

Exposure to Arsenic and Uranium in Private Well Water in Connecticut, New Mexico, and New Hampshire

Assessment of Potential Exposure from Private Wells for Drinking Water Generic Information Collection Request

OMB Control No. 0920-1173

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Supporting Statement Part A

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Table of Contents

A.	Justification.....	3
A.1.	Circumstances Making the Collection of Information Necessary.....	3
A.2.	Purpose and Use of Information Collection.....	4
A.3.	Use of Improved Information Technology and Burden Reduction.....	4
A.4.	Efforts to Identify Duplication and Use of Similar Information.....	5
A.5.	Impact on Small Businesses or Other Small Entities.....	5
A.6.	Consequences of Collecting the Information Less Frequently.....	5
A.7.	Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	5
A.8.	Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	5
A.9.	Explanation of Any Payment or Gift to Respondents.....	5
A.10.	Protection of the Privacy and Confidentiality of Information Provided by Respondents..	5
A.11.	Institutional Review Board (IRB) and Justification for Sensitive Questions.....	7
A.12.	Estimates of Annualized Burden Hours and Costs.....	8
A.13.	Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers.....	9
A.14.	Annualized Cost to the Federal Government.....	9
A.15.	Explanation for Program Changes or Adjustments.....	10
A.16.	Plans for Tabulation and Publication and Project Time Schedule.....	10
A.17.	Reason(s) Display of OMB Expiration Date is Inappropriate.....	10
A.18.	Exceptions to Certification for Paperwork Reduction Act Submissions.....	11
	REFERENCES.....	12

Goal of the study: This investigation will assess exposure to arsenic and uranium in drinking water from private wells in a number of geographic areas specified in requests from three states—Connecticut, New Mexico, and New Hampshire.

Intended use of the resulting data: The data will inform the state health departments as to whether there is a need for public health intervention activities to reduce exposures, and will 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 include telephone interviews to determine eligibility, and face-to-face interviews. Data collection will also involve collection of urine samples from residents and private well water samples to assess arsenic and uranium levels.

The subpopulation to be studied: The subpopulation to be studied comprises adults at least 18 years of age who meet the following criteria: 1) use private wells for drinking water, 2) will allow us to collect water samples from their well and tap, 3) will provide a urine specimen, and 4) agree to answer survey questions. Participants will be enrolled from the geographic area of concern as defined by the requesting agency, specifically: n=100 in Connecticut, n=100 in New Mexico, and n=100 in New Hampshire.

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 urine samples will be analyzed by the CDC National Center for Environmental Health (NCEH), Division of Laboratory Science (DLS).

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

This is a request for OMB PRA review and re-approval of the GenIC titled, “Exposure to Arsenic and Uranium in Private Well Water in Connecticut, New Mexico, and Vermont”, OMB Control No. 0920-1173, Expiration Date 3/31/2020. The states involved have changed, and the new title is “Exposure to Arsenic and Uranium in Private Well Water in Connecticut, New Mexico, and New Hampshire.” The applicable generic clearance is titled, “Assessment of Potential Exposure from Private Wells for Drinking Water” (OMB Control No 0920-1173, Expiration Date: 01/31/2024).

The National Center for Environmental Health (NCEH) is authorized to collect this information under section 301 of the Public Health Service Act: Research and Investigation, 42 U.S.C. § 241.

The Centers for Disease Control and Prevention (CDC) recently supported a study that estimated the total damages of arsenic in private wells to be \$9.4 billion dollars annually, half attributed to

Exposure to Arsenic and Uranium in Private Well Water in Connecticut, New Mexico, and New Hampshire: Supporting Statement A

cancer and half to heart disease mortality (Abt 2014). The literature linking arsenic to adverse health effects is growing, and the work done by Abt (2014) was illustrative in nature. It is important to capture a more precise estimate of exposures in all areas of the United States that have arsenic in ground water. Uranium in drinking water is also of concern because the metal is highly toxic; however, the health effects have not been studied as extensively as those associated with arsenic. Uranium tends to co-occur with arsenic, so we will assess uranium exposure as well as arsenic exposure in areas where exposures haven't been characterized. Without knowing if private wells are at risk for contamination with arsenic and uranium, states are unable to reach out to households with public health protection efforts, such as information about exposures, filtration devices to limit exposure, etc.

