REQUEST FOR APPROVAL UNDER THE GENERIC CLEARANCE OF ASSESSMENT OF CHEMICAL EXPOSURES (ACE) INVESTIGATIONS DATA COLLECTIONS (0923-0051)

Instruction: This form should be completed by the primary contact person from the ATSDR CIO that will be sponsoring the investigation.

ATSDR is occasionally called upon to conduct Assessment of Chemical Exposures (ACE) investigations at the request of state regional, local, or tribal health authorities seeking assistance to respond rapidly to an acute chemical incident. ACE investigations are to be carried out in the event of an acute chemical release of toxic substances. During these investigations, ATSDR and CDC staff provides epidemiological assistance to describe the potential exposure and health status, identify needs of those impacted by the chemical release, and asses the emergency response to the incident. The inviting agency will use the information to direct the public health response and improve preparedness to decrease the morbidity and mortality caused by future mass casualty incidents.

DETERMINE IF YOUR INVESTIGATION IS APPROPRIATE FOR THIS GENERIC CLEARANCE MECHANISM:
Instruction: Before completing and submitting this form, complete the checklist below. If you select "yes" to the questions below, the ACE investigations Generic ICR mechanism can be used.

Criteria
Was ATSDR assistance requested by one or more external partners (e.g., state, local, regional, tribal, health department (the requesting agency) where the release occurred? [X] Yes [ ] No
Did the event involve the release of a toxic substance at levels that may cause acute human health effects? [X] Yes [ ] No
Did the event involve reports of people with acute health effects consistent with health effects of the chemical listed on reference materials (ATSDR Toxicological Profiles, Safety Data Sheet, etc.)? [X] Yes [ ] No This surveillance activity will investigate potential causes of rash associated with the Flint water supply.
Is the ACE investigation urgent in nature (i.e., timely data are needed to inform rapid public health action to prevent or reduce injury, disease, or death or provide other public health response)? [X] Yes [ ] No
Is the ACE investigation a non-research public health response designed to prevent or control disease or injury and reduce risk in the requesting agency's jurisdiction, including improving the requesting agency's public health response? [X] Yes [ ] No
Is the ACE investigation restricted to domestic incident and response under CERCLA? [X] Yes [ ] No
Will one or more CDC/ATSDR staff (including trainees and fellows) be deployed to the field? [X] Yes [ ] No
Will the data collection be completed in 90 days or less? [X] Yes [ ] No

Did you select "Yes" to all criteria above? If yes, the ACE Investigations Generic ICR might be appropriate for your investigation. → You may proceed with this form. If no, the ACE Investigations Generic ICR is not appropriate for your investigation. → Stop completing this form now.

TITLE OF INFORMATION COLLECTION: Flint Rash Investigation

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Chemical incident to be Investigated:

   The city of Flint, Michigan changed from one source of drinking water to a different one. The second source contained a higher amount of corrosive components in it than the first, which broke down the biofilm coating inside the pipes bringing water to homes, allowing lead to leach into the drinking water. An astute pediatrician noticed high blood lead levels in the children she tested. This prompted her to look at blood lead level data, and she saw a 3-5% increase in the prevalence of high blood lead levels in children over a certain period. That raised the alarm, and started the probe into what was happening.

   There have been reported cases of rash potentially associated with Flint water exposure from affected members of the public as well as some treating physicians. In response, the Michigan Department of Health and Human Services (MDHHS) began an investigation and requested assistance from the ATSDR Assessment of Chemical Exposures (ACE) team to more quickly complete it. The investigation was undertaken to characterize potential rash cases, develop hypotheses for potential causes of rash associated with Flint water supply, and make recommendations for public health interventions aimed at mitigating any future risk of rashes linked to Flint water exposure The ACE team is concluding surveys of persons who reported rashes and continues abstracting medical charts of persons receiving treatment for rashes. A preliminary report is being drafted. In addition, MDHHS continues to coordinate with the Environmental Protection Agency to offer water testing to persons with rash concerns.

