

Information Collection Request

Existing Collection Without an OMB Control Number

# National Surveillance of Community Water Systems and Corresponding Populations with the Recommended Fluoridation Level

## Supporting Statement A

Program Official/Contact

Tracy Boehmer, National Fluoridation Engineer

National Center for Chronic Disease Prevention and Health Promotion, Division of Oral Health,  
Centers for Disease Control and Prevention

Atlanta, Georgia

Phone: 404-498-0774

Fax: 770-488-6080

E-mail: [opm9@cdc.gov](mailto:opm9@cdc.gov)

September 23, 2019

## **Table of Content**

**S**

**Section A – Justification**.....4

1. Circumstances Making the Collection of Information Necessary.....4

2. Purpose and Use of Information Collection.....7

3. Use of Improved Information Technology and Burden Reduction.....10

4. Efforts to Identify Duplication and Use of Similar Information.....11

5. Impact on Small Businesses or Other Small Entities.....12

6. Consequences of Collecting the Information Less Frequently.....13

7. Special Circumstances Related to the Guidelines of 5 CFR 1320.5.....13

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....13

9. Explanation of Any Payment or Gift to Respondent.....15

10. Protection of the Privacy and Security of Information Provided by Respondents.....15

11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....16

12. Estimates of Annualized Burden Hours and Costs.....16

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers.....18

14. Annualized Cost to the Federal Government.....18

15. Explanation for Program Changes or Adjustments.....20

16. Plans for Tabulation and Publication and Project Time Schedule.....20

17. Reason(s) Display of OMB Expiration Date is Inappropriate.....23

18. Exceptions to Certification for Paperwork Reduction Act Submission.....23

## ATTACHMENTS

1. Public Health Service Act [42 U.S.C. 241]; Oral health promotion and disease prevention [Section 247b-14]
- 2a. Instructions for collecting fluoridation status and population data
- 2b. Email invitation to request data on fluoridation status and population
- 2c. Email invitation to request fluoride testing data
- 2d. Respondent reminders
- 3a. 60-Day Federal Register Notice
- 3b. 60-Day Federal Register Notice public comments and agency response
4. Institutional Review Board exemption determination
  - Worksheet I
  - Worksheet II
  - Privacy Narrative
  - PIA

**Goal of this collection:** To assess and report to the public the fluoridation status of individual community water systems (CWS) relative to the US Public Health Service (PHS) recommended level for the oral health of the nation.

**Intended use of the resulting data:** To provide a national fluoridation surveillance report on the proportions of state and local populations served by fluoridated water, assist states to manage their fluoride level data and monitor and improve the quality of community water fluoridation programs, measure national performance toward the Healthy People 2020 objective for Americans to have fluoridated water, evaluate outcomes of CDC's cooperative agreements with states, inform the public, and, facilitate creation of state-specific reports for states' programmatic and policy use.

**Methods for collecting information:** State governments are invited to provide fluoridation status and population data for all CWS, and fluoride testing level data for fluoride-adjusted CWS through a CDC Web-based data management tool or email at least once a year.

**Subpopulation:** This is an information collection concerning approximately 52,000 CWS that serve 50 states and Washington, DC, representing approximately 86% of the US population. CWS are a subset of approximately 150,000 public water systems (PWS) in the nation.

**How data will be analyzed:** The fluoridation status and testing monitoring data are analyzed using simple calculations, such as data distribution, sum, percentage, and data aggregation.

## A – JUSTIFICATION

### **1. Circumstances Making the Collection of Information Necessary**

CDC requests three-year approval for an existing collection in use without an OMB control number to collect fluoridation levels and status of community water systems (CWS) nationwide and the corresponding populations served.

CDC is authorized to collect the information under the Public Health Service Act, Title 42, Section 247b–14, oral health promotion and disease prevention, and Section 301 (Attachment 1).

