

Justification for Change

Pursuant to the terms of clearance, a non-substantive change request is required after completion of the pilot study.

Household Survey

The pilot results evidenced both successes and challenges in survey administration. Nearly all selected households had deliverable addresses, and there were apparent boosts in survey response following each of the mail prompts from CDC. Although the overall survey response rate of 37% was lower than anticipated, response rates were similar in low pressure event (LPE) (38%) and non-LPE areas (36%), suggesting that there was limited bias between the two groups. The item response rates for the survey were over 90% for all but 4 items (i.e., illness onset date and number of days with symptoms for respondents that reported AGI/ARI symptoms), and system data from web surveys indicated that the median time to complete the survey was 11 minutes, which is similar to the anticipated burden estimate of 12 minutes. Web survey break-off was low (6% of respondents stopped before survey submitted). To improve response rates, the study team will modify the survey and procedures and will increase efforts to promote the study in the participating communities. These efforts are detailed in the Supporting Statement, outlined in Table 1. The pilot survey informed minor changes to wording to improve consistency across similar questions and suggested additional response options based on common write-in responses. Specific changes to the survey instrument are outlined in Table 2.

Low Pressure Event (LPE) form

After reviewing the pilot LPE form data and discussing the form's usability with the utility study team, we re-organized the form by grouping similar items together, considering the chronological order of the repair process, and simplified the form by removing questions that were not field knowledge (i.e., questions that required additional follow up to answer). Feedback from our pilot utility indicated that the form did not have fields to describe planned repairs, so we added 3 items to capture the planned repair information. We simplified questions when possible and indicated which questions could be skipped for planned repairs. The specific modifications are listed in Table 2. As outlined in the Supporting Statement, we do not anticipate this will change the time burden; the previous LPE form had 32 items, and the revised form has 34 items.

Utility Customer Information and Study Areas

As outlined in the protocol, the choice of the study areas was communicated to CDC with a map; we added a template for the map to the utility customer information form to facilitate standard data collection across the different utility sites. This change is described in the Supporting Statement and outlined in Table 2.

Table 1. Survey and Protocol Modifications to Increase Survey Response

Additional Effort to Increase Survey Response	Rationale for Change
Increase promotion in participating communities <ul style="list-style-type: none">• Health communicator contract time• Local public service announcements• Periodic advertisement in local print media	<ul style="list-style-type: none">• Multiple contact strategy showed reminders boost response• 46% of page views for study website in 30 days after press release, before survey materials sent, showing media generated community interest
Add e-mail contact when available	<ul style="list-style-type: none">• Encourage use of web survey because more convenient than typing link from paper form• Increase overall response rate; e-mail mode might appeal to certain respondents• Utilities moving to electronic consumer confidence reports, so might have more complete e-mail contact data
Add follow-up telephone call between 2 nd survey and final appeal	<ul style="list-style-type: none">• Multiple contact strategy showed reminders boost response• Telephone mode might appeal to certain respondents
Clarify, simplify content of survey and materials <ul style="list-style-type: none">• Specific changes in Table 2• Shorten recall period• Simplify illness and water use questions• Reduce number of words in cover letters•	<ul style="list-style-type: none">• Encourage response by making it easier to fill out the survey
Improve web survey interface <ul style="list-style-type: none">• Simplify instructions• Improve formatting	<ul style="list-style-type: none">• Discourage web survey break-off• Decrease reading time• Make survey seem shorter

Title: Epidemiologic Study of Health Effects Associated with Low Pressure Events in Drinking Water Distribution Systems

