Drinking Water Exposure Investigation Dimock, PA

ATSDR Exposure Investigations (EI) Generic Information Collection Request OMB No. 0923-0048
Expiration Date: 03/31/2019

Attachment 1: Supporting Statement Part A

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Science Support Branch (SSB)
Division of Community and Health Investigations (DCHI)
Agency for Toxic Substances and Disease Registry (ATSDR)

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Attachments:

- 1. Supporting Statement A
- 2. Supporting Statement B
- 3. Dimock EI Consent Form
- 4. Dimock EI Questionnaire
- 5. Dimock EI Protocol
- 6. Dimock EI Sample Results Letter
- 7. Example of Prior EI Final Report
- 8. Dimock EI ATSDR Research Determination
- 9. Dimock EI Letter of Invitation to Participate and Fact Sheet

Goal of the study: The goals for the Drinking Water Exposure Investigation (EI) in Dimock, PA are to test residential well water, bulk water sources and indoor air to assess ingestion and inhalation exposure pathways at specific Dimock residences. The Agency for Toxic Substances and Disease Registry (ATSDR) will perform the following actions:

- 1. Test private well water (at the tap and raw groundwater), as well as supplied bulk water sources, for a list of contaminants associated with natural gas drilling methods.
- 2. Monitor indoor air for total volatile organic compounds (VOCs) and combustible gas during water testing.
- 3. Test water and indoor air for radon.

Intended use of the resulting data: Based on the results of the testing, ATSDR will provide recommendations to federal, state, and local officials, and homeowners to reduce risks from exposure to contaminants detected in residential well water, bulk water and indoor air.

Methods to be used to collect: Homes will be sampled for:

- 1. Private well water (at the tap and raw groundwater) for contaminants associated with natural gas activities in the area.
- 2. Bulk supplied water will be tested for the same contaminants as private well water.
- 3. Indoor air will be assessed in the field for hazardous conditions during water sampling and radon test kits will be left in the home to sample radon.

Subpopulation to be studied: Private well water in 64 homes was tested by Environmental Protection Agency (EPA) in 2012 for contaminants associated with natural gas drilling activities. Participants in this EI will be chosen from those included in the EPA 2012 sampling event; up to 20 of the 64 homes will be retested.

How Data will be analyzed: The water samples will be analyzed by an accredited laboratory and results screened using ATSDR comparison values (CVs). Further evaluation of contaminants that exceed CVs will be completed to provide the basis for a public health evaluation. Radon will be screened against the EPA reporting limit. Appropriate recommendations will be made to reduce exposure of participants to contaminants from water

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

This data collection is being conducted using the Generic Information Collection mechanism of the Agency for Toxic Substances and Disease Registry (ATSDR) Exposure Investigations (EIs) – OMB Control No.0923-0048, expiration date 3/31/2019. The data collection for the Dimock Drinking Water EI aligns with the agency's mission. Paperwork Reduction Act (PRA) clearance for this GenIC needs to be in place by June 28, 2017 as ATSDR is committed to conduct a pretesting visit in early July 2017.

The data collection is authorized by the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), commonly known as the "Superfund" Act, as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986.

The Exposure Investigation will be conducted in summer 2017. It is important for the testing to be completed in a timely manner to ensure that any public health issues associated with drinking water in the Dimock area are identified and recommendations can be made to reduce exposure.

ATSDR Public Health Assessment Process and the Role of the Exposure Investigation

As part of the Public Health Assessment (PHA) process, ATSDR conducts Exposure Investigations (EIs) to perform targeted biologic and environmental sampling to *determine* whether people are or have been exposed to unusual levels of pollutants at specific locations (e.g., where people live, spend leisure time, or anywhere they might come into contact with contaminants under investigation). ATSDR uses EIs to fill data gaps that are essential for evaluating community exposure pathways and determining if a health hazard is present. The EI team conducts environmental and/or biological sampling focused on areas where exposures are expected to be high.