A CWS is a type of a public water system (PWS) that is regulated under the Safe Drinking Water Act.<sup>1</sup> A CWS supplies water to the same population year-round, serving at least 25 people at their primary residence or at least 15 service connections. Fluoride is found in all surface and ground water sources, but typically is lower than the recommended concentration beneficial for oral health to prevent dental caries.<sup>2,3</sup> Approximately 86% of the US population is served by CWS; the remaining rely on private wells that are not regulated by the Safe Drinking Water Act.<sup>4</sup>

Dental caries (also called tooth decay) is one of the most common chronic diseases in the United States, leading to pain, infection, and diminished quality of life throughout the lifespan. Tooth decay disproportionately affects populations with low socioeconomic status, and racial and ethnic minority populations. It causes substantial societal cost due to absence from school and work, and expensive treatments.<sup>5-8</sup>

Community water fluoridation is a major factor contributing to the large decline in caries in the US in the past 70 years and is recognized as 1 of 10 great public health achievements of the twentieth

century.<sup>9-11</sup> Community water fluoridation is the process of adjusting the fluoride concentration of a CWS to the level beneficial for the prevention of dental caries as recommended by the PHS.

Community water fluoridation reduces dental caries by 25% and is a safe and the most cost-effective way to deliver fluoride to people of all ages, regardless of education and income level. It is especially important for populations with limited access to clinical preventive dental measures.

Community water fluoridation is recommended by major public health, medical, and dental organizations (e.g., PHS, American Dental Association, American Academy of Pediatrics, and World Health Organization) as an effective public health intervention; however, since the decision to fluoridate water systems is made by state, tribal, territorial, and local governments, it is not uniformly provided to the U.S. population.

Although the percentage of the population served by CWS with fluoridated water has increased steadily in the 50 states and DC, from 65% in 2000 to 74% in 2014, more than half the nation's 52,000 CWS, mostly in rural communities, are below the recommended fluoridation level, demonstrating the critical need to collect and report the data.<sup>12, 13</sup>

This data collection aligns with CDC's strategy to use public health surveillance to inform programs and policies to improve the oral health of the nation by reducing disparities and expanding access to effective prevention programs.

In 1956, PHS began collecting and reporting fluoridation and population surveillance data based on states' self-reported information. CDC assumed responsibility in 1975 but found the state reporting inconsistent and time-consuming to collect and analyze. From the 1980s to 1992, CDC

prepared estimates of fluoridation status using PWS data from the US Environmental Protection Agency's (EPA) Safe Drinking Water Information System (SDWIS).

However, EPA data proved to be incomplete as a data source and resulted in inaccurate data when used for public health surveillance for CWS. This is largely due to EPA's regulatory responsibility for collecting fluoride concentrations in PWS only above the Maximum Contaminant Level (4 mg/L) and Secondary Maximum Contaminant Level (2 mg/L) to protect against adverse health effects, such as skeletal fluorosis.<sup>14</sup> The Safe Drinking Water Act ([www.epa.gov/safewater](http://www.epa.gov/safewater)) restricts EPA from carrying out public health interventions that benefit health but are not related to the regulatory requirements. EPA only receives state reports of CWS fluoride levels if they are above the Maximum Contaminant Level. Both contaminant levels are substantially higher than the beneficial level of 0.7 mg/L recommended for dental caries prevention by the PHS in 2015. Thus, CDC's system is needed to assess the degree to which the nation is reaching this PHS-recommended level and provide complementary information to the EPA data.

CDC's system serves the purpose of public health surveillance about water fluoridation status relative to the PHS recommended level and proportion of state and local populations served by fluoridated water. It also assists states to manage their fluoride level data and monitor and improve the quality of community water fluoridation programs.

As EPA's SDWIS (OMB number: 2040-0090) contains some CWS profile indicators that are also necessary for CDC's system, CDC has established ongoing collaboration with the EPA's SDWIS from development of the CDC's system through its annual data collection to support agency data exchange and comparison, and reduce the respondent response burden.

In order to improve analysis and reporting for the public health surveillance of community water fluoridation for the nation, state, and localities, CDC developed a Web-based data management tool – Water Fluoridation Reporting Systems (WFRS) -- in collaboration with the Association of State and Territorial Dental Directors (ASTDD), launched in 2000.<sup>15</sup>

## ***2. Purpose and Use of Information Collection***

The purpose of this information collection is to provide surveillance information about water fluoridation status relative to the PHS recommended level and populations served in the 52,000 CWS from 50 states and DC. It is the basis for a national biennial fluoridation surveillance report which documents the proportion of state and local populations served by fluoridated water.