OMB Control Number: 0920-0960

Expiration Date: 03/31/2016

Table 2. Summary of Non-substantive Changes to Data Collection Forms

Form	Current Question/Item	Requested Change
Survey	Section 1 Household Water Use: In this first section we'd like to ask some general questions about your household water use. By "tap water", we mean drinking water supplied by your water company.	Change "By tap water, we mean drinking water supplied by your water company" to "We are asking about drinking water from your water utility, or "tap water" that comes from your house. For these questions, it does not matter if you filter the water."
Survey	1. Please mark all of the ways that you and the people in your household have used tap water in the last 30 days	Move answer option "Mixing infant formula" after "Making hot drinks"; Change "Filling pool or hot tub" to "Filling swimming pool or hot tub"
Survey	2. At home, what type of water do you and other members of your household drink most often?	Remove question
Survey	5. What water filters are used in your home?	Add answer option "Whole house filter"
Survey	6. Which of the following best describes where you live?	Add answer option "Townhouse or duplex"
Survey	7. What pets do you have in your home or yard	Add answer option "Fish"; re-order answer options
Survey	8. Are there any livestock or animal enclosures located within 50 yards of your household?	Change to: Are there any livestock located within 50 yards of your household?; Add answer options "Goats, Sheep"; Change "No livestock or animal enclosures" to "No livestock", "Cattle or feedlots" to "Cattle", "Poultry or poultry houses" to "Poultry", "Other livestock/animal enclosures" to "Other livestock."
Survey	Section 3 Recent Water Service: In this section, we are asking about your recent water service. Please refer to the label on the front of this booklet or the enclosed calendar for the dates of the <u>3-week period</u> .	Change "3-week" to "2-week"
Survey	9. At any time during the 3-week period on the label, Did anyone in your home notice low water pressure?; Did you completely lose water service?; Did anyone notice a change in the odor, taste, or color of your tap water at home?; Were you told to boil your water before drinking it?; If YES, what did you use for drinking water during that time?	Change "3-week" to "2 week"; Add "Was any work done on the pipes near your home?"
Survey	10. How many people, including you, live in your household? Do not include short term visitors.	Delete "Do not include short term visitors"
Survey	Section 5 Drinking Water Use: In the next 2 questions, we are asking about drinking water from your water utility, or "tap water," that comes from your house. For these questions, it does not matter if you filter the water.	Change instructions to: On this page, we are asking about drinking water from your water utility, or "tap water," that comes from your house, as well as other kinds of water you drink. For questions 15 and 16, it does not matter if you filter the water. (1 cup = ½ of a pint = 8 ounces)
Survey	14. What is each person's main source of drinking water at home? (Put an X in 1 box for each person).	Change to: At home, which kinds of water does each person usually drink? (circle yes or no for each kind of water). Add answer option "Water from a refrigerator dispenser"; Change "Water from the tap, not filtered" to "Tap water, directly from faucet (that you do not filter)", "Water from the tap, filtered" to "Tap water that you filter (for example, filter in pitcher, on faucet, under sink)
Survey	15. On average about how many 8 ounce glasses of your home tap water does each person drink per day? Include water from home that you drink at another location such as work, school, or sports activities.	Change "8 ounce glasses" to "cups"; Delete "Include water from home that you drink at another location such as work, school, or sports activities"
Survey	16. On average about how many 8 ounce glasses of drinks mixed with your home tap water, such as Kool-Aid, instant iced tea, or watered-down juice, does each person drink per day? Do not include hot beverages, like brewed coffee or tea.	Change "8 ounce glasses" to "cups"; add "infant formula" after "Kool-Aid"
Survey	Section 6 Recent Activities: In this section, we are interested in recent activities you and your household members did	Change "3-week" to "2-week"

Title: Epidemiologic Study of Health Effects Associated with Low Pressure Events in Drinking Water Distribution Systems

