

Federally Unregulated Drinking Water Programs: Assessing Strategies Leading to Policy Change

**OSTLTS Generic Information Collection Request
OMB No. 0920-0879**

Supporting Statement – Section A

Submitted: January 27th, 2016

Program Official/Project Officer

Max Zarate-Bermudez
Epidemiologist
Environmental Health Services Branch
Division of Emergency and Environmental Health Services
National Center for Environmental Health
4770 Buford Highway NE, MS F-58
Atlanta, GA 30341
Phone: 770.488.7421
Email: mcz4@cdc.gov

Table of Contents

Table of Contents	2
Section A – Justification	3
1. Circumstances Making the Collection of Information Necessary	4
2. Purpose and Use of the Information Collection	7
3. Use of Improved Information Technology and Burden Reduction	8
4. Efforts to Identify Duplication and Use of Similar Information	8
5. Impact on Small Businesses or Other Small Entities	8
6. Consequences of Collecting the Information Less Frequently	8
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5	9
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency	9
9. Explanation of Any Payment or Gift to Respondents	9
10. Assurance of Confidentiality Provided to Respondents	9
11. Justification for Sensitive Questions.....	9
12. Estimates of Annualized Burden Hours and Costs.....	9
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers	10
14. Annualized Cost to the Government.....	10
15. Explanation for Program Changes or Adjustments	11
16. Plans for Tabulation and Publication and Project Time Schedule	11
17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	11
18. Exceptions to Certification for Paperwork Reduction Act Submissions	11
LIST OF ATTACHMENTS – Section A	11
REFERENCE LIST	12

- **Goal of the study:** Collect information from state and local environmental health practitioners to: 1) understand the influence of water projects on policy; 2) Identify challenges to influencing policy through water projects and strategies for overcoming challenges; 3) Understand the type of partnerships needed to facilitate policy development; 4) Identify the benefits gained to the local communities from the water project and 5) Identify training and resource needs of STLT staff working on water projects.
- **Intended use of the resulting data:** Information gleaned will help investigators understand the differences and nuances of how policy is developed and used at STLT health departments in relation to water projects and develop guidance tools/ “how to” guides for State, Tribal, Local, and Territorial (STLT) health departments outlining examples of water projects and their relationship to policy.
- **Methods to be used to collect information:** In-person interviews will be conducted to collect information from respondents.
- **The subpopulation to be studied:** 18 state and local-level Environmental Health Practitioners.
- **How data will be analyzed:** Qualitative thematic analyses will be performed to compile responses and

Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. The respondent universe for this information collection aligns with that of the O2C2. Data will be collected from 18 Environmental Health (EH) practitioners within 6 STLT public health departments (4 state and 2 county) acting in their official capacities. A listing of these state and county health departments can be found in (see **Attachment A–List of Participant State and County Health Departments**).

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). This information collection falls under the essential public health service(s) of:

- 1. Monitoring health status to identify community health problems
- 2. Diagnosing and investigating health problems and health hazards in the community
- 3. Informing, educating, and empowering people about health issues
- 4. Mobilizing community partnerships to identify and solve health problems
- 5. Development of policies and plans that support individual and community health efforts
- 6. Enforcement of laws and regulations that protect health and ensure safety
- 7. Linking people to needed personal health services and assure the provision of health care when otherwise unavailable
- 8. Assuring a competent public health and personal health care workforce
- 9. Evaluating effectiveness, accessibility, and quality of personal and population-based health services

□ 10. Research for new insights and innovative solutions to health problems ¹

In 2010 more than 44 million people (>14 percent of the U.S. population) used private (non-public) drinking water systems with groundwater as their source, mostly private wells.² Private drinking water systems are those that have <15 service connections or serve <25 people. Unlike public water systems, which are regulated by the U.S. Environmental Protection Agency's (EPA) Safe Drinking Water Act (SDWA), there is currently no national water quality monitoring program for private systems to ensure that the water they supply is safe to drink.