   As the investigation progressed, MDHHS worked with local dermatologists to develop free clinics to provide examinations for persons who had reported rashes. Participants in the Flint Rash Investigation Survey were offered appointments. In these clinics, which are ongoing, local dermatologists examine patients and send recommendations to the patients' primary care physicians for treating their rashes.

   In this new request for assistance, MDHHS is asking for CDC/ATSDR assistance in calling approximately 150 persons seen at the free dermatology clinics to make sure the dermatology screening process is working, including transitioning of care to the participants' primary care physicians, ensuring that records have been received and results communicated clearly, and identifying any further need for assistance. Any gaps identified will result in notification of staff who will work to fill those gaps immediately.

   The objectives of the dermatology follow-up include:

   1. Identifying any obstacles to an effective transition of care from dermatology back to primary care physicians for each rash investigation participant who has received a screening evaluation
   2. Assessing the impact of the dermatologic screening evaluations as a whole and for each participant, and determine the need for any improvements to the screening evaluations to maximize the potential benefit for each participant

For the individual level, outcome measures will include: symptom improvement or resolution, whether or not the participant was able to connect with their medical home, and how well they understood results communicated to them. Results will be used to assist the individual patient, such as facilitating a call from the dermatologist to the patient's primary care physician or arranging transportation for an appointment with the primary care physician.

Overall outcome assessment will include: proportion of patients with improvement or resolution of rash, proportion of participants who successfully made the transition of care from the dermatologist to their medical home, and proportion of participants who understood results communicated to them. Results will be used to determine if there is need to change any process (e.g., the dermatologist change ways to communicate to participants so they better understand or are more inclined to follow up with their primary care physicians).

2. Characteristics of the Assessment:
   [ ] Standard approval (up to 5 days) is requested for this assessment
   [ ] 72 hour approval is requested for this assessment
   [X] 24 hour approval is requested for this assessment
   The Michigan Department of Health and Human Services (MDHHS) is investigating rashes associated with the contaminated water and needs ATSDR assistance in completing the investigation in order to quickly respond to the affected community.

3. Location of the Investigation:
   Flint, Michigan

4. Agency Requesting Epidemiological Assistance/Name and Title of Requestor:
   Michigan Department of health and Human Services/Jevon McFadden, MD, MPH,
   Medical Epidemiologist & Career Epidemiology Field Officer

5. Target Population (check all that apply):
   [X] Exposed Individuals (complete Question 7, Section A)
   [ ] Households (complete Question 7, Section B)
   [ ] Health Care Facility Staff (complete Question 7, Section C)
   [ ] Veterinary Facility Staff
   [ ] Other [insert]

6. Method of Data Collection (Check all that Apply):
   [X] Questionnaire (specify mode)
   [ ] Face-to-Face Interview
   [X] Telephone Interview
   [ ] Self-administered Paper-and-Pencil
   [ ] Self-administered Internet
   [ ] Focus Groups
   [ ] Medical Chart Abstraction
   [ ] Hospital Survey
   [ ] Laboratory Sample
   [ ] Other. Please describe: [insert]

7. Data to be Collected:
   MDHHS is requesting that the data collection use the form that they have developed.

8. Burden Estimate for Data Collection:

	Minutes
Exposed individuals (150)	10

INVESTIGATION LEAD:
Name: Jevon McFadden, MD, MPH
Title: Medical Epidemiologist & Career Epidemiology Field Officer
Affiliation: Michigan Department of Health and Human Services

US EPA CONTACT:
Name: Mark Durno
Title: On Scene Coordinator (OSC), Homeland Security Advisor / Deputy Chief
Affiliation: US Environmental Protection Agency, Emergency Response Branch

CDC/ATSDR SPONSORING PROGRAM: Assessment of Chemical Exposures (ACE) Program

NAME, TITLE, AND CONTACT INFORMATION OF PROGRAM CONTACT: Mary Anne Duncan, Epidemiologist, maduncan@cdc.gov, 404-567-3256.

