Supporting Statement of the Request for

OMB Review and Approval of

Assessment of Potential Exposure from Private Wells for Drinking Water

OMB Control No. 0920-NEW

Generic Clearance

(Part A: Justification)

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PART A. JUSTIFICATION

Goal: The goal of this generic clearance information collection request (Generic ICR) is to expedite investigations to assess private well water for drinking in response to specific investigation requests. Each investigation will assess exposure to contaminants in drinking water from private wells in a geographic area specified by the requesting entity. Requesting entities may be any state, territorial, local, or tribal health department in the United States.

Intended use of the resulting data: The data will be used to support local public health action to improve the quality of water from private wells.

Methods to be used to collect data: The methods used to collect data may include but are not limited to face-to-face interviews, telephone interviews, secure on-line questionnaires, and respondent-administered pen-and-paper questionnaires that are either mailed or delivered in-person. Additional data include results from analysis of clinical specimens and/or environmental samples.

The subpopulation to be studied: Adults at least 18 years of age, who use private wells for drinking water, who are willing to receive and return a tap water sampling kit and urine specimen kit or to provide a blood specimen, and who are willing to answer survey questions. They will be enrolled from the geographic area of concern as defined by the requesting entity.

How data will be analyzed: Results will be compared with those from existing surveys (e.g., National Health and Nutrition Examination Survey [NHANES], Behavioral Risk Factors Surveillance System [BRFSS]), EPA's drinking water standards, and historical environmental sampling where data exist.

The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention, requests a three-year Paperwork Reduction Act (PRA) clearance for a new generic clearance information collection request (Generic ICR) titled "Assessment of Potential Exposure Associated with Private Wells for Drinking Water." NCEH is authorized to collect this information under the Public Health Service Act Section 301 (241) (Attachment A). The 60-day Federal Register Notice was published on March 11, 2016 and is further discussed in Section A8 (Attachment B).

1. Circumstances Making the Collection of Information Necessary

The Safe Drinking Water Act of 1974 (SDWA) ensures that most Americans are provided access to water that meets specific public health standards.[1] However, for over 38 million Americans who rely on private wells or other drinking water not protected by the SDWA (herein referred to as private wells), that is not the case.[2] There is no comprehensive knowledge about the locations of private wells, the populations served by these sources, potential contaminants (e.g., heavy metals) that might be present in private well water in specific areas of the country, or the potential health risks associated with drinking water from these sources. Data from the investigations done under this Generic ICR are designed to support state and local jurisdictions

interest in characterizing drinking water from private wells in specific regions of the country and to assess potential exposure from drinking water contaminants in private wells in the area of investigation.

To assess private wells for drinking water, a comprehensive approach that includes exposure data is needed. The quality of private well water is determined by local characteristics, such as aquifer characteristics, including hydrogeochemistry (i.e., the chemical interactions between water and surrounding rocks and soils); local land use; precipitation; the quality of ground water recharge; and well characteristics.

For an investigation to occur under this Generic ICR, the following criteria must be met:

1. Investigations will be undertaken at the request of and in collaboration with state, territorial, local, or tribal health departments (STLTs) (the requesting agency) interested in characterizing exposure to drinking water contaminants in private wells. A letter or memo detailing this explicit request will be included with al substudies submitted under this generic pathway.

2. Investigations will be non-research responses designed to inform the public health decisions of the requesting agency's jurisdiction. Thus, investigations are not designed to produce outcomes that are generalizable to broader populations who utilize well water for drinking.

3. Results from investigations will be used to improve the requesting agency's public health activities.

4. Investigations will be restricted to domestic concerns in a geographic area specified by the requesting agency.

5. A full protocol will be developed prior to submitting a generic information collection (GenIC), as these investigations are not governed by emergencies.

6. A full Supporting Statement Part A and Part B, and necessary attachments, will be included with each GenIC submitted under this Generic ICR.

2. Purpose and Use of the Information Collection

The purpose of this Generic ICR is to respond to state and local areas that request assistance with assessing potential exposure to contaminants in drinking water from private wells in their jurisdiction. The new information obtained from these investigations will be the description of exposure to contaminants in drinking water from private wells within a well-defined time period and, in some cases, geographic distribution. This information will be used by the requesting agency to inform whether there is a need for public health intervention activities to reduce exposures.

