



## REGION 8

DENVER, CO 80202

September 3, 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:

This letter provides notice to you that the U.S. Environmental Protection Agency (EPA) is immediately revoking certification for EPA Method 353.2 (Nitrate-Nitrite), EPA Method 300.0 (Inorganic Anions), and EPA Method 552.2 (Haloacetic Acids and Dalapon) pursuant to EPA regulations and guidance issued under Section 1401(1)(D) of the Safe Drinking Water Act (SDWA). As explained in greater detail below, the EPA is taking this action because you have identified these additional methods as having been impacted by known or suspected data manipulation or other deceptive quality control practices.

The EPA Manual for the Certification of Laboratories Analyzing Drinking Water (2005) specifies that “falsification of data or other deceptive practices” is among the criteria for revocation of certification. Certification for EPA Method 200.7 was revoked on April 18, 2024, due to the initial discovery of data manipulation. The same chemist responsible for Method 200.7 worked on the three other methods and since data manipulation or deceptive quality control practices have either been found through the Colorado Department of Public Health and Environment (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.

We recognize that CDPHE is taking action to identify the root cause and extent of the manipulation, and that that analysis will take additional time. While the review process continues and corrective actions are pending, we have determined it is appropriate to revoke certification for these three additional methods.

### ***I.*** Background of data manipulation

As described in EPA’s April 18, 2024 letter, during an on-site evaluation of the CDPHE Laboratory Services Division on April 3-4, 2024, CDPHE laboratory management shared information with EPA certification officers about an active internal investigation into a chemist’s data manipulation of EPA Method 200.7, which evidence indicated had been occurring since at least 2020. As stated in CDPHE’s May 17, 2024 letter and August 30, 2024 Corrective Action Response (CAR) and supporting documents, the pattern of quality control errors in this method shows that a failing quality control result was routinely being replaced with a passing result. The April 18, 2024 letter notified CDPHE of the immediate revocation of the laboratory’s certification for EPA Method 200.7, and of the EPA’s intent to downgrade the laboratory’s certification to “provisionally certified” for all other drinking water methods, pursuant to EPA regulations and guidance issued under Section 1401(1)(D) of the Safe Drinking Water Act. The downgrade to provisional certification was formalized in a subsequent May 31, 2024 letter from EPA to CDPHE.

On August 23, 2024, CDPHE laboratory management notified the EPA via email and in a subsequent meeting later that day that the previously identified CDPHE chemist responsible for data manipulation occurring in analyses by EPA Method 200.7 was also responsible for deceptive quality control actions involving EPA Method 353.2 and EPA Method 300.0. CDPHE indicated that this chemist also ran EPA Method 552.2, but that issues associated with data retrieval are preventing CDPHE from performing a historical investigation of results associated with this method. Based on this email, subsequent meetings and CDPHE's August 30, 2024 CAR, the EPA understands that CDPHE has recalled all data with quality control deficiencies identified thus far by CDPHE's internal reviews for EPA Method 200.7, EPA Method 300.0, and EPA Method 353.2, and all data that the chemist ran for EPA Method 552.2.

In examining the EPA Method 200.7 results, CDPHE has found that data manipulation extends back through all five years of the data that they have reviewed. CDPHE's current data recall includes over 6,500 samples for EPA Method 200.7 (including 439 SDWA compliance samples), over 200 samples for EPA Method 300.0 and EPA Method 353.2 (including 9 SDWA compliance samples), and over 200 samples for EPA Method 552.2 (including 234 SDWA compliance samples). In the Internal Data Manipulation Root Cause Analysis submitted with the August 30, 2024 CAR, CDPHE also stated that due to the chemist's substantial impact on staff training, test analysis, and data review, all Chemistry Program Methods shall be reviewed by a third party contractor. EPA agrees that this approach is prudent and requests prompt notification if any additional data quality control issues are discovered during this full review.

**II. Corrective actions are not yet complete**

Since the EPA on-site evaluation on April 3-4, 2024, and the EPA's April 18, 2024 letter, CDPHE has initiated actions to investigate the cause and extent of the data manipulation issues, and to identify and implement corrective actions as indicated in CDPHE's May 17, 2024 letter. The EPA's May 31, 2024 letter established a 90-day timeframe for CDPHE to complete and submit a CAR. The May letter noted that failure to correct problems at the laboratory could result in further downgrades of test method certification status to revoked status. While progress is being made to resolve the quality control issues, the data review and corrective actions are not yet complete. Additionally, CDPHE's internal investigation has generated information that diverges from the initial facts presented in CDPHE's May 17, 2024 letter, and the scope and timeline for the data review and corrective actions were further expanded in CDPHE's August 30, 2024 CAR and associated documents.