Another key purpose is to assist states to manage their fluoride level data and monitor and improve the quality of community water fluoridation programs. Other purposes and uses of the data collection include:

- For CDC to measure national performance toward the Healthy People objective to increase the proportion of the US population served by CWS with fluoridated water, and to provide a benchmark to states and local governments.
- To evaluate outcomes of CDC's cooperative agreements with states, for example, evaluating the improvement of the grantee states' data management and reporting of fluoride level testing data for all adjusted CWS over the five-year funding period.
- To facilitate the creation of state-specific reports for states' programmatic and policy use.
- To inform health care providers who deliver prevention and treatment, for example, determining the use of fluoride supplements for children living in fluoride-deficient areas.

- To monitor the number and percentage of fluoride-adjusted CWS in each state which adopts the 2015 PHS recommended fluoride level and the expected operational control range.

To CDC's knowledge, no other data collections serve these purposes.

Respondents to the information collection are stated fluoridation managers or other state government officials designated by the state dental director or drinking water administrator.

Washington, DC is not included in the data collection because water is supplied by a CWS from Virginia and therefore the data is already collected by Virginia.

State respondents are requested to respond to the data collection on two forms annually, including 20 states currently funded by a cooperative agreement – State Actions to Improve Oral Health Outcomes (DP18-1810). CDC provides training and ongoing technical assistance for the data collection to states.

One form records fluoridation status of, and population served by, each CWS in their state (Attachment 2a). CDC emails the request to each state annually (see Attachment 2b) and sends reminders through email or phone (Attachment 2d). All 50 states participate in the data collection. Approximately 50% of states respond via entering data into WFRS, and the other half responds by emailing data to CDC to upload or enter. Historically collected natural fluoride concentrations are available in WFRS for all CWS; once collected, they rarely change over time.

Because EPA's SDWIS contains some CWS profile indicators that are also included in WFRS (i.e., water system name and identification number, the principal community served, the population of community served, and water source), CDC compares the CWS data profile in WFRS with the

EPA SDWIS. CDC then prepares a validation data report called a discrepancy report annually for each state, which identifies CWS with differences between the two, and requests validation and updates by states. Attachment 2a provides states instructions on how to use the discrepancy report to facilitate their annual data update in WFRS. The states' feedback on WFRS indicated that the discrepancy report is an essential tool to facilitate not only the annual data collection, but also interagency collaboration and communications about fluoridation data management.

The second information collection form which respondents complete was added to WFRS in 2002 to respond to states' requests to monitor and manage fluoridation quality information for CWS that adjust fluoride (referred to as fluoride-adjusted CWS) using a centralized platform. Respondents enter the high, low, and average fluoride testing level data for each month annually for their fluoride-adjusted CWS (Attachment 2c). CDC emails states annually to invite them to enter the fluoride testing level data (Attachment 2c) and sends reminders through email or phone (Attachment 2d). Although CDC requests the information annually, respondents may enter testing data monthly or whenever they choose in order to improve their quality and surveillance.

Currently, 33 states respond to the request for fluoride testing level data via completing the form in WFRS, or by emailing the data to CDC to upload.

CDC analyzes and publishes results of the data collection through interactive, public-facing Web pages: 1) Biennial reports documenting the percentage of the population with fluoridated water at national, state, and local levels; and, 2) *My Water's Fluoride*, which automatically publishes the fluoridation status of individual CWS and fluoride level data for states which choose to display the collected fluoridation data from their WFRS account.

CDC plans to use the fluoride testing level data to monitor the number and percentage of fluoride-adjusted CWS in each state that adopts the 0.7 mg/L target and its control range, and publish the results on the website of CDC's Division of Oral Health.

To encourage fluoridation quality efforts, CDC, jointly with ASTDD and the American Dental Association, issues Water Fluoridation Quality Awards annually. These recognize state programs that achieve excellent data management as measured by the completeness of fluoride testing level data reporting in WFRS, and CWS which achieve a consistent fluoride level within the recommended range in a calendar year (Attachment 2d).

### ***3. Use of Improved Information Technology and Burden Reduction***

Given the enormity of surveilling the recommended fluoridation level for 52,000 CWS, CDC's electronic data collection via WFRS replaced the labor-intensive data analysis and compilation states and CDC used in the past. This has both improved the data accuracy and reduced the burden of the states' response efforts significantly, and provides states with data analysis tools and enhanced reporting to benefit their programs. CDC provides a guide, training, and ongoing technical assistance to water system operators responsible for adjusting their fluoride level quality, and to governments that use WFRS.