Contamination in Dimock, PA

Unconventional natural gas drilling activities have been ongoing in the Dimock area for nearly 10 years. In 2012, EPA sampled private wells at 64 residences in the Dimock area and requested

ATSDR assistance in the analysis of the sampling results. In 2016, ATSDR prepared a Health Consultation (HC) for the private well water data collected during the EPA 2012 sampling event (ATSDR 2016). The 2016 HC included the following recommendations:

- Homes with elevated levels of inorganic contaminants of concern in their well water should install a home treatment system for their well water or obtain an alternative source of drinking water.
- Homes with high levels of methane in their well water should vent and treat the water to eliminate the buildup of the flammable methane gas.
- Additional sampling of the tested wells be completed for further assessment of groundwater in the area.

Site conditions have changed since 2012, when the last groundwater data set was acquired by EPA. In August 2012, the Pennsylvania Department of Environmental Protection (PADEP) lifted the moratorium on completion of previously drilled natural gas wells in the area. In December 2012 and February 2013, several residents reported to PADEP and one resident reported to the National Response Center (NRC) visual changes in their private drinking water quality (turbidity, color changes, increased methane) (NRC 2012, verbal communications to ATSDR Region 3 from EPA Region 3 and residents).

In a follow-up to the release of the ATSDR 2016 Dimock HC, ATSDR met with community residents, PADEP, EPA and Pennsylvania Department of Health (PADOH). ATSDR met with these stakeholders to (1) discuss the current status of groundwater quality, (2) communicate the conclusions and recommendations of the HC, (3) determine whether any additional environmental sampling data were available from state agencies or residents that had not been evaluated and (4) further support and recommend additional groundwater and indoor air assessments to address data gaps regarding current exposures in the site area.

The data gaps identified from the 2016 HC and from communications with stakeholders include:

Retesting of private well water at residences tested in 2012 because conditions associated
with natural gas extraction activities in the area have changed since 2012 and residents
have concerns about the quality of their water.

- Testing of water supplied to residents (bulk water) because the source of the water varies and some residents are concerned about the quality of the supplied water.
- Testing radon in the home based on residents' concern. Radon testing in both water and
 indoor air will be conducted in response to community concerns given that radon is
 naturally-occurring in the Dimock area. The radon testing in indoor air will be provided
 in the homes where water testing is completed.

ATSDR designed the EI to address these data gaps. A panel of water contaminants potentially associated with natural gas production has been developed by ATSDR and is consistent with sampling performed by EPA in their 2012 sampling event. In addition, radon in water and indoor air will be tested. The EI report will summarize the data, present conclusions about potential health hazards, and provide recommendations for further actions by property owners, PADEP or local agencies, and the EPA. ATSDR will provide a health interpretation of individual sampling results to participants in the EI.

The Exposure Investigation Criteria and Recommendation Process

An EI is an approach developed by ATSDR that employs targeted biologic and environmental sampling to *determine whether people are or have been exposed to unusual levels of pollutants at specific locations* (e.g., where people live, spend leisure time, or anywhere they might come into contact with contaminants under investigation).

ATSDR uses EIs to fill data gaps that are essential for evaluating community exposure pathways and determining if a health hazard is present. An EI is NOT a research study. Rather, it is an attempt at identifying the most highly exposed individuals and determining their exposure. The results are a public health service directed to individual participants and are not generalizable to other populations.

EIs must consider the following four questions:

- 1. Can an exposed population be identified?
- 2. Does a data gap exist that affects the ability to determine if a health hazard exists?
- 3. Can an EI be designed that will address this data gap?

4. Will the EI results impact the public health decision for the site?

If the answers to these questions indicate that an EI would allow ATSDR to make a better-informed public health call, the DCHI EI Team may conduct agency-led EIs. For the Dimock site, the responses to the four questions (provided below) indicate that an EI is warranted at the site.

The EI Team from ATSDR Region 3 office and the DCHI Science Support Branch (SSB) will lead the investigation, evaluate the results, and communicate their public health findings and recommendations to the community (further discussed in Section A.2)

The four questions used to establish whether it was appropriate to conduct an EI for the Dimock, PA site were as follows:

1. Can an exposed population be identified?

Yes – Sampling conducted in 2012 by EPA identified constituents in private well water that may result in health effects or a safety hazard (ATSDR 2016). Dimock residents have expressed concern about exposure to their groundwater since 2009 and some residents continued to express concern in 2016.