An example of a prior study conducted by CDC that has yielded information used to reduce exposures include the following:

- NCEH provided technical assistance (OMB approval was not needed) to assess the health risks associated with drinking water from various sources used by the Navajo Nation (2007-2011). The investigation identified contaminants, including uranium, in these drinking water sources. Based on this information, the Navajo Nation Environmental Protection Agency (NNEPA) and Navajo Nation Division of Health (NNDOH) collaborated to develop a consumer awareness campaign to help people understand sources of drinking water contamination, learn where to get safe drinking water, and learn how to protect the quality of water stored at home.

Having a generic mechanism in place will facilitate a faster processing and clearance of information collection approvals requested by NCEH and partners.

3. Use of Improved Information Technology and Burden Reduction

Whenever possible, NCEH staff will employ electronic technology (e.g., computer-assisted personal and phone questionnaires, web-based questionnaires) to collect and process data to reduce respondent burden and aid in data processing and reporting efficiency. Particular emphasis will be placed on compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII.

Each submission of a proposed GenIC will include the data collection instruments, including questionnaires and screenshots of web-based questionnaires. The number of questions posed will be held to the minimum required in all information collections to elicit the necessary data.

4. Efforts to Identify Duplication and Use of Similar Information

Investigations conducted under this Generic ICR will be designed in collaboration with other CDC programs and other federal agencies, as well as STLTs so that redundant data collection is avoided and the utility of the data collected are maximized. As part of the planning process for each investigation, NCEH will identify whether there are existing data on environmental monitoring, exposure, and health risks.

Other federal entities, such as the U.S. Geological Survey (USGS) conduct some private well sampling and we will review such data sources for information about testing results so as not to duplicate well testing during our studies. If USGS (or other entity) has relevant data, we will use that data in the appropriate GenICs.

Table 4.1 provides a comparison of OMB-approved Generic ICRs and the Generic ICR proposed here. The purpose of this table is to demonstrate that the proposed Generic ICR does not overlap with currently approved Generic ICRs.

Table 4.1 Comparison of OMB approved Generic ICRs and the proposed Generic ICR.

Name of Generic ICR	Purpose of data collection	Environmental data collected	Biological data collected	Health symptoms data collected	Time frame for data collection
ATSDR Exposure Investigations (EI) (0923-0048)	To find out whether people have been, are being, or may be exposed to hazardous substances and, if so whether that exposure is harmful, or potentially harmful, and should therefore be stopped or reduced. The process also serves as a mechanism through which the agency responds to specific community health concerns related to hazardous waste sites.	Environmental sampling may include ambient air, personal air, indoor air, dust, soil, sediment, biota including food sources, ground water, tap water and surface water sampling. Depending on individual site characteristics, the sampling period may vary from days to several months.	Biological sampling may include, but is not limited to, blood and urine sampling for exposure biomarkers.	Relevant self-reported health symptoms and medical information potentially related to site-specific exposures may be assessed. Data on symptoms and illnesses are limited to underlying conditions that may make people more sensitive to chemical exposures.	Most EIs sampling events are done in rapid response to a particular event, are completed over a period of days to months, and are a one-time occurrence
ATSDR Assessment of Chemical Exposure (ACE) Investigations (0923-0051)	To conduct rapid assessments after a toxic release incident has occurred, in partnership with the requesting agency. ATSDR will provide tools, technical expertise, laboratory support, and personnel support to the health departments. When existing data sources fail to provide enough information for the implementation of effective response, and to strengthen prevention efforts for such incidents, new data must be collected.	NA	Clinical samples, either blood or urine, may be collected to test for the chemical(s) or metabolites of interest. The laboratory testing may be performed at a state facility or the laboratory at the CDC's National Center for Environmental Health (NCEH). ATSDR will not store clinical samples for future research; any unused samples will be discarded at the completion of the testing.	Questions referring to self-reported symptoms will be limited to those deemed by ATSDR toxicology staff to have reference in the literature as being related, plus one unrelated symptom to test reliability. Medical chart abstraction to collect patient information. If data about potential exposure to pets is needed to supplement human data, veterinary chart	ACE investigations will be conducted in the days or weeks following an acute chemical release with the intent to gather data to inform the public health response and identify areas of the response that could be improved in future mass casualty chemical incidents in the jurisdiction. This ICR is for a rapid assessment of potential exposure and the health status of persons in the area of acute chemical releases and a review of the response to the incident; it is not designed to be a study of the health effects associated with the release of chemicals or to produce generalizable information (ATSDR will not have before