CERTIFICATION:
[INSERT NAME OF ATSDR SPONSORING PROGRAM CONTACT], certify the following to be true:
1. The collection is voluntary.
2. Respondents will not be personally identified in any published reports of the study.
3. Information gathered will be primarily used to inform effective public health response.

ATSDR Sponsoring Program Primary Contact: Date:

Mary A. Duncan -S5
Digitally signed by Mary A. Duncan -S5
DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=2000208371, cn=Mary A. Duncan -S5
Date: 2016.04.19 13:23:36 -04'00'

04/19/2016

REQUESTED APPROVAL DATE:
4/20/2016

DATE REQUEST SUBMITTED TO THE INFORMATION COLLECTION REQUEST LIAISON:
4/19/2016

Instructions for completing Request for Approval under the "Generic Clearance for Assessment of Chemical Exposures Investigation"

TITLE OF INFORMATION COLLECTION: Provide the name of the collection that is the subject of the request.

DESCRIPTION OF THIS SPECIFIC COLLECTION:

1. Chemical Incident to be Investigated: Instruction: Provide a summary of the event. The summary should include all the information you know at this time about the event. At a minimum, please provide the following information: 1) background necessary to understand the importance of the event; 2) justification of the need for an assessment, including a description of any data already available or data gaps that exists; and 3) an explanation of how the information collected will be used to inform response, recovery, preparedness, or mitigation measures. Use as much space as necessary (suggested length: 250-500 words).

2. The standard approval using this assessment is up to 5 days. If a 72 – 24-hour approval is requested, an explanation must be provided as to why it is needed. Specifically, ATSDR must make a case as to why collection must begin within 72 to 24 hours, and it must be related to a public health need.

3. Location of the Investigation: Indicate the location where the investigation will occur, including city and state or country.

4. Agency Requesting Epidemiological Assistance/Name and Title of Requestor: Specify the name of the agency requesting epidemiological assistance. Include name and title of person of the requestor. Attach the letter of invitation requesting support. The letter should include the following information: 1) background on the event and 2) request for ATSDR assistance. Sensitive information in the Letter of Invitation not appropriate for public dissemination should be redacted.

5. Target Population: Select or provide a brief description of the targeted group or groups (e.g., the general public, health care providers, emergency responders, employees of the company) for this collection of information.

6. Method of Data Collection: Check the data collection method(s) planned for this investigation.

7. Type of Data to be collected from Exposed Individuals (Section A), Households (Section B), and Responding health care facility staff (Section C): Check the type(s) of data to be collected from potentially exposed persons during this investigation and the questions being used. If questions from a module are being modified, please indicate so with a (*). List any new modules being added.

8. Burden Estimate for Data Collection: Provide the estimate of time needed to answer the Questions listed in 7. If other respondents are being surveyed, list them on the table. If any survey will be longer than 30 minutes per individual, provide a justification for this burden.

INVESTIGATION LEAD: Indicate the name, title, and affiliation of the person who will be leading the investigation.

SPONSORING PROGRAM: Indicate the sponsoring CIO/Division/Branch for this investigation.

NAME, TITLE, AND CONTACT INFORMATION OF PROGRAM CONTACT: Indicate the name and title, and contact information of the ATSDR Primary Contact for this Investigation.

CERTIFICATION: Please read the certification carefully. Type your name to validate that you are providing certification. Note: If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved. Certification should be signed by the ATSDR Primary Contact for this Investigation.

REQUESTED APPROVAL DATE: Indicate the date (MM/DD/YYYY) by which approval is needed.

DATE REQUEST SUBMITTED TO THE INFORMATION COLLECTION REQUEST LIAISON: indicate the date (MM/DD/YYYY) the request is submitted to the Information Collection Request Liaison (ICRL).

E-mail the completed form to the Information Collection Request Liaison (ICRL), Stephanie Davis, at sgd8@cdc.gov. If submitting outside business hours and immediate approval is needed, call 404.213.2967 to notify the ICRL of the submission.