

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

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**Non-substantive Change Request**

**Part A**

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- A. Authorizing Legislation
- B. 60 day Federal Register Notice
- C. Pilot Evaluation Logical Framework
- D. Reminder Phone Script (revised)
- E. IRB Approval Continuation
- F. Cover Letter – E-mail (revised)
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- L. CDC Water and Health Study – Household (revised) paper version
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- N. Thank you/Reminder Letter
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- P. Final Appeal Letter
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## **A. Justification**

A team from the CDC Waterborne Disease Prevention Branch completed a successful pilot for an epidemiologic study to assess whether individuals exposed to low pressure events (LPE) in drinking water distribution systems are at an increased risk for acute gastrointestinal illness (AGI) or acute respiratory illnesses. Pursuant to the terms of clearance, a non-substantive change request is required after the completion of the pilot study. Overall, the pilot demonstrated that the study design and procedures will allow the study team to collect the data needed to meet the study goal and aims (see Attachment C for logical framework tool for evaluating the pilot). Field, laboratory, and epidemiologic components of the study were well-coordinated and data collection proceeded smoothly. Data collection for the pilot took longer than expected; to address this, we plan to ask for 24 months of new data collection following the OMB full study approval. The approved OMB expiration date is 03/31/2016, but this might not allow enough time to complete the survey data collection. Following minor modifications to the study materials and protocols to streamline field data collection and improve the household survey response rates, the study team will be ready to implement the full study to determine whether LPEs are associated with illness. There were no anticipated changes to the burden and annualized cost to survey respondents, and there was a slight increase in the burden and annualized cost to the volunteer water utility partners.

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

Following OMB approval for the pilot study, CDC conducted a pilot study at one water utility site to evaluate whether the study design and methods would yield high-quality data needed to answer the research question of whether low pressure events in distribution systems are associated with illness. The pilot demonstrated the feasibility of collaboration between CDC and water utilities to investigate water quality and health impacts related to LPEs. Most households surveyed in LPE (exposed) areas were unaware of low pressure, and customers did not express concern about the reasons for the study, thus illness reporting in the multisite study is expected to be unbiased. Since the pilot was designed to evaluate whether study procedures yield sufficiently high-quality data to answer the research questions, the pilot was not adequately statistically powered to answer the research question. Thus, CDC is seeking OMB approval of the full study data collection.

The purpose of the full study data collection is to conduct an epidemiologic study in the U.S. to assess whether individuals exposed to LPEs in the water distribution system are at an increased risk for acute gastrointestinal or respiratory illnesses. No existing U.S. data sources can be used to answer this research question. Systematic data collection across many LPEs, with a study design tailored for the purpose of answering the research question, is needed to identify the health impacts of LPEs. 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. The study will have over 90% statistical power to detect an association of the magnitude identified in a similar study conducted in Norway (~1.6) (Nygard et al., 2007). Smaller effect sizes might still have policy relevance, and finding a non-significantly increased risk in the current study would indicate that more research is needed to achieve the level of precision needed to verify health effects from low pressure events in the United States.

We plan to conduct a prospective cohort study among households that receive water from five water utilities across the United States. The water systems will be geographically diverse and will include systems that use chlorine or monochloramine as their secondary disinfectants. Participating water utilities will provide information about LPEs that occur during the study period. Following approximately 65 (one per month per utility, on average) LPEs, an estimated 6,750 households (2,250 from areas exposed to the LPE and 4,500 from comparable but unexposed areas) will be invited to participate. We estimate that 4,050 surveys will be completed and returned, providing data on 8,100 individuals. A total of 571 estimated annualized hours of respondent burden are expected for the full multi-site epidemiologic study.

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**

Overall, the pilot study demonstrated that the study design and procedures will allow the study team to collect the data needed to answer the research question. The utility operator and CDC study team's selection of the matched LPE (exposed) and non-LPE (unexposed) areas was completed accurately and efficiently using knowledge of the water system and hydraulic principles. Hydraulic models were developed for three events, and results corroborated the selection of the study areas based on the field assessment and knowledge of the water system. An important assumption of the cohort study design is that the exposed and unexposed areas can be classified correctly, and the pilot results demonstrated that it will be feasible to correctly select the study areas during the full study. The LPE form was nearly complete for all six pilot study events, with the exception of a few items that the team was unable to measure or observe, such as pressure readings and interior conditions of pipes. All standard operating procedures were followed for water sample collection and shipment, and the water sample chain of custody information was complete for all events.