OMB Control Number: 0920-0960

Expiration Date: 03/31/2016

	during the <u>3-week period</u> . Please refer to the label on the front of this booklet or the enclosed calendar for the dates of your <u>3-week period</u> .	
Survey	17. During the 3-week period, did anyone, Swim or wade in a lake, river, stream, or ocean?; Swim in a pool?; Swallow or drink any water directly from a spring, lake pond, stream, or river?; Drink any water from a well?; Go hiking or camping?; Attend, work volunteer in a day care?; Visit a petting zoo or farm with animals?; Travel outside of the United States? Spend any nights away from home? Enter number of nights away from home.	Change “3-week” to “2-week”; Change to: “Spend any nights away from home? Yes, No; How many nights away from home?”; Add “Eat any meals prepared in a restaurant? (includes deli, fast food, take-out) About how many restaurant meals?”
Survey	Section 7 Stomach Problems: Please refer to the label on the front of this booklet or the enclosed calendar for the dates of the <u>3-week period</u> . In this section, we are asking about new stomach problems that started during the <u>3-week period</u> , not problems you normally have.	Change “3-week” to “2-week”; At bottom of page, add “If you answered Yes to any stomach problems in section 7, please go to section 8, Illness Details on the next page. If no one in your household had any stomach problems, please skip to section 9.
Survey	18. During the 3-week period, did anyone start having new stomach problems? (not problems they normally have) Vomiting; Nausea; Diarrhea (defined as 3 or more loose stools or bowel movements in any 24-hour period); Stomach cramps; Did they have a fever (100°F or higher) at the same time as stomach problems?	Change “3 week” to “2 week”; Change diarrhea, stomach cramps, fever answer options to: “Diarrhea? (3 or more loose stools in a 24-hour period)”, “Abdominal pain or cramps? “, Fever (100°F or higher) at the same time as stomach problems?”
Survey	20. When did the stomach problems start? (MM/DD/YY) If you are unsure of the exact date, please give your best guess.	Replace “if you are unsure of the exact date, please give your best guess” with “This date is: Exact []; Best guess []”
Survey	Section 9 Illness Details: Please complete the section only if you answered Yes to any symptoms in section 7 or section 8. If no one had stomach problems, cold or flu symptoms in the 3-week period, you can skip to section 10 on the next page. These questions are asking about how illnesses during the 3-week period affected you.	Change to “Section 8 Illness Details – Stomach Problems”; delete “or section 8” and “cold or flu symptoms”; change “3-week” to “2-week”; change “section 10” to “section 9”. At bottom of page, add “Do you have any other information to share about recent stomach problems?”
Survey	24. How many days of school or work did each person miss because of stomach problems, cold or flu?	Delete “colds or flu”
Survey	25. Did anyone seek a healthcare provider for stomach problems, cold, or flu symptoms?	Delete “cold, or flu symptoms”
Survey	Section 8 Colds and Flu: Please refer to the label on the front of this booklet or the enclosed calendar for the dates of the <u>3-week period</u> . In this section, we are asking about new cold and flu symptoms that started during the <u>3-week period</u> , not symptoms you normally have. At bottom of page, “If you answered Yes to any stomach problems or cold and flu symptoms in section 7 or section 8, please go to section 9, Illness Details on the next page. If no one in your household had any stomach problems, cold or flu symptoms, please skip to section 10.	Change “Section 8 Colds and Flu” to “Section 9 Other Recent Illnesses or Symptoms “; change “3-week” to “2-week”; change “cold or flu” to “illnesses or”; remove instructions at bottom of page
Survey	21. During the 3-week period, did anyone start having new cold or flu symptoms (not problems they normally have)? <ul style="list-style-type: none"> Cough; Runny nose; Muscle/body aches; Difficulty breathing; Did they have a fever (100°F or higher) at the same time as the cold or flu symptoms? 	Change “3-week” to “2-week”; delete “cold or flu”; Add answer option “Sore throat”, change “Runny nose” to “Runny or stuffy nose”, remove “Muscle/body aches”, change “Difficulty breathing” to “Shortness of breath”, Add answer options “Rash”, “Eye infection (for example, pink eye)”, “Ear infection”, change fever answer option to “Fever (100°F or higher) at the same time as these symptoms?”
Survey	22. How many days did the cold/flu symptoms last?	Change to: How many days of school or work did each person miss because of these symptoms?
Survey	23. When did the cold/flu symptoms start (MM/DD/YY).If you are unsure of the exact date, please give your best guess.	Change to: Was anyone admitted to the hospital for at least one day as a result of these symptoms?

