Epidemiologic Study of Health Effects Associated With Low Pressure Events in Drinking Water Distribution Systems (0920-0960)

Request for an Extension of Existing Collection of Information

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Epidemiologic Study of Health Effects Associated With Low Pressure Events in Drinking Water Distribution Systems

Goal of the Study: Conduct an epidemiologic study in five water utility service areas of the U.S. to assess whether individuals in sampled regions exposed to low pressure events (e.g., main breaks) in the water distribution system are at an increased risk for acute gastrointestinal or respiratory illnesses.
Intended use of data: Data will be used to assess whether individuals in areas exposed to low pressure events evaluated in this study have an increased risk for illness. Results will help health departments and water utilities build capacity to respond to low pressure events, quickly identify populations impacted by events, and appropriately implement boil water advisories.. Results will be summarized in scientific manuscript(s) and shared with public health and water industry stakeholders.
Methods for collection: Five water utilities will provide information about 65 low pressure events. An estimated 6,750 households will be invited to participate in the household survey; we estimate that 4,050 surveys will be completed, providing data on 8,100 individuals.
Subpopulation to be studied: Individuals living in households that receive water from five water utilities; water systems will be geographically diverse and will include systems that use chlorine and monochloramine as their secondary disinfectants.
How data will be analyzed: We will measure symptoms associated with AGI and ARI among exposed and unexposed individuals and calculate odds ratios (OR), risk difference, and attributable risk percent for symptoms of AGI and ARI associated with low pressure events. Conditional logistic regression will be implemented to appropriately evaluate the effect of event exposure within each event. We will also control for individual-level covariates, such as age and chronic medical conditions. Additionally, we plan to stratify our analyses by type of secondary disinfectant used. Descriptive and inferential statistical analyses will be conducted using statistical software.

iii. Extension

A. Justification

1. Circumstances Making the Collection of Information Necessary

This is a request from CDC for a 30 month extension of existing data collection. The purpose of this data collection is to conduct an epidemiologic study in the U.S. (similar to a study conducted in Norway (Nygard, Wahl et al. 2007)) to assess whether individuals exposed to low pressure events in the water distribution system are at an increased risk for acute gastrointestinal or respiratory illnesses. Pursuant to the terms of clearance, a non-substantive change request was required after completion of a pilot study and was approved on 11/12/2014. Pilot study data collection, analysis, and evaluation took longer than expected, and there were delays in implementing data infrastructure and IT updates needed to scale-up the procedures for a multi-site study. To address this, we are asking for a 30 month extension for data collection. The approved OMB expiration date is 03/31/2016, but this will not allow enough time to complete the data collection. Additionally, the extension would allow the study team to stagger the utility enrollment to help streamline data collection over all study events.

There are no proposed changes to the methodology, respondents, or information collection forms in this extension request. The site from the pilot volunteered to participate in the multi-site study, and four additional utilities have expressed interest in participating. The five utilities are diverse in their geographic locations, size of population served, and secondary disinfectant types (i.e., two use monochloramine and three use chlorine), which would facilitate stratified analyses by disinfectant type, which is one of the team's analysis goals. Annualized costs to respondents were updated with May 2014 U.S. Department of Labor's national occupational employment and wage estimates data to reflect changes to the mean hourly wages. Annualized costs to the government were updated to reflect the 30 month extension request.

The CDC study team finalized the study design, protocols, household survey, and other data collection instruments following the completion and post-evaluation of the pilot study (see Attachment C for pilot evaluation logical framework and Attachment D for pilot summary and evaluation report). The team produced a pilot evaluation report (Gargano, Hill et al. 2014) to create awareness of the study within the water industry and to solicit utility participants for the multi-site study (Attachment D). The team also presented pilot results to water industry stakeholders at the American Water Works Association (AWWA) 2014 Water Quality Technology Conference (Hill, Gargano et al. 2014). The team obtained necessary human subjects research approvals and negotiated the terms of the project funding contract to secure the remaining external funds for the study. Following full study OMB and IRB approval, the team developed data infrastructure and data management guidelines for the full study and recruited additional volunteer utility participants.