A secure web survey and database were developed specifically for this project to manage utility customer data, collect survey data, and track participation. CDC contacted approximately 600 households following a total of six events. The study team maintained the privacy of the utility customer data and tracked participation. Survey response rates were similar in LPE (exposed) and non-LPE (unexposed) areas, suggesting there was limited bias between the two groups. The overall survey response rate of 37% was lower than anticipated, and efforts to improve response rates are outlined in this non-substantive change request; the study team will modify the survey and procedures and will increase efforts to promote the study in the participating communities. The survey item response rate was over 90% for all but four items. The survey data quality was

high; the study team was able to summarize findings through descriptive statistics and visual aids to guide the evaluation of the survey instrument and administration methods.

Another important assumption of the epidemiologic study design was that the surveyed households consumed their tap water and were therefore exposed to the LPE. The majority of survey respondents reported drinking and using tap water for potable purposes, and this was similar in the LPE and non-LPE areas. Most households in LPE areas did not report observing low pressure, complete service loss, or a change in tap water during the three weeks following the LPE, indicating that customers were usually unaware of their exposure status.

A minority of households mistakenly thought they were under a boil water notice, advisory, or order. This was uncommon, but occurred more in LPE-areas, so it is possible that customers misinterpreted a work notice communication, such as a door hanger, from the utility. There is a lack of consensus nationally regarding how to respond to LPEs in terms of triggers for public notification or the public health need for boil water advisories. In part, this is because we have no empirical data on the health impacts from low pressure events gathered from disinfected water utilities in the United States. Results from this study can ultimately be used to build the knowledge base for future policy decision-making.

The pilot study demonstrated that the study procedures will yield high-quality data needed to answer the research questions. Continued data collection is needed to evaluate whether LPEs are associated with illness.

### **3. Use of improved information technology to reduce the burden on the public**

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 D for telephone reminder script).

### **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.

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

No small businesses will be involved in this data collection.

## **6. Consequences of Collecting the Information not collected/ collected Less Frequently**

Respondents will be asked to respond to this data collection only one time. There are no legal obstacles to reduce the burden.

## **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 March 23, 2012, vol. 77, No. 57, pp. 17066-68 (see Attachment B). One non-substantive comment was received by a private citizen.

**B.** Consultation outside the CDC began in 2008 and those are listed with the original submission.

## **9. Explanations of Any Payment or Gift to Respondents**

Study participants received a refrigerator magnet calendar that included information on emergency preparedness from the CDC with the initial survey mailing. This magnet highlighted the period of interest for the survey, 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. Assurance of Confidentiality Provided to Respondents**

### IRB Approval

This study has been approved by CDC's IRB (see Attachment E).

### Privacy Impact Assessment Information

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 Attachment F for e-mail survey invitation)

## **11. Justification for Sensitive Questions**

There are no sensitive questions being asked in this data collection

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

There are no anticipated changes to the total burden and annualized cost to survey respondents. System data demonstrated that the web-based survey took customers a median of 11 minutes to complete, suggesting that the time burden for participation was low and in line with the anticipated time of 12 minutes. However, we anticipated that 60% of respondents would respond via the web-based survey, and in the pilot, 30% of respondents responded via the web-based survey. To encourage web survey participation, the study team will send the survey link electronically to customers that have email addresses on file (approximately 10% of pilot utility

customers). Considering the pilot data and the new e-mail contact, we now 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. This change does not impact the total burden and annualized cost to survey respondents as 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 ( $1/2 \times (1,620) \times 12/60$ ) and the paper-based questionnaire is 243 hours ( $1/2 \times (2,430) \times 12/60$ ), for a total of 405 (162+243) annual burden hours for households filling out the household survey. Following the second survey mailing, staff will attempt to call non-responders by telephone to encourage them to complete the paper or web survey. If respondents indicate they would like to complete the survey by phone rather than web or paper, staff will complete a telephone survey interview by accessing the respondent's web survey link and administering the web survey over phone. This is not expected to change the overall respondent burden.