Name of Generic ICR	Purpose of data collection	Environmental data collected	Biological data collected	Health symptoms data collected	Time frame for data collection
				abstractions may also be performed.	and after health status data).
CDC's Emergency Epidemic Investigations (EEIs) (0920-1011)	To allow CDC to have the quick turn-around necessary for conducting Emergency Epidemic Investigations (EEIs) in response to acute public health emergencies resulting from outbreaks or events with undetermined agents, undetermined sources, undetermined modes of transmission, or undetermined risk factors.	Data collected will be determined by the specific EEI will include all information needed to characterize undetermined agents (e.g., a microorganism or chemical substance), undetermined sources (e.g., person, animal, object, or substance), undetermined modes of transmission (e.g., direct contact, vector, vehicle, airborne, droplet), or undetermined risk factors (e.g., behavior, genetic characteristic, environmental exposure).			Most EEIs involve 2 to 3 weeks of data collection. Data collection for investigations conducted under this new generic will not exceed 90 days.
Assessment of Private Wells for Drinking Water (Proposed)	To expedite investigations to assess the health risks from using private well water for drinking. Investigations will focus on exposure to contaminants in drinking water from private wells across varied geographic areas of the United States. Unlike emergency generic clearances, there is usually no emergency triggering an event. Rather, states or other public health partners may ask for assistance when they become aware of a contaminated water source (e.g. arsenic in ground water) and need to characterize the problem to inform whether to take public health action.	Environmental sampling may include well water and tap water and surface water sampling.	Biological sampling maybe included, but analyses will be limited to exposure assessment purposes. Assessment of biomarkers of health effect are not included in the scope of this clearance.	No health information collection is authorized.	Investigations will be done to assess exposure to contaminants in drinking water from private wells.

5. Impact on Small Businesses and Other Small Entities

No small businesses will be involved in these information collections.

6. Consequences of Collecting the Information Less Frequently

Each investigation under this Generic ICR will be a one-time GenIC.

There are no legal obstacles to reduce the burden.

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

The data collections will fully comply with the guidelines of 5 CFR 1320.5.

Information about the Generic ICR and instructions on how to submit a GenIC will be maintained and used by the NCEH program (Attachment C - Instructions for Using the Generic ICR). The NCEH program will submit the following package ***for each GenIC***: a GenIC Request Form (Attachment D), a full Supporting Statement A and B, the letter of STLT invitation, a research determination, and the data collection forms (Attachments F-J – Example Forms).

The clearance process for each GenIC will include review and routing of each package through the NCEH/ATSDR PRA Contact, the CDC Information Collection Request Office (ICRO), Department of Health and Human Services (DHHS), and then to OMB.

The NCEH program will maintain a library of data collection forms created for the individual GenIC investigations that may be accessed by NCEH programs and their collaborators when initiating new investigations.

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

A 60-day Federal Register Notice was published on March 11, 2016 (Attachment B). Four public comments were received in response to the Federal Register Notice during the public comment period. One public request for documents was received. The public comments and the agency's responses are provided in Attachment B1.

Below is a list of individuals and groups outside of the agency who were consulted between 2010 and 2015 to obtain their views on the availability of data, and the clarity of instructions and information,

Private Well Community of Practice (2014-2015)
E-mail distribution list of interested public health practitioners and others.

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Johns Hopkins Expert Panel
Future and Emerging Issues for Private Wells: Strategic Planning Workshop
January 15, 2015
Baltimore, MD

Participants:

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9. Explanation of Any Payment or Gift to Respondents

For most investigations conducted under this Generic ICR, participation will be requested on a voluntary, non-remunerated basis.

We may offer tokens of appreciation if the requesting agency recommends that we do so. The requesting agency will need to provide strong justification and evidence from previous experience or the scientific literature which demonstrates the need for tokens of appreciation. This justification will be submitted with any GenICs that entail such tokens of appreciation.

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

The NCEH/ATSDR Information Systems Security Officer (ISSO) conducted the IT security review and found that a full privacy impact assessment is not required (see Attachment E – Privacy Impact Assessment). From the PIA review form:

Information Systems Security Officer Recommendations: No Privacy Impact Assessment (PIA) required. Please contact the NCEH/ATSDR ISSO if any CDC system is created that will store, transmit, or process information described in this ICR.

The NCEH/ATSDR PRA Contact has reviewed this Generic ICR and has determined that the Privacy Act applies to this information collection. The applicable System of Records Notice is SORN No. 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems" (Federal Register: December 31, 1992; Volume 57, Number 252; pages 62812-62813) (records retrievable by name and ID number). Information in identifiable form (IIF) will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

The following categories of IIF may be collected: name, age, mailing address, phone numbers, biological specimens, latitude and longitude of the respondent's private well. This information will be stored in electronic form by the requesting entity. A subset of the data without identifiers may be provided to NCEH for assistance with statistical analyses.