The study team launched the full study in July 2015 and started data collection at the first utility site; utility enrollment is being staggered to streamline data collection. Six low pressure events have occurred at two utility sites. CDC has received completed surveys from 127 households in low pressure (exposed) areas and 186 households in unexposed control areas, although survey administration is still ongoing for 4 of the 6 events. The average response rates for the first four events is 40%, although data collection is still ongoing for two of these events. CDC brought a third utility site on board in January 2016 and will begin data collection at this site once an eligible main break or repair occurs. The fourth utility site is expected to begin data collection in March 2016, and the remaining site later in 2016. The study team developed field protocols to guide water utility partners in the epidemiologic components of the study and conducted extensive training with utility personnel responsible for field and laboratory data collection at the first few sites. The study team also worked with the utility communications teams to draft a study promotional and community outreach packet including a press release (Attachment E1), radio PSA scripts (Attachment E2), newsletter text (Attachment E3), social media posts (Attachment E4), promotional postcards (Attachment E5), and fact sheets (Attachment E6-7). Utility communications staff distributed these on utility letterheads as a tool to help ensure customers of the study's importance and legitimacy and to boost survey response.

No existing U.S. data sources can be used to answer this research question. Systematic data collection across many low pressure events, with a study design tailored for the purpose of answering the research question, is needed to identify the health impacts of low pressure events. This study would be, to our knowledge, the first U.S. study to systematically examine the association between low pressure events and acute gastrointestinal and respiratory illnesses. Study findings will help the EPA, CDC, and other drinking water stakeholders prioritize and direct future research and policy efforts that address public health risks associated with drinking water distribution systems. This data collection supports CDC's research agenda goal of "Decreasing health risks from environmental exposures," as waterborne illnesses are environmental exposure health risks. Data collection authority is found in Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment A).

2. Purpose and Use of Information Collection

The pilot study demonstrated that the study procedures will yield high-quality data needed to answer the research questions (see Attachment D for pilot summary and evaluation report). Continued data collection is needed to evaluate whether LPEs are associated with illness.

Contamination of water in distribution systems is a risk factor for disease, accounting for approximately 15% of drinking water outbreaks in community water systems reported during 1971–2006 (Craun, Brunkard et al. 2010). Each year, approximately 240,000 water main breaks occur in the U.S. (U.S. Environmental Protection Agency 2009) -- occasionally boil water advisories are issued, but we do not have good data to assess whether people are getting sick when water pipes break and pressure is lost. Few published studies have identified the human health risk associated with low pressure

events in drinking water distribution systems (Payment, Siemiatycki et al. 1997; Hunter, Chalmers et al. 2005; Nygard, Wahl et al. 2007; Etheridge 2011). Two of these were prospective studies conducted outside the United States (Payment, Siemiatycki et al. 1997; Nygard, Wahl et al. 2007), and two were retrospective studies that relied on self-report of low pressure as well as self-report of symptoms (Hunter, Chalmers et al. 2005; Etheridge 2011). One retrospective study conducted in the United States, following a water emergency in Alabama, identified significant dose-response associations between number of days of low water pressure or loss of water service and increased prevalence of self-reported AGI (Etheridge 2011).

The U.S. EPA estimates that we will need to invest approximately $300 billion over the next 20 years to upgrade and replace our aging drinking water infrastructure (U.S. Environmental Protection Agency 2009). In development of the Revised Total Coliform Rule (TCR) under which water quality in the distribution system is measured and regulated (as part of the Safe Drinking Water Act), EPA established a Research and Information Collection Partnership (RICP) to identify the highest priority research needs regarding drinking water distribution systems and to help determine whether regulatory action is needed to address distribution system risks (U.S. Environmental Protection Agency 2008). This study was selected as one of ten high priority areas for the drinking water sector (U.S. Environmental Protection Agency and Water Research Foundation 2010). CDC, EPA and the Water Research Foundation (WRF) have provided financial support for the study, recognizing the importance of understanding the risk that low pressure events in the nation's water distribution system infrastructure present for public health. While no single study can provide all information needed to inform EPA regulations, and the proposed study cannot claim to fully represent all utilities in the U.S., the proposed study will supply the first systematically collected epidemiologic data on health effects from low pressure events as evaluated among selected households supplied by five water utilities in the U.S.

This study may also supply data that may contribute to a larger effort to estimate the burden of waterborne disease in the U.S., an activity which has been proposed in multiple agency budgets and is funded in part with full time equivalent (FTE) and other programmatic support by the Waterborne Disease Prevention Branch within the Division of Foodborne, Waterborne and Environmental Diseases at CDC. These gaps include the association between low pressure events and illness (largely unknown in the U.S.), swimming frequency, and the amount of tap water consumed per day.