As indicated in CDPHE's May 17, 2024 letter, the laboratory has implemented various modified procedures to address the quality control issues including modified workflow and supervisory review practices, an Ethics and Data Integrity Training for all Lab staff, and human resources actions concerning the chemist known to have manipulated data. An internal data review is ongoing, and CDPHE has contracted for third-party data reviews of results involving EPA Methods 200.7, 300.0, and 353.2 (third party review of Method 552.2 is not possible due to a data retrieval issue). However, according to the Internal Root Cause analysis submitted with the August 30, 2024 CAR, the multiple external reviews will not be complete until October and December, 2024, with an initial summary report on EPA Method 200.7 anticipated by September 30, 2024.

The EPA is also concerned about several discrepancies between the May 17, 2024 letter and more recent information provided by the laboratory. The letter stated "EPA 353.2 for combined nitrite and nitrate is not utilized for drinking water compliance testing"; however, CDPHE laboratory management subsequently notified EPA on August 23, 2024 and confirmed in the August 30, 2024 CAR that compliance samples analyzed using this method were subject to deceptive quality control practices. Furthermore, during the August 23, 2024 meeting, CDPHE shared with EPA that additional chemists may be implicated in data manipulation. CDPHE subsequently indicated that this may not actually be the case. The Internal Data Manipulation Root Cause analysis submitted with the CAR on August 30, 2024 referenced two additional chemists with quality control irregularities, the extent of which is not currently clear.

We note that during the August 23, 2024 meeting with the EPA and subsequently included in the Internal Data Manipulation Root Cause analysis submitted with the August 30, 2024 CAR, CDPHE also shared that it had identified records demonstrating that in June 2022 significant lapses in quality control within the chemistry program were noted on a coaching form. CDPHE explained that it had no records showing that a subsequent corrective action was ever completed, or that the Laboratory Director or the EPA were notified of the lapses. The EPA has not required a corrective action associated with this discovery at this point, but this is relevant information for the CDPHE's ongoing reviews and plans for needed process improvements. The EPA will be evaluating the outcome of the review and CDPHE's plans for addressing the quality control issues in the future.

As CDPHE works to gain a complete understanding of the facts regarding its data infrastructure, which methods were used to support regulatory compliance, and 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.

### **III. Protection of public health**

The EPA's Manual for the Certification of Laboratories Analyzing Drinking Water describes the requirement that all laboratories analyzing drinking water compliance samples must adhere to any required quality control procedures specified in the methods. This is to ensure that analytical data are scientifically valid and defensible, and are of known and acceptable precision and accuracy. Data manipulation and patterns of deceptive quality control practices are serious concerns and can carry significant implications for public health.

Some of the methods implicated in the data manipulation and deceptive quality control issues involve acute contaminants; therefore, it is appropriate for the EPA to take prompt action under its regulatory and statutory civil authorities to revoke certification of those testing methods.

### **IV. Conclusion**

In conclusion, the information provided to EPA on August 23, 2024, and the August 30, 2024 CAR and associated documents broaden the scope of deficiencies in CDPHE's laboratory operations related to drinking water analyses, and merits action for the protection of public health. Please see below for an updated table reflecting the laboratory's certification status for EPA-certified methods, revoking certification for EPA Methods 300.0, 353.2, and 552.2 due to likelihood of data manipulation or other deceptive practices. In recognition of the anticipated completion date of December 13, 2024, for the third-party review of the 11 remaining EPA methods, EPA is also extending provisional certification status for these methods to December 30, 2024, to allow for submission to EPA and subsequent EPA review. The EPA also requests that CDPHE promptly provide updates on any additional deficiencies or quality control issues it identifies as the reviews continue; keep EPA apprised of any changes to the timelines for completing the additional data reviews and customer notifications outlined in the August 30, 2024 CAR and supporting documents; and ensure that appropriate corrective actions and best practices are applied across all EPA-certified methods to prevent similar quality control vulnerabilities going forward.

The EPA continues to review CDPHE's August 30, 2024 CAR and associated documents and will provide a written response by September 13, 2024.