When WFRS was developed, CDC pre-loaded CWS information from EPA's SDWIS and CDC's 1992 water fluoridation surveillance data to support agency data exchange and comparison, and reduce the respondent response burden. Respondents only need to validate or update a few CWS fields annually: PWS ID, name, address and status, the county served, population served, fluoridation status, natural fluoride concentrations, and any CWS from which they buy water (Attachment 2a). The respondent only has to either enter a few digits of the ID or the name, and it

pops up among the 52,000 CWS. For example, the PWS ID is AL-0000068 and if the respondent enters “068” the system displays all PWS IDs that contain “068.”

WFRS also incorporates functionalities of data field validation and diagnostic reporting. For example, the pre-populated US Census county population fields allow respondents to identify counties where the respondent may have overestimated the population of an individual CWS.

WFRS uses responsive design to benefit the user experience across four different screen formats: desktop, laptop, tablet, and phone screen sizes. WFRS is accessed via the internet and is hosted by CDC; therefore, it requires no system maintenance burden at the respondent location. No special hardware or software is required.

WFRS has multiple reporting functions that allow states to display, print, and export customized reports sorted and filtered by fluoridation status, and grouped by county and CWS name. The data validation report assists states to focus their data management and quality control resources.

#### ***4. Efforts to Identify Duplication and Use of Similar Information***

No other agency or entity produces similar analyses or reports, and it is the only data collection resource of its origin to facilitate and monitor states’ adoption of the recommended 0.7 mg/L target and operational control range.

CDC investigated the potential of collaborating with EPA to adapt SDWIS to support public health surveillance needs and determined that important differences in programmatic needs between the

agencies were incompatible. EPA's SDWIS, which encompasses all PWS nationwide including both CWS and non-CWS, is oriented for regulatory violation reporting; it does not serve the surveillance purpose of water fluoridation status relative to the PHS recommended level.

Furthermore, EPA classifies a water system as fluoridated only if fluoride is directly added; its data reflect only the 6,000 water systems that adjust fluoride directly. It does not classify as fluoridated the 6,500 water systems that purchase fluoridated water from an adjacent water system, nor the more than 6,000 water systems with natural fluoride at beneficial levels — two-thirds of the water systems CDC considers fluoridated.

CDC's complementary information collection is a necessity for public health surveillance, but CDC did use portions of the EPA SDWIS database as the basis for the design of WFRS, and the CWS profile in WFRS was modeled on a trimmed PWS profile from SDWIS.

### ***5. Impact on Small Businesses or Other Small Entities***

States must collect fluoridation data from the CWS in their state to comply with the Safe Drinking Water Act except for Wyoming; therefore, this request adds minimum burden to enter the results into WFRS or otherwise provide the data to CDC. No other small entities, including CWS/PWS personnel, have access to the WFRS online systems, nor are they expected to participate in this collection. The collection is not sponsored.

### ***6. Consequences of Collecting the Information Less Frequently***

Collecting the information less frequently than annually would impact the completeness, accuracy, and timeliness of the data provided to the public. The annual schedule of data collection is

important to capture and coordinate with the EPA's SDWIS data update, which is annual and enables the collection of any new population data for more accurate analysis.

Decreasing the frequency between collections would also limit the ability of public health programs to plan and evaluate, thus limiting national, state, and local governments to respond to continuously changing surveillance data in a timely and effective manner. This, in turn, would delay oral disease prevention and negatively affect the oral health status of populations, especially populations without or limited access to oral health preventive services.

### ***7. Special Circumstances Related to the Guidelines of 5 CFR 1320.5***

This request fully complies with the information collection guidelines of 5 CFR 1320.5.

### ***8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency***

Part A: Public Notice

A 60-day Federal Register notice was published in the Federal Register on December 6, 2018, Volume 83, Number 234, pages 62867–62869 (Attachment 3a). Two public comments were received and the CDC provided corresponding responses (Attachment 3b).

B: Consultation

CDC consulted with water fluoridation managers or their equivalents in six state governments in 2018 to determine the burden of time and cost to enter the data, including assistance from support staff and administrators. CDC also solicited feedback on the benefits and drawbacks of WFRS. No unresolved problems surfaced. The states all indicated that they consider the discrepancy report an

essential tool to facilitate not only the annual data collection, but also interagency collaboration and communications about fluoridation data management.