The results from this epidemiologic study may direct future research efforts that address public health risks associated with drinking water distribution systems. The results will also address EPA's research goals by providing a characterization of the baseline risks of adverse health effects associated with low or negative pressure events in the distribution system and the potential for reduction in those risks associated with different water treatment types. The negative impact of not conducting this study is that policy-makers, government agencies and the water sector will not have the data and information they need on the potential health impact associated with low pressure events and other

breakdowns in our nation's drinking water infrastructure, which is critical to assess the safety and reliability of our public drinking water supply.

3. Use of Improved Information Technology and Burden Reduction

This data collection will involve two response options for survey participants: mail and internet. During the pilot, the majority of respondents chose to return the survey by postal mail (70%), using the provided return envelope. The data quality of the web surveys was higher than the paper surveys because data verification rules and question skip patterns were built into the survey interface. Since the web survey instructions and access information were printed on the survey materials, rather than sent electronically to customers, it might have been inconvenient for respondents to access a computer, type the link to the website, and log-in to take the survey. To encourage web survey participation and an increase in overall survey response rates, the study team will send the survey link electronically to customers that have email addresses on file. Additionally, the study team will add an outbound telephone call as a reminder and additional opportunity for survey participation before the final appeal letter is sent (see Attachment O for telephone reminder script).

All respondents will have the opportunity to respond via the internet. A web-based version of the survey is being offered because it will:

- Reduce the time burden on respondents as compared to other methods of survey completion because of the built in skip patterns and internal logic controls for efficiently routing the respondent to the relevant questions;
- Employ a variety of prompts to encourage survey completion;
- Have data entry validation to limit data entry errors and reduce data cleaning efforts; and
- Data entry into the database is automatic thereby eliminating the need for manual data entry, which also limits data entry errors.

We expect both versions of the survey to take approximately 12 minutes to complete.

Participation in this data collection is voluntary, individuals will be able to discontinue participation at any time point, and all efforts will be made to reduce the time burden on participants.

4. Efforts to Identify Duplication and Use of Similar Information

There are no similar data available, and this study would not be a duplication of any studies currently being conducted in the U.S. No existing U.S. data sources can be used to answer this research question. During the past two decades, only a handful of epidemiologic studies looking at the risk for gastrointestinal illness associated with drinking water have been conducted globally (see Table A.1.2). Two of these studies looked at distribution system risks using a prospective study design, and neither of these studies were conducted in the U.S. Through consultation with other government agencies and national and international water experts, we feel confident that this type of study has not been conducted in the U.S. and would not be a duplication of efforts. Additionally, we have searched databases of scientific literature in the disciplines of public health,

environmental engineering, and water microbiology (e.g., PubMed, Web of Science, Google Scholar), and attended national meetings (American Public Health Association, American Water Works Association, and American Backflow Prevention Association meetings as well as EPA symposia) to attempt to identify similar epidemiological studies that may have been conducted in the U.S. and elsewhere. This study would be, to our knowledge, the first U.S. study to prospectively examine the association between low pressure events in the water distribution system and illness (AGI or ARI).

5. Impact on Small Businesses or Other Small Entities
This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently
Respondents will be asked to respond to this data collection only one time.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
This request fully complies with the regulation 5 CFR 1320.5.

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

A. A 60-day Federal Register Notice was published in the *Federal Register* on 08/28/2015, Vol 80, No. 167, p. 52287. No comments were received. (Appendix B).

B. Consultation outside the CDC began in 2008 with the following persons and is ongoing:

U.S. Environmental Protection Agency (EPA)
Stig Regli (2008-2011)
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Water Research Foundation (WaterRF)
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9. Explanations of Any Payment or Gift to Respondents

Study participants will receive a refrigerator magnet calendar that includes information on emergency preparedness from the CDC with the initial survey mailing. This magnet will highlight the two week period of interest for the study, thus serving as a visual aid to improve recall for participants. The magnet can also be regarded as a token gift. Including a token gift has been shown to improve response rates in mailed surveys (Dillman 2007).