If the laboratory wishes to appeal the EPA's decision to revoke the laboratory's certification for EPA Method 353.2, EPA Method 300.0, and EPA Method 552.2, a notice of appeal should be submitted in writing to EPA within 30 days of receipt of this letter, or by October 3, 2024. The notice of appeal should be supported with an explanation of the reasons for the appeal and should be signed by the laboratory director.

If you have comments or questions, 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).

Sincerely,

**OBrien, Wendy** Digitally signed by OBrien,  
Wendy  
Date: 2024.09.03 17:01:38  
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Wendy O'Brien, Director  
Laboratory Services and Applied Sciences Division

cc: Andrea Dakan  
Quality Assurance Coordinator, Laboratory Services Division

Scott Bookman, MPA, EMT-P  
Senior Director for Public Health Readiness and Response, Colorado Department of Public Health and Environment

Jill Ryan, MPH  
Executive Director, Colorado Department of Public Health and Environment

**CDPHE Drinking Water Laboratory Test Method Certification Status  
September 3, 2024 Update**

Parameter	Method(s)	Certification		
		Begin Date	End Date	Status
<b>Group: Disinfection Byproducts</b>				
Bromate	300.1	6/1/2024	12/30/2024	Provisional
Chlorite	300.1	6/1/2024	12/30/2024	Provisional
HAA5	552.2	9/3/2024	N/A	Not Certified
TTHM	524.2	6/1/2024	12/30/2024	Provisional
<b>Group: Copper &amp; Lead</b>				
Copper	200.7	4/18/2024	N/A	Not Certified
	200.8	6/1/2024	12/30/2024	Provisional
Lead	200.8	6/1/2024	12/30/2024	Provisional
<b>Group: Nitrate &amp; Nitrite</b>				
Nitrate	300.0	9/3/2024	N/A	Not Certified
Nitrite	300.0	9/3/2024	N/A	Not Certified
Nitrate + Nitrite	353.2	9/3/2024	N/A	Not Certified
<b>Group: Metals</b>				
Antimony	200.8	6/1/2024	12/30/2024	Provisional
Arsenic	200.8	6/1/2024	12/30/2024	Provisional
Barium	200.7	4/18/2024	N/A	Not Certified
	200.8	In review		
Beryllium	200.8	6/1/2024	12/30/2024	Provisional
Cadmium	200.8	6/1/2024	12/30/2024	Provisional
Chromium	200.7	4/18/2024	N/A	Not Certified
	200.8	In review		
Mercury	200.8	6/1/2024	12/30/2024	Provisional
Selenium	200.8	6/1/2024	12/30/2024	Provisional
Thallium	200.8	6/1/2024	12/30/2024	Provisional
<b>Group: Inorganic</b>				
Fluoride	300.0	9/3/2024	N/A	Not Certified
<b>Group: Radiochemical Contaminants</b>				
Total Uranium	200.8	6/1/2024	12/30/2024	Provisional
<b>Group: Synthetic Organic Contaminants</b>				
2, 4, 5-TP (Silvex)	555	6/1/2024	12/30/2024	Provisional
2, 4-D	555	6/1/2024	12/30/2024	Provisional
Alachlor	525.2	6/1/2024	12/30/2024	Provisional
Atrazine	525.2	6/1/2024	12/30/2024	Provisional
Benzo[a]pyrene	525.2	6/1/2024	12/30/2024	Provisional
Carbofuran	531.2	6/1/2024	12/30/2024	Provisional
Chlordane	505	6/1/2024	12/30/2024	Provisional
Dalapon	552.2	9/3/2024	N/A	Not Certified
Di(2-ethylhexyl)adipate	525.2	6/1/2024	12/30/2024	Provisional
Di(2-ethylhexyl)phthalate	525.2	6/1/2024	12/30/2024	Provisional
Dibromochloropropane	504.1	6/1/2024	12/30/2024	Provisional
Dinoseb	555	6/1/2024	12/30/2024	Provisional
Diquat	549.2	6/1/2024	12/30/2024	Provisional