Title: Epidemiologic Study of Health Effects Associated with Low Pressure Events in Drinking Water Distribution Systems

OMB Control Number: 0920-0960

Expiration Date: 03/31/2016

Survey	30. Is each person of Hispanic or Latino ethnicity? (Please answer for yourself and Persons 2-6)	Delete (Please answer for yourself and Persons 2-6)
Survey	31. What is each person's race? Mark one or more boxes. (Please answer for yourself and Persons 2-6). Check all that apply.	Delete (Please answer for yourself and Persons 2-6). Check all that apply.
LPE form	2. Date and time event reported: MM/DD/YY/HR:MIN AM or PM (Circle)	3. Response Planned; Emergency; 3a. When was emergency reported? Date ____ Time ____
LPE form	3. Date and time repair crew arrived on site: MM/DD/YY/HR:MIN AM or PM (Circle)	5. When did repair/maintenance crew arrive on site? Date ____ Time ____
LPE form	4. Date and time repair completed: MM/DD/YY/HR:MIN AM or PM (Circle)	6. When was repair/maintenance completed? Date ____ Time ____
LPE form	5. Location: (street, city, state)	8. Location of work site (address, cross streets, GPS coordinates)
LPE form	6. Cross streets:	Delete question
LPE form	7. GPA coordinates:	Delete question
LPE form	8. Main housing type: Single family homes; Apartments/condos; Mobile homes; Other/mixed (Describe)____	7. Main housing type in affected area Single family homes (detached); Duplexes/townhomes (attached); Apartments/condos; Mobile homes; Other _____
LPE form	9. Diameter of pipe:	9. Pipe diameter
LPE form	10. Age of the pipe:	10. Pipe age
LPE form	11. Depth of the pipe?	11. Pipe depth
LPE form	12. Describe soil (e.g., sand, clay, dirt, rock backfill):	13. Soil type (for example, sand, clay, rock backfill)
LPE form	13. Origin of water (Name of water storage facility, well, or plant):	15. Source water type Surface water; Groundwater; Mixed 16. Name of water storage facility, well, or plant serving area
LPE form	14. Pipe material (<i>check one</i>):	Remove "check one"
LPE form	15. Interior condition (1-Smooth-> 5 Highly tuberculated): 1 2 3 4 5 Comments on condition of pipe:	14. Pipe interior; 14a. Tuberculation 1 (smooth) 2 3 4 5 (highly tuberculated); 14b. Describe sediment or biofilm
LPE form	16. What type of event occurred? Planned main repair; Main break; Pump station outage; Other maintenance activity (<i>Describe</i> __)	4. Event type Main break (answer 4a and 4b); Planned repair; Supply disruption (describe below) ; Other____
LPE form	17. Describe the reason for the causes of low pressure: (<i>check all that apply</i>): Water Hammer (Surge); Defective Pipe; Deterioration; Corrosion; Excessive Operating Pressure; Temp. Change; Differential Settlement; Contractor Main break; Contractor Valve Shutoff; Pumping Changes; Accident; Other (<i>Describe</i> :__)	4b. What factors contributed to the break? (mark all that apply) Change "Defective Pipe" to "Defective part", "Temp. Change" to "Temperature change". Change "Accident" to "Vehicle accident". Remove "Contractor Valve Shutoff"
LPE form	18. If main break, please describe the nature of the break: Circumferential; Longitudinal; Both circumferential and longitudinal; Blowout; Joint; Sleeve; Split at Corporation; Other (<i>Describe</i> :__)	4a. What type of break? Add (mark all that apply) Remove "Both circumferential and longitudinal"
LPE form	19. Number of households affected by break/repair:	29. Number of households that experienced low pressure. Add follow-up "Duration of low pressure ____ hrs. ____ min."
LPE form	20. Was there a loss of household water service? Yes; No 20a. Num. of households lost service: 20b. Date/time of lost service: ; 20c. Date/time service restored:	Change 20b & 20c to "30b. Duration of lost service ____ hrs. ____ min."
LPE form	21. Were service branches turned off? Yes; No 21a. Num. of residential units out of service: 21b. Date/time turned off: ; 21c. Date/time restored:	Change 21 to "31. Was service to homes turned off? Add follow up Main lines closed? Service branches to homes closed? Change 21b & 21c to "31b. Duration of shutoff ____ hrs. ____ min."
LPE form	22. Pressure reading during and after event: (grid format) (Rows): Hose Bib Location Nearest connection to break/repair Upstream Downstream	Before grid question, add: 17. How was low pressure verified? Pressure readings; Verified at hose bibs (ground-level); Customer complaint; Assumed (describe why____) 18. Pressure readings (grid format)