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

- Data collection is being extended
- Water utility respondents might be local governments
- Household survey participants are not state and/or local governments
- Postal survey responses arrive at CDC with no identifiable information and in aggregate form
- Web survey output datasets contain no identifiable information and responses are in aggregate form
- Data management procedures have not changed since previous approval, and the instruments have not been through extensive revisions

The Privacy Act applies to this data collection because personally identifying information (e.g., contact information) will be requested and could potentially be linked to survey responses, although its intended use is (a) to randomly select study participants, (b) to identify exposed and unexposed households and (c) to calculate water distribution system-specific measures (e.g., water residence time, distance from location of low pressure event, etc.) of consented participating households. The applicable System of Records Notice is 09-20-0136.

To protect respondent privacy, the study team has put the following technical, physical, administrative and procedural safeguards in place:

- Personal identification information (e.g., mailing address and other contact information) for each household is collected by water utility collaborators as part of their routine business operations (e.g., for billing and service purposes). Once an LPE has been identified, the water utility will provide the CDC study team

with a list of addresses in the area potentially exposed to the LPE and a comparable or larger number of addresses in an area not exposed to the LPE, through a secure, encrypted file transfer protocol (FTP) site. At CDC, mailing addresses will be uploaded into the study participant management database.

- Address information will be deleted no later than two years after study completion. All addresses of households that were not selected to receive a survey will be deleted within two years of study completion. Permanent data will be anonymous. Respondents will not and cannot be contacted for further follow-up.
- We plan to report only anonymous, aggregate data.
- We have no plans to share participant personal identification information (e.g., address) and will keep individuals' answers private and secure to the extent allowed by law. The measures to safeguard privacy are described to respondents in the informed consent process (Attachment I).
- A link with the CDC-generated user ID and password for access to the web-based questionnaire will now also be sent via e-mail, when customer e-mail addresses are available (see Attachments H and N for e-mail survey invitation).
- Access to the web-based questionnaire will be obtained through the use of a personal pass code that is sent to each household in the survey packet that includes the paper version of the questionnaire. The personal pass code allows only that specific household to access the website. No personal identification information will be collected in the web-based version of the questionnaire.
- Personal identification information (e.g., mailing address) and questionnaire answers (including from the web-based and paper-based versions of the survey) will be stored on a CDC password-protected computer server. Completed paper surveys will be stored in a locked office. Access to the electronic data and to the paper documents will only be granted to authorized personnel at CDC who are working on the study.

CDC study staff who are contractors are subject to a non-disclosure agreement.

Return of a completed survey constitutes consent, as stated in the instructions on the cover of the survey booklet. (Attachments J and K).

Participants are told that the information they provide will be treated in a secure manner and that no identifying information will be shared or appear on any reports. Specifically, the consent brochure states:

> "When the study is complete, your contact information will be removed from our files. No personal information about you will appear on any report. Survey responses will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law."

Study participants are informed that participation is voluntary and that they are not required to answer any specific questions. Specifically, the consent form states:

> "There is no penalty if you decide not to participate. However, we hope that you will choose to participate in this important study."

The only IIF that will be collected will be the contact information of potential study participants, which will be provided from utility billing records or publically available tax assessor information; no other personally-identifiable information will be collected. Address information is necessary in order to identify households that are within the potentially exposed and unexposed areas, and names will only be used to personalize study correspondence. Survey participants' addresses will also be used to calculate water distribution system-specific variables, such as water residence time in the distribution system, distance from the address to the site of the break or repair and other factors. These data will only be made available to the study team. The collection of contact information is expected to have minimal impact on the respondents' privacy.

Information for this data collection will be obtained from the public in two ways: paper surveys filled out by study respondents and returned via postal mail to CDC study staff; and web-based surveys filled out by respondents who respond via a password-protected website housed at CDC. Data from the paper surveys will be entered into a Microsoft Access (2007) database and data from the web-based survey will be provided from the computer developers in a SAS® 9.3 file.

Data will be collected by CDC staff and CDC contractors affiliated with the study. No other data collection partners will be involved. Data will be maintained for the lengths of time outlined in the sections below. Contact information (which is the only Information in Identifiable Form (IIF) that will be collected during this study) will be kept in a password-protected database separate from the survey information and will be deleted and blacked out from paper records within two years of study completion.

