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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-0960]

[Docket No. CDC-2015-0073]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on Epidemiologic Study of Health Effects Associated With Low Pressure Events in Drinking Water Distribution Systems.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0073 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e)

estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Epidemiologic Study of Health Effects Associated With Low Pressure Events in Drinking Water Distribution Systems (OMB Control Number 0920-0960, Expiration 3/31/2016) – Extension – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In the United States (U.S.), drinking water distribution systems are designed to deliver safe, pressurized drinking water

to our homes, hospitals, schools and businesses. However, the water distribution infrastructure is 50–100 years old in much of the U.S. and an estimated 240,000 water main breaks occur each year. Failures in the distribution system such as water main breaks, cross-connections, back-flow, and pressure fluctuations can result in potential intrusion of microbes and other contaminants that can cause health effects, including acute gastrointestinal and respiratory illness.

Approximately 200 million cases of acute gastrointestinal illness occur in the U.S. each year, but we lack reliable data to assess how many of these cases are associated with drinking water. Further, data are even more limited on the human health risks associated with exposure to drinking water during and after the occurrence of low pressure events (such as water main breaks) in drinking water distribution systems. A study conducted in Norway from 2003–2004 found that people exposed to low pressure events in the water distribution system had a higher risk for gastrointestinal illness. A similar study is needed in the United States.

The purpose of this data collection is to conduct an epidemiologic study in the U.S. to assess whether individuals exposed to low pressure events in the water distribution system are at an increased risk for acute gastrointestinal or respiratory illness. 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 inform the Environmental Protection Agency (EPA), CDC, and other drinking water stakeholders of the potential health risks associated with low pressure events in drinking water distribution systems and whether additional measures (e.g., new standards, additional research, or policy development) are needed to reduce the risk for health effects associated with low pressure events in the drinking water distribution system.

We will conduct a cohort study among households that receive water from six water utilities across the U.S. The water systems will be geographically diverse and will include both chlorinated and chloraminated systems. These water utilities will provide information about low pressure events that occur during the study period using a standardized form (approximately 11 events per utility). Utilities will provide address listings of households in areas exposed to the low pressure event and comparable households in an unexposed area to CDC staff, who will randomly select participants and send them an introductory letter and questionnaire. Consenting household respondents will be asked about symptoms and duration of any recent gastrointestinal or respiratory illness, tap water consumption, and other exposures including international travel,

daycare attendance or employment, animal contacts, and recreational water exposures. Study participants may choose between two methods of survey response: A mail-in paper survey and a web-based survey.

Participation in this study will be voluntary. No financial compensation will be provided to study participants. The study duration is anticipated to last 30 months. An estimated 6,750 individuals will be contacted and we anticipate 4,050 utility customers (18 years of age or older) will consent to participate in this study. The total estimated annualized hours associated with this study is expected to be 548.

There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Households	Paper-based questionnaire	1,215	1	12/60	243
Households	Web-based questionnaire	810	1	12/60	162
Utility employees	Household listing	6	5	3	90
Utility employees	Water sample collection (grab samples)	6	3	130/60	39
Utility employees	Water sample collection (ultrafiltration samples)	6	2	30/60	6

Utility employees	Low pressure event form	6	5	15/60	8
Total					548

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Leroy A. Richardson
Chief, Information Collection Review Office
Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

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