2. Does a data gap exist that affects your ability to determine if a public health hazard exists?

Yes - There are insufficient data to assess current exposures to contaminants in private well water. A limited amount of data has been made available for certain Dimock private wells. However, the last comprehensive sampling activities were conducted over four years ago (2012) when EPA sampled 64 wells in the Dimock area. Without current groundwater assessment data, and given the considerable changes in the area (e.g., completion activities including hydraulic fracturing), ATSDR cannot determine whether unhealthy exposures to chemicals in groundwater are occurring. Residents have also had complaints regarding the quality of the bulk water that has been supplied as an alternate source of drinking water. The results of the drinking water and bulk water testing will assist regulators in determining whether residents should obtain or continue using alternate sources of drinking water. Residents have also been concerned about radon in the

area. Radon is found naturally in the Dimock area and will be tested as a public service in homes where water testing will be conducted.

3. Can an EI address the data gap?

Yes - The sampling of groundwater, bulk water and radon and an analysis of the chemical constituents detected in these exposure media will provide a health-based evaluation for residents in the community. Screening indoor air in the field for total VOCs and combustible gas emissions is included to ensure the safety of personnel during water sampling because methane has been detected in elevated concentrations in past sampling events. Testing of radon in indoor air will be provided in those homes where water testing will be conducted.

4. How will the EI results impact public health decision making?

More information on the chemical composition of area well water will provide important information to guide public health recommendations and actions. Assessment of bulk water will determine the quality of these replacement supplies that have been provided to numerous residents in the Dimock area. Although municipal water is not available to residents in this area, point of use and whole house water treatment and other alternative water supplies can be considered as an exposure mitigation alternative. Indoor air testing for radon will provide important information regarding exposures to a known carcinogen. Information from this EI and the subsequent health consultation may also be useful in triggering remedial actions to mitigate exposures or safety hazards.

The EI will include obtaining consent from the homeowner to conduct the testing (Attachment 3) and administering a questionnaire to evaluate water use in the home (Attachment 4). The cleared EI protocol including a Sampling and Analysis Plan (SAP) is included as Attachment 5. Results of water and radon testing will be provided to the participants in a letter (Attachment 6). Once the EI data collection and analysis from the follow up EI is complete, the ATSDR Team will conduct a public availability session for participants in the EI and for the community as a whole to discuss recommendations to reduce exposure and potential health concerns associated with drinking water and radon in the area.

A full EI Final Report will be completed and made available to the public and to all partners once all samples and data have been collected and analyzed. An example of a past EI Final Report is included as Attachment 7.

A.2. Purpose and Use of Information Collection

The purpose of the Drinking Water EI at Dimock, PA is to determine whether constituents associated with natural gas drilling activities may be present in drinking water at levels that may result in health effects (chemical or radon exposure) or safety concerns (methane). If this is the case, ATSDR will make the following recommendations to residents:

- a. install a home water treatment system to address chemicals and methane in water or obtain an alternative source of drinking water, and
- b. install a radon treatment system if radon levels are found to be above the action level.

Data from ATSDR's Dimock EI report may be used by public health professionals, environmental risk managers, and other decision makers in determining the source and extent of the exposures.

ATSDR will produce this needed information to support public health action. Further, the results of this EI are not intended to be generalized and are applicable only to the participants.

ATSDR only collects information that will help us interpret the laboratory data and recognize likely exposure scenarios. Once we conduct an EI, we match the unique answers given by participants with their laboratory results or environmental samples to determine whether intervention is needed on an individual level. The information collection is therefore *inherently person- or location-specific*.

If greater than 20 residences meet the criteria, participants will be selected based on the results of the 2012 EPA testing: Those with well water with the highest number and/or concentration of contaminants of concern will be given priority for inclusion in the EI. As such, the test results from this investigation will be specific to these participants and are not generalizable to the community-at-large or to other populations. The participants will be tested in summer 2017.

Data are treated to protect privacy; access to computer files is password-protected and access is limited to authorized EI personnel, including contractors. All staff working on the project agrees to safeguard the data and not to make unauthorized disclosures. Published reports may present responses in aggregate form and no individuals are identified by name.

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

ATSDR will conduct computer-assisted personal interviews (CAPIs) as well complete a hard-copy questionnaire (Attachment 4) with the participants at their homes. The information will be recorded electronically on a laptop computer.