**States consulted regarding the burden of annual data collection, 2018**

Name	Title	State Health Department	Email address
Glenn Greenway	Environmental Engineer	Arkansas	<a href="mailto:Glenn.Greenway@arkansas.gov">Glenn.Greenway@arkansas.gov</a>
Beth Wyatt	Fluoridation Specialist	Colorado	<a href="mailto:beth.wyatt@state.co.us">beth.wyatt@state.co.us</a>
Sara Carmichael	Water Fluoridation Coordinator	Iowa	<a href="mailto:sara.carmichael-stanley@idph.iowa.gov">sara.carmichael-stanley@idph.iowa.gov</a>
Sandra Sutton	Community Water Fluoridation Coordinator	Michigan	<a href="mailto:SuttonS2@michigan.gov">SuttonS2@michigan.gov</a>
Mary DeLeon	Fluoridation Specialist	Oklahoma	<a href="mailto:MaryJD@health.ok.gov">MaryJD@health.ok.gov</a>
Deba Dutta	Water Fluoridation Engineer	Texas	<a href="mailto:deba.dutta@dshs.texas.gov">deba.dutta@dshs.texas.gov</a>

CDC receives feedback and addresses concerns through its ongoing technical assistance with WFRS users and cooperative agreement assistance from project officers. In general, users contribute ongoing feedback to CDC, resulting in items such as added functionality for monthly fluoride testing level data in 2002, and enhanced reporting in 2011.

CDC also collects feedback to improve and streamline the user interface, consistency, utility, and functionalities of the collection tool through the WFRS User Assessment conducted every 2-3 years among fewer than 10 respondents.

**State representatives that participated in the WFRS User Assessment, 2018**

Name	State Health Department	Email address
Summer Gagnon	Alabama	<a href="mailto:summer.gagnon@adph.state.al.us">summer.gagnon@adph.state.al.us</a>
Sean Isaac	Florida	<a href="mailto:sean_isaac@doh.state.fl.us">sean_isaac@doh.state.fl.us</a>
Dixianne Parker	Georgia	<a href="mailto:Dixianne.parker@dph.ga.gov">Dixianne.parker@dph.ga.gov</a>

Sara Carmichael-Stanley	Iowa	<a href="mailto:sara.carmichael-stanley@idph.iowa.gov">sara.carmichael-stanley@idph.iowa.gov</a>
Jim Bolton	Maryland	<a href="mailto:jim.bolton@maryland.gov">jim.bolton@maryland.gov</a>
Sandra Sutton	Michigan	<a href="mailto:SuttonS2@michigan.gov">SuttonS2@michigan.gov</a>
Prasad Subbanna	Tennessee	<a href="mailto:Prasad.Subbanna@tn.gov">Prasad.Subbanna@tn.gov</a>

**Agencies and organizations consulted, 2018**

<b>Name</b>	<b>Title</b>	<b>Agency/Organization</b>	<b>Email address</b>
Judy Feinstein	Fluoridation Committee Chair	ASTDD	<a href="mailto:jafme52@gmail.com">jafme52@gmail.com</a>
Alex Porteous	SDWIS Prime Manager	EPA	<a href="mailto:porteous.alex@epa.gov">porteous.alex@epa.gov</a>

**9. Explanation of Any Payment or Gift to Respondent**

No payments or gifts are included in this information collection.

**10. Protection of the Privacy and Security of Information Provided by Respondents**

CDC’s Privacy Office has reviewed this submission and determined that the Privacy Act does not apply. Activities in this collection do not involve individually identifiable information.

CDC hosts the data collection tool, WFRS, a Web-based enterprise application maintained on a secure CDC server. It has completed a security assessment and has the authority to operate (ATO). WFRS adheres to all federal, HHS, and/or CDC IT security policies and procedures. WFRS is an authenticated access data application so only designated users can enter data for state programs. States designate users and create an authenticated password. CDC keeps the password and other

information private and secure to the extent permitted by law. WFRS Administrators cannot view user password credentials.

Only approved members of the project team at CDC and the direct contractor, personnel hired by Northrop Grumman, have access to the data collected.

CDC will maintain information collected in WFRS and published on the CDC website so that states and the public have historical fluoride surveillance data. CDC will retain records in accordance with the applicable CDC records control schedule. It has a plan in place to implement, in the unspecified future, a National Archives and Records Administration (NARA) archive in compliance with requirements on records before the WFRS application is retired.

