	12/31/2024	N/A	Not Certified
Vinyl Chloride	524.2	12/31/2024	N/A	Not Certified
Xylenes	524.2	12/31/2024	N/A	Not Certified

CDPHE Drinking Water Laboratory Test Method Certification Status
December 30, 2024 Update

Parameter	Method(s)	Certification		
		Begin Date	End Date	Status
Group: Microbiological Contaminants				
Total Coliforms	9223 B Colilert (24&18 Detect)[a]	12/31/2024	3/31/2025	Full Certification
	9223 B Colilert QuantiTray (24&18, Count)[b]	12/31/2024	3/31/2025	Full Certification
	9221 B Multiple Tube Fermentation (LTB → BGLB) (Detect)[a]	12/31/2024	3/31/2025	Full Certification
E. coli	9223 B Colilert (24&18 Detect)[a,c]	12/31/2024	3/31/2025	Full Certification
	9223 B Colilert QuantiTray (24&18, Count)[d]	12/31/2024	3/31/2025	Full Certification
Heterotrophic Plate Count	9215 B Pour Plate with PCA[a,b]	12/31/2024	3/31/2025	Full Certification

a - Drinking Water – Revised Total Coliform Rule 40 CFR 141.852
b- Source Water - Surface Water Treatment Rule 40 CFR 141.74(a)
c- Ground Water - Ground Water Rule 40 CFR 141.402(c)
d- Source Water - Long Term 2 Enhanced Surface Water Treatment Rule (LT2) 40 CFR 136.3(a)