CDC will respond to three states that have requested assistance with assessing potential exposure to arsenic and uranium in drinking water from private wells in areas (one area for each of the three states) where there are no data about arsenic and uranium concentrations in ground water. 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 geographic distribution. This information will be used by the requesting agency (Attachment A – Letters of Collaboration) to target public health intervention activities to reduce exposures.

A.2. Purpose and Use of Information Collection

The purpose of this one-time information collection is to respond to the requests for assistance received from Connecticut, New Mexico, and New Hampshire. The primary target audience is public health practitioners with responsibilities for private domestic wells in their jurisdictions. Our state partners (Connecticut, New Mexico, and New Hampshire) will use data generated by this investigation to geographically target existing and/or planned public health outreach, education, and intervention activities to reduce exposure to arsenic and/or uranium from private well water.

The subpopulation to be studied comprises adults at least 18 years of age, who use private wells for drinking water; will allow us to collect water samples from their well and tap; will collect a first morning void urine specimen; will complete a three-day food diary, and will agree to answer survey questions during an in-person interview. They will be enrolled from the geographic area of concern as defined by the requesting agency, specifically: n=100 in Connecticut, n=100 in New Mexico, and n=100 in New Hampshire. Participants will respond to a survey (see Table 10.1 for an overview of the question topics).

Without this information, states may miss opportunities to target populations at risk from exposure to arsenic and uranium with programs to reduce or eliminate exposures.

A.3. Use of Improved Information Technology and Burden Reduction

The United States Geological Survey (USGS) reports that they recruit about 30% to 50% of people who receive notification of an upcoming water quality study like this (personal

Exposure to Arsenic and Uranium in Private Well Water in Connecticut, New Mexico, and New Hampshire: Supporting Statement A

communication, Joe Ayotte, May 2018). Thus, we will send out letters and prepaid postcards to the randomly identified households in the 100 cells (approximately 200 – 300 households) identified in the relevant geographic area in each state to recruit one household per cell, for a total of 100 households per state. We will send letters and prepaid response cards to potential participants' homes. For those households that respond, we will interview one adult per household to confirm eligibility using a telephone screener, which will eliminate the need for potential participants to travel. We will use a laptop and survey software (Epi Info) to collect survey data. Epi Info employs skip logic to reduce participant burden.

We have added the statement below about COVID-19 precautions that is included in the invitation letter (Attachment B Invitation Letter Response Form), screening survey (Attachment C Screening Survey), and consent form (Attachment D Consent Form):

Please be assured that CDC will take all necessary steps to protect members of your community from COVID-19. The study will be conducted following all state, local, and CDC guidelines in place at the time the study is conducted. CDC team members will be monitored twice daily for fever and any COVID-19-related symptoms. Although we don't anticipate face-to-face contact with study participants, if this does occur (e.g., when a study team member picks up water samples and urine specimens), study team members will wear surgical masks and gloves to ensure the protection of participants. Again, although we do not anticipate face-to-face contact with study team members, if that occurs, participants will be asked to always wear a face covering or mask. If you do not have a mask, one will be provided to you. If you are unable to wear a mask for medical reasons, please let us know."

Additional precautions: The Survey (Attachment G Survey) will be conducted by phone rather than in-person, study participants will collect the water sample from the tap inside their home and leave that, along with their signed consent form, the food log, the home tap water sample, and urine specimen outside for the study team to pick up.