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

Private well data from 64 residences was collected by EPA in 2012. Data collected included samples at the well, the tap and, where applicable, before and after any existing home water treatment system. Sampling results were used to determine whether residents should be supplied an alternative source of drinking water (bulk water).

Site conditions have changed since 2012, when the last comprehensive groundwater data set was acquired for the site area: (1) PADEP lifted a moratorium on completion of previously drilled wells in the site area in August 2012; and (2) In December 2012 and February 2013, several residents reported to PADEP and one resident reported to the National Response Center visual changes in their private drinking water quality (turbidity, color changes, increased methane) (NRC 2012, verbal communications to ATSDR Region 3 from EPA Region 3 and residents). Residents in the area have also been concerned about radon levels in the Dimock area. Given the changes in site conditions and the lack of information regarding levels of radon in water and indoor radon in the area, the samples collected for this EI will include:

- Samples of drinking water and raw groundwater, as appropriate
- Samples of bulk water supplies that are being provided to residents
- Samples of radon in water and indoor air.

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

Small businesses are not included in the sampling plan for the Dimock EI.

A.6. Consequences of Collecting the Information Less Frequently

This request is for a one-time data collection in the summer of 2017. There are no legal obstacles to reduce the burden.

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

There are no special circumstances associated with this data collection. The data collection will fully comply with the guidelines of 5 CFR 1320.5 and will be voluntary.

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 Exposure Investigations – OMB Control No. 0923-0048 (expiration date: 03/31/2019). A 60-day Federal Register Notice was published in the *Federal Register*, Vol. 80, No. 189 on Wednesday, September 30, 2015. No comments were received.

ATSDR is conducting this EI in collaboration with EPA, the Pennsylvania Department of Environmental Protection (PADEP) and the Pennsylvania Department of Health (PADOH).

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

ATSDR will not provide payments or gifts to participants.

A.10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by the NCEH/ATSDR Information Systems Security officer who determined that the Privacy Act does apply. The relevant Privacy Act System of Records Notice (SORN) for this EI is Privacy Act System Notice 09-19-0001, Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances (HHS/ATSDR).

This SORN is intended to allow for the implementation of the legislated mandate of ATSDR to identify the public health threat caused by exposure to toxic and hazardous substances using exposure investigations. The following Information in Identifiable Form (IIF) Categories apply to this information collection:

☐ Name	☐ Phone Numbers
☐ Date of Birth	☐ Mailing Address
☐ Email Address	

The paper document containing IIF are kept in locked file cabinets at ATSDR. Data obtained during the EI will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. The Pennsylvania Sunshine Law requires openness in government, which may result in personal identification being accessible by the general public. The consent form (Attachment 3) includes a statement indicating that these laws may apply and the EI will comply with all appropriate requirements. All identifying information maintained by the agency will be managed by ATSDR and is subject to the ATSDR Comprehensive Record Control Schedule (CRCS), B-371, which contains authorized disposition instructions for ATSDR's administrative and program records.

Data are treated to protect privacy; access to computer files is password-protected and access is limited to authorized EI personnel, including contractors. ATSDR computers comply with the HHS Standard 2008-0007.001S for encryption in accordance with information systems security requirements for safeguarding personally identifiable information. All staff working on the project agree to safeguard the data and not to make unauthorized disclosures. Published reports may present responses in aggregate form and no individuals are identified by name.

The Dimock EI will involve up to 20 residences. ATSDR provides homeowners with information on the EI process and what it can and cannot determine. After providing the participants this information, ATSDR will send invite letter (Attachment 9) to residents to participate in testing their water and indoor air as part of the EI and all participants will sign a consent form (Attachment 3) to confirm participation. Participation is completely voluntary; participants can stop participating in the EI at any time.

To facilitate contact with participants, consent, and to provide them with results, collecting identifying information is necessary. ATSDR will ask participants questions about their household water use, including whether they use supplied bulk water. Only questions needed to determine the extent of exposure in a particular situation will be asked. The questions are intended to estimate how long and how frequently participants may have contact with water.