### ***11. Institutional Review Board (IRB) and Justification for Sensitive Questions***

CDC has determined that IRB approval is not applicable (see Attachment 4). The collection is not research and does not include human subjects. No sensitive data are collected.

### ***12. Estimates of Annualized Burden Hours and Costs***

This information collection includes an annual collection on two forms. All states that participate have designated personnel to monitor CWS to comply with the Safe Drinking Water Act.

Respondents are state fluoridation managers or other state officials designated by the state dental director or drinking water administrator.

The estimated annualized burden hours per respondent are 37.5 hours for 50 respondents to respond to the request for CWS fluoridation status and population served, and 27.5 hours for the

annual response for fluoride testing level data for fluoride-adjusted CWS by an estimated 33 respondents. The total burden hours is 2,783 per year (Table A.12-1).

The burden hours are estimated through consulting with 6 states in 2018 and accounting for the varying quantities of CWS and fluoride-adjusted CWS. A state with a large number of CWS usually requires more time to respond than a state with a small number. The estimated burden time per CWS is 2 minutes for the first form, and 12 minutes (1 minute per month) for the second form. For example, Rhode Island has 91 and 6 CWS and fluoride-adjusted CWS respectively, and Texas has 6,022 and 118 respectively; and although Illinois has a much smaller number of CWS (1,812) than Texas, it has a much larger number of fluoride-adjusted CWS (860).

**Table A.12-1. Estimated Annualized Burden Hours**

<b>Type of Respondent</b>	<b>Form Name</b>	<b>No. of Respondents</b>	<b>No. of Responses per Respondent</b>	<b>Avg. Burden per Response (in hrs)</b>	<b>Total Burden (in hrs)</b>
State Official	Fluoridation status and population	50	1	37.5	1,875
State Official	Fluoride testing data	33	1	27.5	908
Total					2,783

Annualized burden costs to respondents are summarized in Table A.12-2 below. The average wage rate of \$29.40/hour with a range of \$18.00 to 35.00, is estimated based on consulting with states and by using the states' cost when they submitted their cooperative agreement salary budgets for the designated respondents.

**Table A.12-2. Estimated Annualized Burden Cost**

<b>Type of Respondent</b>	<b>Form Name</b>	<b>No. of Respondents</b>	<b>Total Burden (in hrs)</b>	<b>Avg. Hourly Wage</b>	<b>Total Cost</b>
State Official	Fluoridation status and population	50	1,875	\$29.4	\$55,125
State Official	Fluoride testing data	33	908	\$29.4	\$26,695.2
Total			2,783		\$81,820.2

***13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers***

The data are collected through the Web-based system WFRS, which is accessed by respondents via the internet and is hosted and maintained by CDC, or via email using typical software. No capital or maintenance costs are expected.

***14. Annualized Cost to the Federal Government***

The average annualized cost for data collection, analysis, reporting, and enhancement of data application functionalities to the federal government is \$176,192.82, for a three-year total of \$528,578.46, including salary of CDC technical staff and contractor (Table A.14-A). Additional annualized costs include \$90,000 (Table A.14-B) for a contractor to maintain the WFRS and MWF Web applications and integrate them into the CDC data management system. There are no other maintenance or operational costs, and no equipment, capital, or special costs.

The personnel costs for CDC staff are to 1) provide oversight, guidance, and review for the planning and design of the data collection; extracting data from SDWIS and WFRS; analyzing and reporting data; and data application maintenance and updating; 2) update the technical guide and provide ongoing technical assistance and trainings for this data collection. These activities involve an estimated 18% time of a national fluoridation engineer, with 3% for data collection, analysis, and technical assistance, and 15% for data maintenance and updating annually. The average annualized cost of federal staff is \$18,692.82 for a three-year total of \$56,078.46.

The average annualized contractor cost for this collection is \$157,500 for a three-year total of \$472,500. This cost is for the following activities: data extraction from EPA SDWIS and WFRS; developing annual Discrepancy Reports; uploading state data to WFRS; technical assistance to states; data cleaning and analysis; functionality enhancement of the Web applications; and other associated costs for project management. Additional annualized cost includes \$90,000 for maintenance of the Web applications.

