

**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 B: Collections of Information Employing Statistical Methods)**

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## **PART B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS**

As indicated in Part A, the scope of private well investigations under this generic clearance information collection request (Generic ICR) is to assess potential exposure associated with drinking water from private wells within a well-defined time period and, when possible, the geographic distribution, that is useful for informing whether there is a need for public health action. This umbrella Part B provides a general description of the methods that will be used for each investigation, also called a generic information collection (GenIC).

The National Center for Environmental Health (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 state, territorial, local, or tribal health department (STLT) invitation, a research determination, and the data collection forms. The Part B **submitted for each GenIC** will describe the specific goal(s) of the collection instruments and how the specific data being collected will be used to inform whether there is a need for public health action.

The Part B **submitted for each GenIC** will describe:

1. The relevant (e.g., geographic, demographic) characteristics of the population to be investigated (e.g., the areas or counties where there are suspected exposure to contaminated water from private wells)
2. The respondent sampling frame (e.g., the roster of members of a local well owner network)
3. The respondent sampling type
4. The specific sampling method, including any screening and/or stratification to be done
5. The respondent sample size goals
6. The methods used to collect data (e.g., 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, and analysis of clinical specimens and/or environmental samples)

### **1. Respondent Universe and Sampling Methods**

The NCEH, Centers for Disease Control and Prevention (CDC), in partnership with the requesting agency, will identify the respondent universe for each investigation.

Respondents selected for NCEH investigations will include adults at least 18 years old, 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 agency. Respondent sampling and recruitment methods will vary based on the goals of the investigation, number of potential respondents, geographic range of the potentially contaminated area, available resources, and other data sources that are available.

For our technical assistance on drinking water quality for the Navajo tribes, we recruited between 200 and 300 respondents and successfully used the data collected to develop public

health campaigns emphasizing safe drinking water. Under this Generic ICR, we expect to enroll an average of 200 respondents for each investigation.

Potential respondents will be identified by the requesting agency through well owner records and/or well owner organizations. We anticipate that 80% of respondents answering screening survey questions will participate in investigation activities. See Table B1.1 for respondent sampling universe and the corresponding sample.

**Table B1.1.** Respondent sampling universe and corresponding sample

<b>Sampling Universe</b>	<b>Corresponding Sample Size</b>
Geographic area of interest with <200 households	n ≈160
Geographic area of interest with ≥200 households	~200 respondents
Local well-owners association (e.g., Master Well Program members)	~200 respondents

## 2. Procedures for the Collection of Information

Depending on the situation and the needs of the requesting agency, most investigations will involve collecting information from respondents using a questionnaire (see Attachment I for example questionnaire).

### *Estimation procedure*

- If the population of interest comprises less than 200 households, we will conduct a census survey. All community members in the area will be sent an invitation letter/flyer containing a toll-free number to call to be enrolled (Attachment F). A short screening survey (Attachment G) will be administered by phone.
- If the population is greater than or equal to 200 and less than 500 families, a sample of approximately 250 community members in the area will be sent an invitation letter containing a toll-free number to call to enroll about 200 homeowners (Attachment F). The 250 community members will be randomly selected from a list, such as a list of private well owners. A short screening survey will be administered by phone to approximately 250 interested callers (Attachment G).
- If there is a local well owners’ organization, such as Master Well Owner, we will recruit approximately 200 participants by announcing the project in a newsletter and inviting potential participants to call a toll-free number (Attachment F). A short screening survey will be administered by phone to approximately 250 interested callers (Attachment G).
- If there is a local event, such as a fair, we will recruit approximately 200 participants by being present in a booth at the event and inviting potential participants to call a toll-free number (Attachment F).

For each of the scenarios above, adults who consent (Attachment H), who have a private well for their source of water, who drink their tap water, and who are willing answer survey questions (Attachment I) and to receive and return a tap water sampling kit and urine specimen kit (Attachment J) or to provide a blood sample, will be enrolled.

#### *Unusual problems requiring specialized sampling procedures*

CDC does not expect unusual problems requiring specialized sampling.

Team members on any given investigation are trained public health professionals and could include CDC staff and contractors such as Epidemic Intelligence Service Officers and trainees such as CDC Experience Fellows, and may include staff from state, local, or tribal health agencies. Team members will be trained to administer questionnaires and collect appropriate environmental samples and/or clinical specimens. A code book will be created before the team goes into the field for an investigation, and questionnaire data will be entered into a computer as part of the field work. All paper questionnaires will be kept in a locked drawer or cabinet and computerized files will be password-protected.

### **3. Methods to Maximize Response Rates and Deal with Nonresponse**

In past investigations, such as the work with Navajo described in Section A.1, the participation rate was high because there was a local interest in water quality and associated health risks. We anticipate an 80% response rate for the investigations because they will be done in areas known to be of public health concern to the requesting agencies.

Individual investigations done under the Generic ICR may take different approaches to maximize response rates in specific populations. Possible approaches include trying to reach potential respondents by phone and providing a toll-free number for them to call back, advertising the investigation in a local newsletter, or using mailed surveys with self-addressed envelopes.

### **4. Tests of Procedures or Methods to be Undertaken**

All data collection tools will be pilot tested with fewer than 10 people. These tools will be submitted with the GenIC requests.

### **5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

The investigators leading the data collection and analysis will be trained in biostatistics and epidemiology. Investigators will collaborate extensively with health officials of the agency throughout the process of data collection design, implementation, and analysis. All investigations will be supervised by CDC's experienced epidemiologists. Additional statistical resources will be available at CDC.

Because the investigations will not be research studies, data analysis will be largely descriptive. Statisticians will be consulted if sampling or a more complicated analysis is needed.