From 1991-2001, the U.S. Geological Survey (USGS) implemented the National Water-Quality Assessment (NAWQA) Program to support information needs and decision making related to groundwater-quality management and policy.³ During this time, the program collected data on 1,389 out of the 2,167 sampled wells in 30 U.S. regionally extensive aquifers used for water supply. Tests revealed that about 23 percent of the samples had at least one contaminant present at concentration greater than water-quality benchmarks for human health.⁴

Local, state, and territorial health departments in the United States use the National Outbreak Reporting System (NORS) to report waterborne and foodborne disease outbreaks and enteric disease outbreaks transmitted by contact with environmental sources, infected persons or animals, or unknown modes of transmission to the CDC.⁵ However, outbreak information for private drinking water systems is not readily available through NORS. Also, the nomenclature used to describe these systems is inconsistent making literature searches difficult. Water quality assessments for private wells have focused on assessing risks that have already been identified.⁶⁻⁹

STLT public health departments are currently the only entities working to protect the health and well-being of community household members that rely on private drinking water systems. State laws and regulations for private wells vary widely and focus only on licensing the entities that construct wells and the construction of wells. More than half of states in the U.S. do not require testing of private wells after they are constructed. Where state or local testing requirements do exist, the required or recommended parameters for testing vary across jurisdictions and testing is usually infrequent (e.g., as part of a real estate transaction, new construction, or equipment replacement). Most drinking water programs offering water testing services from wells and other federally unregulated drinking water systems are voluntary and require strong outreach by the STLT health departments to assure the delivery of services. In addition to water testing activities, STLT health departments organize and analyze datasets from various public and private entities to characterize well water contaminants of concern and identify vulnerable populations in an effort to deliver targeted environmental public health services (e.g., informing the public, mobilizing partnerships, developing policy or enforcing local ordinances) and best utilize limited agency resources.

CDC's Environmental Health Services Branch (EHSB) is located in the National Center for Environmental Health. The mission is to strengthen the performance of STLT public health programs to better anticipate, identify, and respond to adverse environmental exposures and their impact on human health. EHSB provides practice-based research, training, technical assistance, and evidence-based guidance needed by state, tribal, local, and territorial environmental health practitioners to prevent environmental exposures and protect health. EHSB is the only U.S. federal agency providing assistance to STLT public health departments to improve the delivery of environmental public health services for drinking water programs. EHSB also dedicates resources to improve the capacity of STLT public health departments to identify, address, and close drinking water program performance gaps based on the 10 Essential Environmental

Public Health Services. Specifically, EHSB has provided funding to STLT public health departments through two separate cooperative agreements to improve drinking water programs:

- EHS-Net Water (Environmental Health Specialists Network Water Program): From 2010 through 2015 EHSB funded 5 (4 state and 1 county) public health departments EHS-Net Water to conduct research and to improve the practice of environmental health while addressing drinking water issues.
- PW/UWDS (Private Well/Unregulated Drinking Water Systems): Additionally, from 2013 through 2015 EHSB funded 11 (9 state and 2 county) public health departments in PW/UWDS to implement interventions to address potential or known unregulated drinking water system health risks and contamination.

Two (1 state and 1 county) health departments received funding from both the EHS-Net Water and the PW/UDWS cooperative agreements. In both agreements, public health departments focused time and resources on information collection (e.g., well water testing), public health messaging, policy development, enforcement, and other important environmental public health services.

These cooperative agreements supported STLT grantees to identify and characterize available private well databases. In many cases this work helped CDC, the grantee, and private well owners to understand the specific contaminants of concern that may lead to unwanted exposures for well water owners and users in their communities. Identifying and characterizing contaminants in private wells are important first steps in the design of prevention measures to protect public health. However, there is still a knowledge gap regarding how and why communities developed and used policies and regulations to enhance the protection of public health. As a result, the purpose of this information collection is to:

- Understand the influence of water projects on policy, specifically, understand which water projects influenced which policies and how;
- Identify challenges to influencing policy through water projects and strategies for overcoming challenges;
- Understand the type of partnerships needed to facilitate policy development;
- Identify the benefits gained to the local communities from the water project;
- Identify training and resource needs of STLT staff working on water projects.