IIF will be collected from the respondents only when essential to support objectives of the investigation (e.g., to facilitate scheduling interviews or provide test results). Respondents will be assigned an ID number to serve as a link between their identity and their response data or their specimens. All records, including IIF, belong to the requesting agency and will reside on its own established record system. The requesting agency will retain the data according to its own record schedule.

During the investigation and on behalf of the requesting agency, NCEH will have access to the link between the respondent's IIF and the respondent ID number. Once the investigation ends, NCEH will not have access to IIF with the exception of private well latitude and longitude, which are needed to create a visual presentation of water sample test results.

Respondents will be recruited using a letter or flyer (Attachment F – Example Recruiting Letter/Flyer). Prior to administering a questionnaire to potential respondents, a screening form will be used to screen potential respondents for interest and eligibility (Attachment G – Example Screening Form). Consent to participate in the investigation will be obtained using a paper or electronic consent form (Attachment H – Example Consent Form), which the respondent will read and sign. The consent forms will provide the following information: purpose of the data collection, list of activities for respondents, description of risks, data/information disclosure possibilities, description of benefits, compensation, treatment for injury, contacts for questions, and a statement about voluntary participation, refusal, and withdrawal.

For each investigation, we expect to construct a questionnaire with approximately 45 questions that fall under six categories (see Attachment I - Example Questionnaire). Table 9.1 below summarizes the breakdown of questions.

Table 9.1. Overview of questions types used for data collection

Question Type	# of Questions Used
Identifying information, listed above	10
Socio-demographics	7
Household water source(s)	6

Household water use	6
Environmental exposures not related to drinking water from private wells (confounders)	7
Perceptions and practices that might affect an individual's exposure level	9

Most questions are yes/no responses or multiple choice. Twenty-four questions are not multiple choice (e.g., name, age, sex, race, ethnicity, household income, mailing address, phone numbers, biological specimens, latitude and longitude of private wells).

We will provide respondents with instructions for collecting household tap water samples and urine specimens (Attachment J – Example Urine Specimen and Tap Water Collection). Clinical specimens (e.g., blood or urine) or environmental samples (e.g., well water), will be collected to test for the chemical(s) or metabolites of interest. The laboratory testing may be performed at a state facility, contract laboratory, or the NCEH laboratory at the CDC. All records and specimens will be coded with respondent ID number only. The laboratories will not store clinical specimens or environmental samples for future research; any unused samples will be discarded at the completion of the testing.

After the investigation team completes its field data collection, the requesting agency will have the discretion to share de-identified data labeled only with respondent ID with NCEH for continued support with statistical analysis and report writing. Findings of the investigation will include summary data only and may be reported as state or local agency reports; *Morbidity and Mortality Weekly Report* or journal articles; media reports; or presentations to the community, responders, and to public health practitioners at local, regional, and national conferences.

All de-identified records maintained by NCEH after the investigation will be subject to the CDC Records Control Schedule (CRCS) which contains authorized disposition instructions for administrative and program records. NCEH is legally required to maintain its program-related records in accordance with CRCS disposition instructions. For example, research records (datasets, field records, and other information necessary to understand a research project) may have implications or usefulness for future scientific investigations. These records must be maintained for at least eleven years, but no longer than twenty years, depending upon program need for scientific, legal, or business reference. Transfer to Federal Records Center is authorized in accordance with Code of Federal Regulations storage regulations of electronic records.

These retention periods have a direct impact on completing Freedom of Information Act requests.

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

The Federal Regulations for Protection of Human Subjects (45 CFR 46) state that "research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

NCEH investigations will be undertaken to identify, characterize, and solve a public health problem and the knowledge gained will directly benefit the affected community. These investigations will not be designed to develop or contribute to generalizable knowledge and will not be research investigations. Human subjects review by an Institutional Review Board (IRB) will not be required.

The NCEH/ATSDR research determination for the overall scope of this Generic ICR is attached (Attachment K). An investigation-specific research determination will be included in each GenIC submission.

Some of the NCEH investigation respondents may find some of the questions asked during an investigation to be sensitive, such as medical conditions, pregnancy status, or race/ethnicity. The responses to these questions, if asked, are needed to assess health risks from drinking water provided by private wells.

Social security numbers will not be needed and will not be collected.

12. Estimates of Annualized Burden Hours and Costs

NCEH estimates the total number of investigations per year to be no more than 10. Each investigation will collect information in one or more limited geographic locations targeting private well owners, as defined by the requesting entity.