The only IIF that will be collected will be contact information for the study participants (i.e., name, mailing address, phone number, e-mail if available). No dates of birth, social security numbers or other types of IIF will be collected. Within one week following an LPE, the water utilities will provide contact information of residential customers (service connections) affected by the LPE and residential customers (service connections) in an area unaffected by the LPE (e.g., persons in a different pressure zone) to CDC study staff, using a secure, encrypted file transfer protocol (FTP) site. From this address list, a random sample of exposed and unexposed households will be generated by CDC study staff. Households will only be surveyed once (either as a household exposed to an LPE or as an unexposed household).

Information will be collected from the public on water service and use and self-reported illnesses (see Attachments F-P for survey instruments and related documents). Information obtained through this data collection will include:

- Symptoms and duration of AGI and ARI
- Impact of illnesses, including hospitalization and loss of school/work
- Presence of chronic health condition with gastrointestinal or respiratory symptoms
- Household water service, use and consumption (type of drinking water, number of glasses of tap water consumed per person/per day, change in taste, color, or odor of tap water)

- Recent international travel
- Children or adult household member attending or employed at daycare
- Pets in the household and other animal contact
- Recreational water exposure
- Basic demographics: age, race/ethnicity and sex

Our primary outcome measure will be self-reported AGI. AGI will be defined as an episode of vomiting or diarrhea (≥3 loose stools in a 24-hour period) during the two weeks after the low pressure event ("two week period"). Our secondary outcome will be self-reported ARI. ARI will be defined as at least two of the following: fever, sore throat, runny nose, or cough during the two week period of interest.

Participants' initials will be asked for on the questionnaire in order to facilitate individual-specific responses. Initials will only be maintained in the study database until data cleaning is complete, after which they will be destroyed. Where paper records exist (i.e., paper surveys), initials will be blacked out within two years of data cleaning completion. Utility customer names will be used to facilitate communication, because personalized correspondence has been shown to improve survey response rates (Dillman 2007). Address information is necessary in order to identify households that are within the potentially exposed and unexposed areas and will also be used to address correspondence and estimate water distribution system-specific variables. Once these variables have been created, addresses will be deleted and blacked out from paper records within two years of data cleaning completion. Address information will be kept in a password-protected database. Records of any address not selected to participate in the study will be deleted within two years of study completion.

Should they choose to participate, survey respondents will have the opportunity to respond to the survey via the internet. No children (<18 years of age) will be asked to respond to the web-based (or postal version) of the survey. Regardless of which manner a person chooses to participate in the study, for households where children <18 years of age are present, we will ask a parent or guardian to answer questions and provide information on behalf of the child. The consent brochure specifies that only an adult (≥18 years of age) is eligible to complete the questionnaire (see Attachment I), and this information is reiterated in the survey booklet (see Attachments J and K).

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

This study has been approved by CDC's IRB (see Attachment Q). There are no sensitive questions being asked in this data collection.

12. Estimates of Annualized Burden Hours and Costs

A. **Annualized Burden to Respondents**

We anticipate a response rate of approximately 60%. Previous recent mailed surveys conducted in the U.S. pertaining to drinking water have achieved response rates of approximately 40%; however, we plan to implement several study design modifications following the Dillman Tailored Design Method to encourage participation and improve

response rates compared to previous studies (see section B.3 for a discussion of how this was derived) (Dillman 2007). We plan to include a total of 65 low pressure events in this study (12 at each of 5 utilities). Based on the expectation that the multi-site study will include 15 small events that affect at least 10 households, 35 medium events that affect at least 37 households, and 15 large events that affect at least 53 households, we expect to obtain data on approximately 4,050 households from 65 events. We estimate that survey responses will include data on 2 individuals per household, on average, resulting in health outcome data on approximately 8,100 individuals. The proposed recruitment schedule will provide over 85% power to detect an odds ratio of 1.8 in a stratified analysis, thus we will be able to analyze data separately by secondary disinfectant type. The recruitment schedule will provide over 90% power to detect an odds ratio of 1.6, the effect size identified in the Nygard study, in an overall analysis (see section B.1 for a description of how this was calculated).

Considering the pilot data and the new e-mail contact, we anticipate that of the estimated 4,050 households that return the survey, 40% of respondents (1,620 households) will respond via the web-based survey, and 60% of respondents (2,430 households) will respond via paper. Each household respondent will complete only one survey and the average burden per response for both versions of the survey is expected to be 12 minutes. The estimated annual burden hours to respond to web-based questionnaire is 162 hours (1/2 x (1,620) x 12/60) and the paper-based questionnaire is 243 hours (1/2 x (2,430) x 12/60), for a total of 405 (162+243) annual burden hours for households filling out the household survey.