For this information collection, CDC's EHSB is partnering with ChangeLab Solutions (CLS). CLS is an interdisciplinary team of lawyers and public health specialists, who develop public health law linking housing, education, jobs, and the environment to healthy outcomes. The mission of CLS is to enhance the health of the nation through the use of the tools of law and policy.¹⁰ CLS will conduct in-depth interviews with 18 environmental health practitioners from 6 of the public health departments (3 from each health department) that participated in the CDC-funded water programs (EHS-Net Water and PW/UDWS).

The information gleaned will help investigators understand the differences and nuances of how policy is developed and used at STLT health departments in relation to water projects focusing on federally unregulated drinking water sources. Specifically, the information collected will be used to:

- Assess which strategies have worked in addressing safe drinking water policies during the conduct of the EHS-Net Water Program and PW/UWDS programs within the small subset of grantees.
- Inform CDC guidance regarding the delivery of essential environmental public health services for STLT drinking water programs.

- Develop “how to” guides for STLT health departments, outlining examples of water projects and their relationship to policy at the six sites that participate in the interviews. Although the sample size (n=6) is small, investigators believe other STLT health departments will benefit from learning from the experiences of these six sites, as they may be able to replicate safe water interventions in their own jurisdictions.

Overview of the Information Collection System

Information will be collected from a total of 18 state and local EH practitioners (6 EH Directors, 6 PIs, and 6 other EH practitioners or designated staff) via in-person interviews conducted by ChangeLab Solutions staff, using a standard interview guide (see **Attachment B —Interview Guide**). Interview notes will be taken by CLS staff on a portable computer during the interviews.

The interview guide was pilot tested by 3 public health professionals, including 2 EH practitioners from the Cerro Gordo County Department of Public Health, Iowa and 1 staffer from CLS. Feedback from these individuals was used to refine questions and to estimate the average time required to complete the interview.

Items of Information to be collected

This information collection will assess what strategies were useful to develop or amend safe drinking water policies during the conduct of the previous EHSB-sponsored drinking water cooperative agreements and lessons learned surrounding those policies (e.g., benefits, challenges).

A standard interview guide (see **Attachment B —Interview Guide**) will be used to guide all interviews. At the beginning of each interview, the interviewer will remind participants of the interview purpose, review logistics and obtain verbal permission for written notes to be taken on a portable computer to document the conversation. The guide consists of 14 questions, 1 to collect respondent demographic information, and 13 open-ended questions. Open-ended interviews allow latitude for respondents to speak about the issues important to them, facilitating a more natural flow of conversation. An effort was made to limit questions whenever possible. Questions will be skipped if the respondent has already addressed the question in a previous response to reduce the burden on respondents.

The interview guide will be used to collect the information summarized in the table below.

Question Type	Number of questions	Purpose
Respondent Information –for archiving purposes only.	1	To gather respondent’s professional contact information; this information will be removed when the results are analyzed and will not be shared.
Project Design –for gathering details on the design of the private wells/unregulated drinking water systems project.	2	To learn if health departments (PIs and EH practitioners) designed project with the aim to influence policy.
Project Process Description –for gathering information on the process health departments followed to successfully address policy.	3	To learn about the process and crucial steps that health departments (PIs and EH practitioners) followed, and the partnerships they formed to successfully address policy or achieve the potential to address policy.

Community Benefits from Policy –for gathering details on how the policy that has been addressed will benefit the community.	3	To learn how the community will benefit from the policy that has been addressed or could potentially be addressed.
Barriers to Policy Implementation –for learning about the barriers that were identified during the implementation of the addressed policy.	2	To learn if health departments identified barriers to the implementation of the policy that has been addressed or the one that could potentially be addressed, and what has been done to overcome those barriers.
Recommendations to Plan and Conduct Projects Aimed at Influencing Policy –for sharing the recommendations that EH practitioners can provide when planning and conducting projects aimed to address policy.	2	To learn if health departments can make recommendations for planning and conducting projects aimed at addressing policy, and if they identified the tools and resources needed to become more effective in promoting and implementing policy change.
Additional Comments –for gathering additional information that EH practitioners would like to share, which can be useful when planning and conducting water policy projects.	1	Any other comments referred to planning projects aimed at developing or amending safe water-related-policies.