The estimated burden to respondents is summarized in Table 12.1 below. Our technical assistance activities with the Navajo Nation involved between 200 and 300 respondents, and this was sufficient to support development of public health education materials about drinking water quality. Thus, we plan to recruit on average about 200 respondents for each investigation covered under this Generic ICR. The estimated annual number of respondents (n=2,000) has been calculated based on the following assumptions: a) 250 respondents per investigation must be screened to yield 200 respondents; b) 10 investigations per year. The total annualized time burden to respondents is estimated at 2,084 hours.

Table 12.1: Estimated Annualized Burden to Respondents

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Adults at least 18 years old using a private well for tap water	Screening Form	2,500	1	6/60	250
	Questionnaire	2,000	1	35/60	1,167
	Urine Specimen and Tap Water Sample Collection	2,000	1	20/60	667
TOTAL					2,084

There are no costs to respondents except their time to participate in the investigation activities.

Table 12.2 presents the calculations for the cost of respondents' time using the general public's mean hourly wages. Hourly mean wage information is from the U.S. Department of Labor's Bureau of Labor Statistics website, using the 2014 National Occupational Employment and Wage Estimates for the United States. Since this data collection would include respondents from the general public, an average rate for all occupations, or $22.71 per hour, is used. The total

estimated annualized respondent cost (including the screening form) is $47,329. The total respondent costs are summarized in Table 12.2 below.

Table 12.2: Estimated Annualized Burden Costs

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Adults at least 18 years old using a private well for tap water	Screening Form	2,500	1	6/60	250	$22.71	$ 5,678
	Questionnaire	2,000	1	35/60	1,167	$22.71	$26,503
	Urine Specimen and Tap Water Sample Collection	2,000	1	20/60	667	$22.71	$15,148
TOTAL							$47,329

*Public wages from http://www.bls.gov/oes/current/oes_nat.htm#00-0

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

There is no other total annual cost burden to respondents or record keepers.

14. Annualized Cost to the Federal Government

The estimated average annual cost to the federal government for the proposed information collection activities is $441,200. This figure encompasses 40% FTE of one GS-14 employee, 50% FTE of 4 GS-13 employees, and information collection contract costs. The average hourly rate was obtained from the Office of Personnel Management's website (http://www.opm.gov/oca/09tables/html/atl_h.asp). The annual rates for a GS-14 and GS-13 in Atlanta, GA are about $113,000 and $98,000, respectively, per year. The contractual cost for an information collection with partners (e.g., the development of a screen and questionnaire, participant recruitment, tokens of appreciation (when applicable), facility rental (when applicable), and final reports is estimated at $200,000. Please see Table 14.1 for details.

Table 14.1: Estimated Annualized Cost to the Government per Activity and Total

Cost Category	Estimated Annualized Cost
Federal employee costs for information collection (40% FTE of 1 GS-14 at $113,000/year plus 50% FTE of 4 GS-13 at 98,000/year)	$241,200
Contractual costs for an information collection: a) Questionnaires (e.g., questionnaire adaptation and translation, Questionnaire administrator training, field work (including travel expenses), data analysis, final report) b) Environmental sample or clinical specimen collection and analysis	$200,000
Total cost per year	$441,200

15. Explanation for Program Changes or Adjustments

This is a new request for a generic clearance.

16. Plans for Tabulation and Publication and Project Time Schedule

The project time schedule for each investigation is found in Table 16.1 below.

Table 16.1 Project Time Schedule

Activity	Time Schedule
Letters sent to respondents	1 month after OMB approval
Information/Data collection	3-8 months after OMB approval
Complete field work	8-9 months after OMB approval
Validation	10-12 months after OMB approval
Analyses	12-18 months after OMB approval
Publication	18-24 months after OMB approval

For each investigation, the lead investigator at NCEH will collaborate with the requesting agency to develop an analysis plan and conduct the data analysis. Preliminary findings are generally provided to the requesting agency at the end of the field investigation. A preliminary report summarizing the early findings of the investigation is written by the lead NCEH investigator in collaboration with the requesting agency and provided to CDC. Any publication of data derived from an investigation is subject to review by the requesting agency, NCEH, CDC, and other collaborating federal agencies.

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

The display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

REFERENCES

1. SDWA. (1974). The Safe Drinking Water Act of 1974. Public Law 93-523. December 16, 1974.

2. National Ground Water Association. 2015. Ground water use in the United States of America. Available online http://www.ngwa.org/fundamentals/use/documents/usfactsheet.pdf (accessed 28 Aug 2015). Calculated by using the 2014 nonmetropolitan average household size multiplied by the number of occupied households using water wells in the American Housing Survey for 2013. This estimate is derived from the most recent population and household data, and is recommended for use by CDC in future documents.