The information collected for the EI will be used to evaluate whether water being used by participants (well water and/or bulk water) may contain contaminants resulting from natural gas drilling activities in the Dimock area. In addition, it will evaluate levels of radon in indoor air. Participants will be notified of their individual results (Attachment 6) and an EI report (sample in Attachment 7) will be prepared that will present the findings of the investigation.

ATSDR only collects information that will help us interpret the laboratory data and recognize likely exposure scenarios. Once we conduct an EI, we match the unique answers given by participants with their laboratory results or environmental samples to determine whether intervention is needed on an individual level. The information collection is therefore *inherently person- or location-specific*. Responses in published reports are presented in aggregate form and no individuals are identified by name.

A.11. 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 EI is intended to be a systematic investigation but is not designed to develop or contribute to generalizable knowledge.

The Dimock EI is a nonresearch activity and human subjects review by an Institutional Review Board (IRB) is not required. The EI was reviewed by the ATSDR Human Subjects Contact (Attachment 8). We will not ask questions on symptoms, medical outcomes, or drug and medication use.

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

A.12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours for the Dimock EI is based on similar EIs that the EI team has conducted in the past. The maximum time burden per respondent is estimated as one hour and thirty minutes to cover all activities including administration of the questionnaire during the site visit (20 minutes) and conducting the water sampling and setting the radon test kits on the testing date (maximum 70 minutes). A typical questionnaire may include up to 20 general questions taking less than 30 seconds each to respond and 10 more in-depth exposure specific questions requiring less than one minute each. The total estimated burden hours are maximum of 30 based on up to 20 residences being included in the EI.

Estimated Annualized Burden Hours

Type of	Name of	No. of	No. of	Average	Total Burden
Respondents	Form	Respondents	Responses	Burden per	(In Hours)
			per	Response	
			Respondent	(in hours)	
EI Participants	Questionnaire for the Dimock Water Exposure Investigation	20	1	1.5	30
Total					30

Annualized Cost to Respondents

Using a rate of \$23.86/hr., the annualized cost to respondents for the hour burdens for the collection of information is \$716. The hourly wage rate is based on the U.S. Department of Labor, Bureau of Labor Statistics' most current statistics [May 2016 National Occupational Employment and Wage Estimates United States,

http://www.bls.gov/oes/current/oes_nat.htm#00-0000].

Estimated Annualized Burden Costs

Type of	Total Burden	No. Responses	Hourly Wage	Total
Respondent	Hours	per Respondent	Rate	Respondent
_				Costs

EI participants	30	1	\$23.86	\$716
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A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no direct costs to the participants other than their time to participate in the EI.

A.14. Annualized Cost to the Government

Costs for ATSDR personnel are estimated based on experience with previous EI activities.

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Regional Director (GS-14)	100	\$50.00	\$5,000
Regional Representative Health Scientist (GS-13)	400	\$45.00	\$18,000
Headquarters Health Scientist (GS-13)	400	\$45.00	\$18,000
Estimated Total Personnel Cost of Exposure Investigation		\$41,000	

Non-Personnel	Cost
ATSDR Regional Personnel	
Travel	\$5,000.00
Contractor (ERG) costs (labor and travel)	
Labor	\$32,350.00
Travel	\$9,250.00
Laboratory costs (samples from 20 locations)	\$94,500.00
Estimated Total Non-personnel Cost of Exposure Investigation	\$141,100.00
Total EI Cost (ATSDR Personnel + Non-personnel costs)	\$182,100.00

The travel costs for ATSDR personnel include the following:

- Travel to the site from Philadelphia (2 persons) for three days for the site visit
- Travel to the site from Philadelphia (2 persons) for one week for the testing
- Travel to the site from Philadelphia (2 persons) for two days to provide the results to the community

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

Project Time Schedule

The project Time Schedule for the Dimock EI is as follows:

Activity	Time Schedule

Start of data collection and field work	2 weeks after OMB approval
Data and laboratory analysis	1-2 months after OMB approval
Respond to participants	3 months after OMB approval
	TBD - based on clearance
process	

Response letters to the participants will be sent to all participants (Samples are provided in Attachment 6). An example of a prior Exposure Investigation report is provided as Attachment 7.

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

We are not requesting an exemption.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to certification for Paperwork Reduction Act.