**Table A.14-A. Estimated Annualized Federal Government Cost Distribution**

Type of Government Cost	Annualized Cost
Data Contractor (Northrop Grumman, Atlanta, Georgia)	\$157,500
CDC GS-13 National Fluoridation Engineer: at 18% FTE of \$103,849/year <sup>a</sup>	\$18,692.82
Total	\$176,192.82

<sup>a</sup> Federal pay table for Atlanta effective January 2018

**Table A.14-B. Estimated Annualized Federal Government Operational and Maintenance Costs**

<b>Web Application Maintenance</b>	<b>Total</b>
\$90,000	\$90,000

**15. Explanation for Program Changes or Adjustments**

This is a new request.

**16. Plans for Tabulation and Publication and Project Time Schedule**

This request is for three years for a recurring annual collection and several types of tabulation/publications.

**Table 16-A. Project Time Schedule**

<b>Activity</b>	<b>Time Schedule</b>
1. Collection of CWS fluoridation status and corresponding population data	
CDC extracts data from EPA’s SDWIS and compares with data in WFRS. It documents discrepancies in a validation tool ( <i>Discrepancy Report</i> ) for each state.	February – March each year
CDC emails an invitation to respondents to conduct the annual data collection through addressing the <i>Discrepancy Report</i> .	April each year
Respondents update and validate data.	May – October each year
CDC cleans and analyzes the data and prepares biennial surveillance reports.	March – October every even year

CDC publishes biennial reports on its Website.	November of every even year
My Water's Fluoride webpage is updated.	As data is entered, it is published at midnight each day.
<b>2. Collection of fluoride testing data for fluoride-adjusted CWS</b>	
CDC emails an invitation to respondents to enter fluoride level data in WFRS.	January each year
Respondents enter fluoride level data in WFRS	February – May each year
CDC reviews, cleans and analyzes the data	March – July each year
ASTDD, ADA and CDC jointly issue state-level water fluoridation quality awards	April each year
CDC issues CWS-level water fluoridation quality awards	October each year
My Water's Fluoride webpage is updated	As data is entered, it is published at midnight each day.
Report of the number and percentage of fluoride-adjusted CWS in each state that adopt the 2015 recommended fluoride level and the expected control range	Approximately two years after the CDC proposed control range is published

**Table A. 16-B Publications**

Products	Description	Distribution Channels
Biennial surveillance report	Percent of the population with fluoridated water at recommended levels by locality and nationally	<a href="https://www.cdc.gov/fluoridation/statistics/reference_stats.htm">https://www.cdc.gov/fluoridation/statistics/reference_stats.htm</a>  <a href="https://www.cdc.gov/oralhealthdata/index.html">https://www.cdc.gov/oralhealthdata/index.html</a>
My Water's Fluoride	An interactive tool that enables the public to learn about the status of the recommended fluoride level in their community water systems (for participating states)	<a href="https://nccd.cdc.gov/DOH_MWF/Default/Default.aspx">https://nccd.cdc.gov/DOH_MWF/Default/Default.aspx</a>

Annual Water Fluoridation Quality Award	Recognition of states and fluoride-adjusted CWS that achieve a consistent fluoride level in a calendar year	Announced at NOHC and published on the ASTDD members only website <a href="https://www.astdd.org/sign-in.php">https://www.astdd.org/sign-in.php</a>  CWS-level awards mailed to State Dental Directors for delivery to individual CWS
Annual Discrepancy Report	A comparison analysis between WFRS data and EPA SDWIS data that CDC provides to each state	Not published; sent by email to state official
Publications	Report of the number and percentage of fluoride-adjusted CWS in each state that adopt the 2015 PHS recommended fluoride level and the expected control range	Peer-reviewed journal or CDC reports

### **Analysis Plan**

For fluoridation surveillance and monitoring of fluoride testing level data, only simple calculations are used, such as distributions of fluoridation status, population, and fluoride levels; sum of populations across CWS by fluoridation status; percentage of CWS population with fluoridated water aggregated to the nation and by locality; and fluoride-adjusted CWS with fluoride data that meet the quality award requirements. As the analyses are based on either a census of CWS or a convenience sample of fluoride-adjusted CWS, no statistical tests or sampling error estimations are performed.

To facilitate states' adoption of the 2015 updated recommended fluoride level of 0.7 mg/L and the expected recommended operational control range around 0.7 mg/L, CDC may use the fluoride testing level data to monitor the number and percentage of fluoride-adjusted CWS in each state that adopt the 0.7 mg/L target with the recommended control range. The data analyses require only simple computational calculations described above.