The burden to the utility personnel participating in the study was also evaluated following the pilot. Because the CDC Environmental Microbiology Laboratory must sometimes respond to public health emergencies that temporarily limit the lab's capacity for research projects, it will not be feasible to collect ultrafiltration samples (UF) for each of the 65 events in the study. Instead, the utility laboratory will collect grab samples from each event and UF samples will be collected from about 2/3 of all events to allow for efficient progress on the epidemiologic study at times when the CDC lab is unable to receive samples. Utilities will work with CDC to verify event eligibility before proceeding with a study response; at that time, CDC will let them know whether to collect the UF samples. The low pressure event (LPE) Form burden per event for events that include UF samples is 145 minutes (15 minutes to write in the information and 130 minutes to collect and ship the samples). The LPE Form burden per event for events that only include grab samples is 45 minutes (15 minutes to write in the information and 30 minutes to collect and ship the samples).

The estimated time of 3 hours needed to provide contact information on affected and unaffected households was also evaluated following the pilot. During the pilot study, it was preferable for utility personnel to use knowledge of the water system and hydraulic principles to select the affected and unaffected areas, instead of using pressure models to identify the areas; the burden and annualized cost of work remained the same. The estimated time to provide contact information on affected and unaffected households is 3 hours (2 hours for utility personnel to use knowledge of the water system and hydraulic

principles to select the affected and unaffected areas and 1 hour of clerical time for a total of 3 hours).

The estimated annualized burden for the LPE form is 9 hours (15 minutes x 5 utilities x 7 events), the estimated annualized burden for the water samples is 51 hours [5 utilities*((130 minutes x 4 events with UF samples) + (30 minutes x 3 events without UF samples))], and the estimated annualized burden for the customer contact information is 105 hours.

Thus, the total annualized response burden for this data collection is estimated at 571 hours (Table A.12.1). The total burden for the 30 month period is estimated to be 1,428 hours.

Table A.12.1- Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (hours)	Total Burden* (hours)
Water Utility customer	Paper-based questionnaire	1,215	1	12/60	243
Water Utility customer	Web-based questionnaire	810	1	12/60	162
Water utility maintenance worker	LPE form, ultrafilter and grab samples	5	4	145/60	49
Water utility maintenance worker	LPE form, grab samples	5	3	45/60	12
Water utility environmental engineer/ Water utility billing clerk	Line listings	5	7	3	105

	Total				571

*Estimates have been rounded up to the nearest whole number.

B. Annualized Cost to Respondents

The annualized cost to water utility customer survey respondents for the multi-site study was estimated using the total annual burden (243 + 162 = 405 hours) and the mean hourly wage in the U.S. for all occupations ($22.71, obtained from the U.S. Department of Labor's May 2014 national occupational employment and wage estimates data, available at: http://www.bls.gov/oes/current/oes_nat.htm#00-0000). Given these numbers, the maximum total annualized cost of this data collection to utility customer respondents is estimated to be $9,197.55 (405 x $22.71 =$9,197.55) (See Table A.12.2).

The annualized cost to the water utility company personnel who complete the LPE forms and collect the environmental samples for the multi-site study was estimated to be 61 hours and the mean hourly wage in the U.S. for industrial machinery mechanics $24.25 (obtained from the U.S. Department of Labor's May 2014 national occupational employment and wage estimates data, available at: http://www.bls.gov/oes/current/oes499041.htm). Given these numbers, the maximum total annualized cost of this data collection to utility company mechanic respondents is estimated to be $1,479.25 (61 x $24.25=$1,479.25) (See Table A.12.2).

To provide line listings of customer contact information, the utilities will first use knowledge of the water system and hydraulic principles to select the affected and unaffected areas (to be performed by an engineer, taking approximately 2 hours), and then use utility billing records identify household contact information (performed by clerical staff, taking approximately 1 hour) for CDC staff to randomly select participants from (Attachment S). The annualized cost to the water utility company personnel who select the affected and unaffected areas for the multi-site study was estimated using the annual burden (105 hours x 2/3 = 70 hours) and the mean hourly wage in the U.S. environmental engineers ($41.51, obtained from the U.S. Department of Labor's May 2014 national occupational employment and wage estimates data, available at: http://www.bls.gov/OES/Current/oes172081.htm). Given these numbers, the maximum total annualized cost of this data collection to utility company engineer respondents is estimated to be $2,905.70 (70 x $41.51=$2,905.70) (See Table A.12.2).