A.4. Efforts to Identify Duplication and Use of Similar Information

As part of the planning process for this investigation, NCEH found that there are no existing data, as determined using United States Geological Survey (USGS) databases, on arsenic and uranium in private wells in the areas defined by the three state requestors.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

A.6. Consequences of Collecting the Information Less Frequently

Exposure to Arsenic and Uranium in Private Well Water in Connecticut, New Mexico, and New Hampshire: Supporting Statement A

This investigation involves a one-time information collection. There are no legal obstacles to reduce the burden.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

This data collection is being conducted using the Generic Information Collection mechanism for Assessment of Potential Exposure from Private Wells for Drinking Water – OMB Control No. 0920-1173 (expiration date: 03/31/2020). A 60-day Federal Register Notice was published in the Federal Register, Vol. 84 No. 48931 on Tuesday, September 17, 2019. Five public comments were received.

A.9. Explanation of Any Payment or Gift to Respondents

NCEH will not offer any payment or gift to respondents.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by the NCEH Information Systems Security officer who determined that the Privacy Act does apply. 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 IIF will be available through state private well records: name, mailing address, phone numbers, and latitude and longitude of the respondent’s private well. This information will be stored in electronic form by the requesting entity and will be used to facilitate scheduling interviews and provide test result to respondents. Respondents will be assigned a unique ID number to serve as a link between their identity and their response data, samples, and specimen. 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. To make the data available to the public, de-identified data

Exposure to Arsenic and Uranium in Private Well Water in Connecticut, New Mexico, and New Hampshire: Supporting Statement A

will be made available on the USGS ScienceBase platform. The resolution will be at the town level.

Respondents will be recruited using a letter (Attachment B – Invitation Letter and Response Form). A telephone-based screening form will be used to screen potential respondents for interest and eligibility (Attachment C – Screening Survey). Consent to participate in the investigation will be obtained using a paper consent form (Attachment D – Consent Form), which the respondent will read and sign. The consent forms 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.

The Food Log has 28 check boxes to capture specific foods eaten during the three days before their interview with project staff (Attachment E – Food Log). The foods listed, e.g., rice crackers, are those most likely to be contaminated with arsenic or uranium. The instructions for collecting a first morning void urine specimen can be found in Attachment F – Urine Collection Directions and Water Collection Log. The survey consists of 44 questions that fall under three categories (Attachment G – Survey). Table 10.1 below summarizes the breakdown of questions. The questions about food consumption on the Food Log and survey were drawn from instruments used in an ongoing CDC-funded biomonitoring study in New Hampshire.

Table 10.1. Overview of question types used on the survey

Question Type for Food Diary	# of Questions Used
Check boxes for foods eaten each day	19
Check boxes for drinks drunk each day	9
Question Type for Survey	
Personal information (date of birth, height, weight, race)	9
Home and household water source	8
Other possible exposures to arsenic or uranium	27

Except for date of birth, height, weight, and questions where the respondent has to specify a place, or number (e.g., number of cups of water per day), the questions will have yes/no/don't know/refused responses.

Urine specimens and environmental samples (well water, tap water), will be collected to test for arsenic and uranium. Urine specimens will be tested by the Division of Laboratory Sciences laboratories at NCEH. Water samples will be tested by the laboratories at USGS. 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.

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. Study participants will be provided a copy of their test results (Attachment H – Participant Results Letter).

Exposure to Arsenic and Uranium in Private Well Water in Connecticut, New Mexico, and New Hampshire: Supporting Statement A

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. These study records are considered “Minor Records” and the Authorized Disposition is as follows: Maintain at least six years, but no longer than ten years, after the retirement of the system—depending upon program need for scientific, legal, or business reference—then delete/destroy.

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.

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

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.”

In contrast, this investigation will be undertaken to identify, characterize, and solve a public health problem and the knowledge gained will directly benefit the affected community. Although this investigation is intended to be a systematic investigation, it is not designed to develop or contribute to generalizable knowledge. Human subjects review by an Institutional Review Board (IRB) is not required. This investigation was reviewed the NCEH/ATSDR Human Subjects Coordinator (Attachment I – Research Determination Form).

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

Social security numbers are not needed nor will they be requested.