## **17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The display of the OMB expiration date is appropriate.

## **18. Exceptions to Certification for Paperwork Reduction Act Submission**

There are no exceptions to the certification statement.

### References

1. US Environmental Protection Agency. Summary of the Safe Drinking Water Act. Available: <https://www.epa.gov/laws-regulations/summary-safe-drinking-water-act>. Accessed: October 9, 2019.
2. Centers for Disease Control and Prevention. Community water fluoridation. 2018. Available: <https://www.cdc.gov/fluoridation/index.html>. Accessed: May 18, 2018.
3. US Department of Health Human Services Federal Panel on Community Water Fluoridation. U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries. *Public Health Rep.* 2015;130(4):318-331.
4. US Department of the Interior. Domestic (private) supply wells. Available: [https://www.usgs.gov/mission-areas/water-resources/science/domestic-private-supply-wells?qt-science\\_center\\_objects=0#qt-science\\_center\\_objects](https://www.usgs.gov/mission-areas/water-resources/science/domestic-private-supply-wells?qt-science_center_objects=0#qt-science_center_objects). Accessed: October 9, 2019.
5. Community Preventive Services Task Force. Preventing dental caries: community water fluoridation. 2013. Available: <https://www.thecommunityguide.org/findings/dental-carries-cavities-community-water-fluoridation>. Accessed: July 2, 2018.
6. Jackson SL, Vann WF, Jr., Kotch JB, Pahel BT, Lee JY. Impact of poor oral health on children's school attendance and performance. *Am J Public Health.* 2011;101(10):1900-1906.
7. Manski RJ, Rohde F. Dental Services: Use, Expenses, Source of Payment, Coverage and Procedure Type, 1996–2015: Research Findings No. 38. 2017. Available: [https://meps.ahrq.gov/data\\_files/publications/rf38/rf38.pdf](https://meps.ahrq.gov/data_files/publications/rf38/rf38.pdf). Accessed: July 2, 2018.
8. US Department of Health and Human Services. Oral Health in America: A Report of the Surgeon General. Rockville, MD: US Department of Health and Human Services, National Institute of Dental and Craniofacial Research, National Institutes of Health; 2000
9. Centers for Disease C, Prevention. Ten great public health achievements--United States, 1900-1999. *MMWR Morb Mortal Wkly Rep.* 1999;48(12):241-243.
10. Centers for Disease Control and Prevention. Oral health surveillance report: Trends in dental caries and sealants, tooth retention, and edentulism, United States, 1999–2004 to 2011–2016. 2019. Available: [https://www.cdc.gov/oralhealth/pdfs\\_and\\_other\\_files/Oral-Health-Surveillance-Report-2019-h.pdf](https://www.cdc.gov/oralhealth/pdfs_and_other_files/Oral-Health-Surveillance-Report-2019-h.pdf). Accessed: October 9, 2019.

11. Kelly JE, Van Kirk LE, Garst CC. Decayed, missing, and filled teeth in adults: United States, 1960–1962. *Vital Health Stat.* 1973;11(23)
12. Centers for Disease Control and Prevention. Fluoridation Statistics. Available: [https://www.cdc.gov/fluoridation/statistics/reference\\_stats.htm](https://www.cdc.gov/fluoridation/statistics/reference_stats.htm). Accessed: July 2, 2018.
13. Hendryx M, Weiner RC, Gurka M. Water fluoridation and dental health indicators in rural and urban areas of the United States. 2011. Available: [https://www.ruralhealthresearch.org/mirror/4/473/2011\\_fluoridation\\_final\\_report.pdf](https://www.ruralhealthresearch.org/mirror/4/473/2011_fluoridation_final_report.pdf). Accessed: October 9, 2019.
14. US Environmental Protection Agency. Questions and answers on fluoride. 2011. Available: [https://www.epa.gov/sites/production/files/2015-10/documents/2011\\_fluoride\\_questionsanswers.pdf](https://www.epa.gov/sites/production/files/2015-10/documents/2011_fluoride_questionsanswers.pdf). Accessed: July 2, 2018.
15. Centers for Disease Control and Prevention. Water Fluoridation Reporting System. Available: <https://www.cdc.gov/fluoridation/data-tools/reporting-system.html>. Accessed: July 2, 2018.