2. Purpose and Use of the Information Collection

The purpose of this collection of information is to:

- Understand the influence of water projects on policy, specifically, understand which water projects influenced which policies and how;
- Identify challenges to influencing policy through water projects and strategies for overcoming challenges;
- Understand the type of partnerships needed to facilitate policy development;
- Identify the benefits gained to the local communities from the water project;
Identify training and resource needs of STLT staff working on water projects.

The information gleaned will help investigators understand the differences and nuances of how policy is developed and used at STLT health departments in relation to water projects focusing on federally unregulated drinking water sources. Specifically, the information collected will be used to:

- Assess which strategies have worked in addressing safe drinking water policies during the conduct of the EHS-Net Water Program and PW/UWDS programs within the small subset of grantees.
- Inform CDC guidance regarding the delivery of essential environmental public health services for STLT drinking water programs.
- Develop “how to” guides for STLT health departments, outlining examples of water projects and their relationship to policy at the six sites that participate in the interviews. Although the sample size (n=6) is small, investigators believe other STLT health departments will benefit from learning from the experiences of these six sites, as they may be able to replicate safe water interventions in their own jurisdictions.

Please note: information collected will not be used to develop or influence policy, but rather, to provide CDC and STLT health departments with the opportunity to learn from six jurisdictions that have experience with implementing water projects that have affected policies.

3. Use of Improved Information Technology and Burden Reduction

All information will be collected via in-person interviews. Conducting in-person interviews will help to minimize burden on the respondents and CLS staff by allowing respondents to complete their responses and make any necessary clarifications in real-time during the interview. The use of open-ended questions will provide respondents ample latitude to speak about the issues important to them, facilitating a more natural flow of the interview. The information collection instrument was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 14 questions).

4. Efforts to Identify Duplication and Use of Similar Information

This is a new data collection effort, for which data do not exist elsewhere. EHSB has reviewed existing published and unpublished literature, which determined that the planned data collection efforts do not duplicate any other current or previous data collection efforts.

Previous water quality assessments for private wells focused on evaluating risks that were already identified.⁶⁻⁹ Other assessments that focused on improving the protection of populations served by private wells recommended the involvement of most stakeholders, including owners of these systems. Findings of those assessments revealed the need for more information regarding water quality of private wells and the associated human health issues, and the development of methodologies to address them.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

This request is for a one time information collection. There are no legal obstacles to reduce the burden. If no data are collected, the CDC's EHSB will be unable to:

- Collect information/recommendations from EH practitioners on how to design and conduct projects that successfully address drinking water policy.
- Gain an understanding of methodologies and activities that EH practitioners and officials of other public health departments are undertaking to shape policy and advance their safe drinking water programs.
- Identify challenges to influencing policy through water projects and strategies for overcoming those challenges

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

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

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 31, 2013, Vol. 78, No. 211; pp. 653 25-26. No comments were received.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

Personally identifiable data from the participant responses will be collected and stored in a secure database maintained by CLS. Upon completion of data analysis, CLS will share the de-identified summary data (in a Microsoft Excel file) and report that summarizes results with EHSB for review.

This information collection is not research involving human subjects.

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

No information will be collected that are of a personal or sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on pilot tests of the interview guide by 3 public health professionals, including 2 EH practitioners from the Cerro Gordo County Department of Public Health, Iowa and 1 CLS staffer. The average time to complete the interview, including time for reviewing instructions, was approximately 60 minutes (range: 45 to 75 minutes). For the purposes of estimating burden hours, the upper limit of this range (i.e., 75 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for environmental scientists and specialists, including health (<http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf>). Based on DOL data, an average hourly wage of \$32.62 is estimated for all 18 respondents. Table A-12 shows estimated burden and cost information.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Information collection Instrument: Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Interview Guide	State and local environmental health practitioners	18	1	1.25	23	\$32.62	\$734
	TOTALS	18	1		23		\$734

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

There will be no direct costs to the respondents other than their time to participate in the information collection.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of two CDC staff members and CLS contractors during the data collection and analysis activities. The total estimated cost to the federal government is \$50,409.12. Table A-14 describes how this cost estimate was calculated.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
EHSB Team Lead (GS-13)	16	\$53.11	\$849.76
EHSB Epidemiologist (GS-13)	48	\$50.32	\$2,415.36
ChangeLab Solutions Contract	NA	NA	\$47,144.00
Estimated Total Cost of Information Collection			\$50,409.12