A.12. Estimates of Annualized Burden Hours and Costs

The estimated burden to respondents is summarized in Table 12.1 below. USGS reports that they recruit about 30% to 50% of people who receive notification of an upcoming water quality study like this (personal communication, Joe Ayotte, May 2018). Thus, we will send out letters and prepaid postcards to the identified households in the 100 cells (approximately 200 – 333 households) in each state to recruit one household per cell for a total of 100 households per state. This is equivalent to sending out approximately 600 to 1,000 letters to recruit a total of 300 participants for all three sites. We anticipate that 40% of households receiving notification of our study (n=375 out of approximately 938) will complete and return the response form (Attachment

Exposure to Arsenic and Uranium in Private Well Water in Connecticut, New Mexico, and New Hampshire: Supporting Statement A

B) and be screened for eligibility. We estimate that 80% of those who are screened will be eligible (n=300) (Attachment C). The study participants (household members) will participate in our study one time for approximately 90 minutes (including urine and water sample collection):

The total annualized time burden to respondents is estimated at 544 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	Invitation Letter and Response Form	375	1	5/60	31
	Screening Survey	375	1	30/60	188
	Food Log	300	3	5/60	75
	Urine Collection Directions and Water Collection Log	300	1	20/60	100
	Survey	300	1	30/60	150
TOTAL					544

Table 12.2 presents the total respondent costs using the mean hourly wage for the general public. Hourly mean wage information is from the U.S. Department of Labor's Bureau of Labor Statistics, using the 2019 National Occupational Employment and Wage Estimates for the United States (https://www.bls.gov/oes/current/oes_nat.htm#00-0000). Since this data collection will include respondents from the general public, an average rate for all occupations, or \$25.72 per hour, is used. The total estimated annualized respondent cost is \$13,985.25. 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	Invitation Letter and Response Form	375	1	5/60	31	\$25.72	\$803.75
	Screening Survey	375	1	30/60	188	\$25.72	\$4,822.50
	Food Log	300	3	5/60	75	\$25.72	\$1,929.00

Exposure to Arsenic and Uranium in Private Well Water in Connecticut, New Mexico, and New Hampshire: Supporting Statement A

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
	Urine Collection Directions and Water Collection Log	300	1	20/60	100	\$25.72	\$2,572.00
	Survey	300	1	30/60	150	\$25.72	\$3,858.00
TOTAL							\$13,985.25

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

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

There are no direct costs to the participants other than their time to participate in this investigation.

A.14. Annualized Cost to the Federal Government

The estimated average annual cost to the federal government for the proposed information collection activities is \$324,060. This figure encompasses 20% FTE of one GS-14 employee, 20% FTE of 4 GS-13 employees, and information collection contract costs (Interagency Agreement with USGS). The average hourly rate was obtained from the Office of Personnel Management’s website (<http://www.opm.gov/oca/09tables/html/atlh.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 screener and questionnaire, participant recruitment, and final reports) is estimated at \$152,010. 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 (60% FTE of 1 GS-14 at \$113,000/year, 60% FTE of 4 GS-13 at 98,000/yea,15% of GS-15 at 160,000/year, travel funds)	\$172,050
Contractual costs for this information collection (IAA with USGS) a) Potential study participant identification, recruitment, appointments b) Field work (including travel expenses), data analysis, final report c) Environmental sample or clinical specimen collection and analysis	\$152,010
Total cost per year	\$324,060

Exposure to Arsenic and Uranium in Private Well Water in Connecticut, New Mexico, and New Hampshire: Supporting Statement A

A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

The project time schedule for this investigation is 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 this investigation, the lead investigator at NCEH will collaborate with the requesting agencies to develop an analysis plan and conduct the data analysis. A preliminary report summarizing the early findings of the investigation will be written by the lead NCEH investigator in collaboration with the requesting agency and provided to CDC. Any publication of data derived from this investigation is subject to review by the requesting agency, NCEH, CDC, and USGS.

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

The display of the OMB expiration date is not inappropriate.

A.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.