The annualized cost to water utility clerical staff who provide CDC with the line listings of addresses of affected and unaffected residents for the multi-site study was estimated using the annual burden (105 hours x 1/3 = 35 hours) and the mean hourly wage in the U.S. for billing and posting clerks ($17.10, obtained from the U.S. Department of Labor's May 2014 national occupational employment and wage estimates data, available at: http://www.bls.gov/oes/current/oes433021.htm). Given these numbers, the maximum total annualized cost of this data collection to billing clerks is estimated to be $598.50 (35 x $17.10=$598.50) (See Table A.12.2).

Summing across the four respondent categories, we anticipate that the maximum total annualized cost for the multi-site study would be $14,181.00.

Table A.12.2- Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Water Utility customer	Paper-based questionnaire/ Web-based questionnaire	405	22.71	9,197.55
Water utility environmental engineer	Line listings	70	41.51	2,905.70
Water utility maintenance worker	LPE form, ultrafilter and grab samples	61	24.25	1,479.25
Water utility billing clerk	Line listings	35	17.10	598.50
Total				14,181.00

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

There are no other costs to respondents or record keepers.

14. Annualized Cost to the Government

The costs incurred by the government for this one-time data collection include the costs for personnel time, printing and mailing paper-based surveys, laboratory supplies, travel, and publication charges (see Table A.14.1). The estimated annualized cost to the federal government is $319,796 (Table A.14.1); this estimated cost did not change following the pilot because the changes to the study were negligible. The total cost, over a 30 month extension would be $599,809 [($186,675 per year for personnel * 2.5 yrs.) + $133,121 for supplies, travel, and publishing)].

Table A.14.1 – Annualized Budget, Multi-site and Pilot Study Item	Hours or Units per Year	Hourly or Unit Cost	Total Cost per Year
Epidemiologist	520	51.38	26,718
Sr. Environmental Engineer (Research)	416	71.76	29,853
Environmental microbiologist	936	37.25	34,866
Project coordinator	2080	33.65	69,992
IT Support staff	104	62.50	6,500
Student Assistant	333	12.00	3,996
Laboratory support staff (contractor)	250	59.00	14,750
Laboratory supplies	426	125.00	53,250
Printing and mailing	6,854[a]	10.5[b]	71,971
Water utility site visits (2 CDC staff/visit)	3	2,300	6,900
Page charges and reprints for publishing study paper	1	1,000	1,000
Total:			319,796

[a]The annual units of mailings were determined from the statistical power calculations and an expected 60% participant response rate. Since the mailings will be sent at different frequencies throughout the study, 6,854 annual units reflects the average number of units needed to reach the total cost of $71,971 from our itemized budget.

[b]The unit cost for mailings include the cost for printing, envelopes, labels, and the calendar magnet. Since there are multiple mailing items that have different unit costs, the unit cost of 10.5 represents the total unit costs for all mailing items.

15. Explanation for Program Changes or Adjustments

The burden for survey participants has not changed from the burden shown in the current inventory. The burden for water utility participants has decreased slightly from the burden shown in the current inventory.

Previously we indicated that we needed 12-18 months for new data collection. To address potential scheduling challenges discovered during the pilot, the study team will plan for scheduling conflicts and conduct a staggered scale-up to multiple utility sites, which will require an extension of 30 months of data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Table A.16.1 provides the data collection activity schedule. Previously we indicated data collection would be completed 12-18 months after obtaining OMB approval. During the pilot, there were scheduling challenges during the winter season or during other busy periods at CDC or the utility. To address this, the study team has planned for scheduling conflicts and implemented a staggered scale-up to multiple utility sites; for these reasons a 30 month extension has been requested. There is no change to the anticipated 6 months needed for data analysis and additional 6 months needed for manuscript development.

Table A.1.6- Data collection activity schedule

Activity	Time Frame
Data collection	24-30 months after obtaining OMB extension approval
Data analysis	30-36 months after obtaining OMB extension approval
Manuscript development	36-40 months after obtaining OMB extension approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate
The display of the OMB expiration date is not inappropriate.

18. Exceptions for Certification for Paperwork Reduction Act Submissions
There are no exceptions to the certification.

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