**CDPHE Drinking Water Laboratory Test Method Certification Status  
September 3, 2024 Update**

Parameter	Method(s)	Certification		
		Begin Date	End Date	Status
Endothall	548.1	6/1/2024	12/30/2024	Provisional
Endrin	525.2	6/1/2024	12/30/2024	Provisional
Ethylene dibromide	504.1	6/1/2024	12/30/2024	Provisional
Glyphosate	547	6/1/2024	12/30/2024	Provisional
Heptachlor	525.2	6/1/2024	12/30/2024	Provisional
Heptachlor Epoxide	525.2	6/1/2024	12/30/2024	Provisional
Hexachlorobenzene	525.2	6/1/2024	12/30/2024	Provisional
Hexachlorocyclopentadiene	525.2	6/1/2024	12/30/2024	Provisional
Lindane	525.2	6/1/2024	12/30/2024	Provisional
Methoxychlor	525.2	6/1/2024	12/30/2024	Provisional
Oxamyl (Vydate)	531.2	6/1/2024	12/30/2024	Provisional
Pentachlorophenol	525.2	6/1/2024	12/30/2024	Provisional
Picloram	555	6/1/2024	12/30/2024	Provisional
Polychlorinated biphenyls (as Aroclors)	505	6/1/2024	12/30/2024	Provisional
Simazine	525.2	6/1/2024	12/30/2024	Provisional
Toxaphene	505	6/1/2024	12/30/2024	Provisional
<b>Group: Volatile Organic Contaminants</b>				
1, 1, 1-Trichloroethane	524.2	6/1/2024	12/30/2024	Provisional
1, 1, 2-Trichloroethane	524.2	6/1/2024	12/30/2024	Provisional
1, 1-Dichloroethylene	524.2	6/1/2024	12/30/2024	Provisional
1, 2, 4-Trichlorobenzene	524.2	6/1/2024	12/30/2024	Provisional
1, 2-Dichlorobenzene	524.2	6/1/2024	12/30/2024	Provisional
1, 2-Dichloroethane	524.2	6/1/2024	12/30/2024	Provisional
1, 2-Dichloropropane	524.2	6/1/2024	12/30/2024	Provisional
1, 4-Dichlorobenzene	524.2	6/1/2024	12/30/2024	Provisional
Benzene	524.2	6/1/2024	12/30/2024	Provisional
Carbon Tetrachloride	524.2	6/1/2024	12/30/2024	Provisional
Chlorobenzene	524.2	6/1/2024	12/30/2024	Provisional
Cis-1, 2-dichloroethylene	524.2	6/1/2024	12/30/2024	Provisional
Dichloromethane	524.2	6/1/2024	12/30/2024	Provisional
Ethylbenzene	524.2	6/1/2024	12/30/2024	Provisional
Styrene	524.2	6/1/2024	12/30/2024	Provisional
Tetrachloroethylene	524.2	6/1/2024	12/30/2024	Provisional
Toluene	524.2	6/1/2024	12/30/2024	Provisional
Trans-1, 2-dichloroethylene	524.2	6/1/2024	12/30/2024	Provisional
Trichloroethylene	524.2	6/1/2024	12/30/2024	Provisional
Vinyl Chloride	524.2	6/1/2024	12/30/2024	Provisional
Xylenes	524.2	6/1/2024	12/30/2024	Provisional

**CDPHE Drinking Water Laboratory Test Method Certification Status  
September 3, 2024 Update**

Parameter	Method(s)	Certification		
		Begin Date	End Date	Status
<b>Group: Microbiological Contaminants</b>				
Total Coliforms	9223 B Colilert (24&18 Detect) <sup>a</sup>	06/1/2024	12/30/2024	Full*
	9223 B Colilert QuantiTray (24&18, Count) <sup>b</sup>	06/1/2024	12/30/2024	Full*
	9221 B Multiple Tube Fermentation (LTB → BGLB) (Detect) <sup>a</sup>	06/1/2024	12/30/2024	Full*
<i>E. coli</i>	9223 B Colilert (24&18 Detect) <sup>a,c</sup>	06/1/2024	12/30/2024	Full*
	9223 B Colilert QuantiTray (24&18, Count) <sup>d</sup>	06/1/2024	12/30/2024	Full*
Heterotrophic Plate Count	9215 B Pour Plate with PCA <sub>a,b</sub>	06/1/2024	12/30/2024	Full*

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)

“Full\*” certification indicates that your laboratory is fully certified to analyze compliance samples for the indicated methods, though minor corrective actions with no impact to data quality are needed. Certification will remain in effect for the periods specified under the conditions that the laboratory follows the specified methods and that Water Supply proficiency testing samples are successfully analyzed by the laboratory for each of the above parameters once per year.