Title: Epidemiologic Study of Health Effects Associated with Low Pressure Events in Drinking Water Distribution Systems

OMB Control Number: 0920-0960

Expiration Date: 03/31/2016

	(Columns): Approximate distance (in yards), Pressure during event (PSI), Date (MM/DD/YY), Time (HH:MM AM or PM), Pressure after cleanup of break/repair (PSI), Date (MM/DD/YY), Time (HH:MM AM or PM),	(Rows): Change "Hose Bib Location" to "Suggested reading locations", "Nearest connection to break/repair" to "Near break/repair" (Columns): Change "Approximate distance (in yards)" to "Location of reading (cross-streets, address, GPs coordinates)", "Pressure after cleanup of break/repair (PSI)" to "Pressure after cleanup (PSI)" Change "Date (MM/DD/YY), Time (HH:MM AM or PM)" to "Date and time"
LPE form	24. Was the pipe ever submerged in trench water while repairs were being made? Yes; No 24a. What type of water was it? (e.g., rain, sewage, groundwater):	Delete "while repairs were being made"; Change follow up question to: "Describe water (rain, sewage, leakage from system)"
LPE form	26. Are sewage or reclaimed water lines adjacent or in close proximity to the main being repaired? If yes, please specify the approximate distance (in feet) that separates the water main and the sewage or reclaimed water line: (grid format) Sewage line present []; Horiz. Dist. ____ Feet; Vert. Dist ____ Feet; Breaks, breaches, or leaks in line? Yes; No Reclaimed Water line present []; Horiz. Dist. ____ Feet; Vert. Dist ____ Feet; Breaks, breaches, or leaks in line? Yes; No	24. Were any sewage lines near the main being repaired? No; Yes -> 24a. Describe location, breaches, leaks _____ 25. Were any reclaimed water lines near the main being repaired? No; Yes -> 25a. Describe location, breaches, leaks _____
LPE form	29. Was the main chlorinated before being brought back into service?	Add Chlorination method and dose? (slug dose, swabbing, 100 mg/L, 25 mg/L)
LPE form	30. Was a boil-water advisory (BWA) or notice administered as a result of this event? Yes; No 30a. When was BWA issued? MM/DD/YR time: HR:MIN AM or PM (Circle) 30b. When was BWA lifted? MM/DD/YR time: HR:MIN AM or PM (Circle) 30c. How was the BWA communicated to the public? Television; Radio; Phone calls; Door hanger/leaflet; E-mail; Other (describe)	Delete questions 30a-30c.
LPE form	32. What is your assessment of the potential for contamination? Low, Moderate, High. Please elaborate on why you selected low, moderate, or high:	33. Based on your observations, do you think there was any potential for contamination? Yes, No, Unsure. 33a. Please explain why you selected yes, no, or unsure:
LPE form	34. Do you have any other comments about the low pressure event or extent of BWA?	Delete "or extent of BWA"
LPE form	n/a	Add 19. Was the repair site valved off? No; Completely valved off; Partially valved off
LPE form	n/a	Add 20. What repair or maintenance activities occurred? (mark all that apply) Repair existing main; Replace existing main; Add new pipes to distribution system; Fix cross-connection; Exercise valves; Flush hydrant; Cut open main for reasons other than pipe work (describe); Other (describe)
LPE form	n/a	Add 2. Briefly describe what happened during the event
Utility customer information	Affected Utility Customer Information: No., Last Name, First Name, Street Address, City, State, Zip, Reclaimed Water Service (Yes, No) Unaffected Utility Customer Information: No., Last Name, First Name, Street Address, City, State, Zip, Reclaimed Water Service (Yes, No)	Add template for event hydraulic map. Remove "Unaffected Utility Customer Information" section and have utility put all customer addresses on the same list. Add "Area" variable to distinguish between exposed/unexposed areas. Replace fields for "No." and "Reclaimed Water Service" with "Phone" and "E-mail" contact fields. Add fields for the premise address.