The burden to the utility personnel participating in the study was also evaluated following the pilot. Prior to conducting the pilot, we anticipated that the estimated time required to complete the Low Pressure Event (LPE) Form would be 45 minutes (15 minutes to write in the information and 30 minutes to collect and ship the water samples). For each event, it did take approximately 15 minutes to fill out the form, but we underestimated the time needed to collect and ship the water samples. Additionally, 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 LPEs 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 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).

There is no anticipated change to the estimated time of 3 hours needed to provide contact information on affected and unaffected households (2 hours for environmental engineer to run pressure models and 1 hour of clerical time for a total of 3 hours). However, for the pilot utility, 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 annualized burden for the LPE form is 9 hours (15 minutes  $\times$  5 utilities  $\times$  7 events), the estimated annualized burden for the water samples is 51 hours [5 utilities  $\times$  ((130 minutes  $\times$  4 events with UF samples) + (30 minutes  $\times$  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.1.3), compared to 537 hours estimated in the original information collection request. The total burden for the two-year study is estimated to be 1,142 hours.

**Table A.12.1- Estimated Annualized Burden Hours**

<b>Form Name</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden per Response (hours)</b>	<b>Total Burden* (hours)</b>
Paper-based questionnaire	1,215	1	(12/60)	243
Web-based questionnaire	810	1	(12/60)	162
LPE form, ultrafilter and grab samples	5	4	(145/60)	49
LPE form, grab samples	5	3	(45/60)	12
Line listings	5	7	3	105
<b>Total</b>				<b>571</b>

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

**B. Annualized Cost to Respondents**

There are no changes to the anticipated annualized costs to water utility customer survey respondents, water utility environmental engineer, and water utility billing clerk (Table A.1.4). The anticipated annualized cost to the water utility maintenance worker that completes the LPE forms and collects the environmental samples increased from \$623.43 to \$1,408.49 because the annualized burden increased from 27 hours to 61 hours; before the pilot, we underestimated the time needed for water sample collection. Therefore, the maximum total annualized cost is estimated to be \$13,595.94. The previous estimate of the annualized cost to respondents was \$12,803.88.

**Table A.12.2- Estimated Annualized Burden Costs**

<b>Respondent</b>	<b>Annualized Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Annualized Respondent Cost</b>
Water Utility customer	405	21.74	8,804.70
Water utility environmental engineer	70	40.17	2,811.90
Water utility maintenance worker	61	23.09	1,408.49
Water utility billing clerk	35	16.31	570.85
<b>Total</b>			<b>13,595.94</b>



### **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 data collection include the costs for personnel time, printing and mailing paper-based surveys, laboratory supplies, travel, and publication charges. The estimated annualized cost to the federal government for the pilot and full study is \$319,796.

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

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 24 months of new data collection following the OMB full study approval. Additionally, there were revisions to the data collection instruments and study procedures to simplify participation and increase response rates.

Previously, we indicated that the data collection would require 588 estimated annualized burden hours for the pilot (51 hours) and full study (537 hours). With this request, we estimate that the estimated annualized burden hours for the full study will be 571 hours.

The increased estimated burden of 34 hours to complete the full study (571 hours compared to 537 hours in the original information request) was informed by the pilot, which demonstrated that we originally underestimated the amount of time required to collect and ship the ultrafiltration water samples.

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

Table A.1.6 provides the data collection activity schedule. We anticipate the data collection will require two years, following the OMB full study approval. 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 will plan for scheduling conflicts and consider a staggered scale-up to multiple utility sites, which will require 24 months of data collection. 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**

<b>Activity</b>	<b>Time Frame</b>
Data collection	24 months after obtaining OMB approval
Data analysis	24-30months after obtaining OMB approval
Manuscript development	30-36 months after obtaining OMB 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.

**Reference**

Nygaard, K.; Wahl, E.; Krogh, T.; Tveit, O.A.; Bohlgeng, E.; Tverdal, A.; Aavitsland, P. Breaks and maintenance work in the water distribution systems and gastrointestinal illness: a cohort study. *International Journal of Epidemiology*. 2007 Aug;36(4):873-880.