15. Explanation for Program Changes or Adjustment

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data from the participant responses will be collected and stored in a secure database maintained by CLS. Upon completion of data collection and analysis, CLS will share the de-identified summary data (in a Microsoft Excel file) and a report that summarizes the results with EHSB for review. CLS, in close collaboration with EHSB, will then organize the information collected into products that will describe the policy work including lessons learned, best practices, key activities, accomplishments and recommendations. These products will then be shared with health departments that participated in the information collection. The collection of state and local environmental health information on safe drinking water policy may ultimately form the basis for the development of “How-to” guides for STLT health departments outlining examples of water projects, focusing on federally unregulated drinking water sources, and their relationship to policy.

Project Time Schedule

- ✓ Design questionnaire (COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan (COMPLETE)
- ✓ Pilot test questionnaire (COMPLETE)
- ✓ Prepare OMB package (COMPLETE)
- ✓ Submit OMB package (COMPLETE)
- OMB approval (TBD)
- Conduct assessment (Assessment open 8 weeks)
- Code, quality control, and analyze data..... (4 weeks)
- Prepare reports (4 weeks)
- Disseminate results/reports (4 weeks)

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

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS – Section A

Note: Attachments are included as separate files as instructed.

- A. Attachment A: List of state and county health departments**
- B. Attachment B: Interview Guide**

REFERENCE LIST

1. Centers for Disease Control and Prevention (CDC). "National Public Health Performance Standards Program (NPHSP): The Public Health System and the 10 Essential Public Health Services." Available at <http://www.cdc.gov/nphsp/essentialservices.html>. Last updated: 5/29/14. Accessed on 8/26/15.
2. Maupin, M.A., J.F. Kenny, S.S. Hutson, J.K. Lovelace, N.L. Barber, and K.S. Linsey. 2014. Estimated use of water in the United States in 2010: U.S. Geological Survey Circular 1405, 56 pp. Available at <http://dx.doi.org/10.3133/cir1405>. ISSN 2330-5703. Accessed on 8/26/15.
3. U.S. Geological Survey (USGS). "The National Water-Quality Assessment (NAWQA) Program." Available at <http://water.usgs.gov/nawqa/>. Last modified: 7/31/15. Accessed on 8/26/15.
4. DeSimone, L.A. 2009. Quality of water from domestic wells in principal aquifers of the United States, 1991-2004: U.S. Geological Survey Scientific Investigations Report 2008-5227, 139 pp. Available at <http://pubs.usgs.gov/sir/2008/5227>. Accessed on 9/14/15.
5. Centers for Disease Control and Prevention (CDC). "National Outbreak Reporting System (NORS)." Available at <http://www.cdc.gov/nors/index.html>. Last updated: 9/03/15. Accessed on 9/14/15.
6. Knobeloch, L., Salna, B., Hogan, A., Postle, J., & Anderson, H. (2000). Blue babies and nitrate-contaminated well water. *Environmental Health Perspectives*, 108(7):675-678.
7. Borchardt, M.A., Bertz, P.D., Spencer, S.K., & Battigelli, D.A. (2003). Incidence of enteric viruses in groundwater from household wells in Wisconsin. *Applied and Environmental Microbiology*, 69(2):1172-1180.
8. Sanders, A., Messier, K., Shehee, M., Rudo, K., Serre, M., & Fry, R. (2012). Arsenic in North Carolina: Public health implications. *Environment International*, 38(1):10-16.
9. Allevi, R.P., Krometis, L-A.H., Hagedorn, C., Benham, B., Lawrence, A.H., Ling, E.H., & Ziegler, P.E. (2013). Quantitative analysis of microbial contamination in private drinking water supply systems. *Journal of Water and Health*, 11(2):244-255.
10. ChangeLab Solutions (2016). ChangeLab Solution – About Us. Available at: <http://www.changelabsolutions.org/about-us>. Accessed on December 9, 2015.