Attachment 3a - 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 environmental incident. ACE investigations are to be carried out in the event of an acute environmental incident including; chemical, radiological, nuclear, explosion, or natural disaster. 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 incident, 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? [ ] Yes [ ] No
Did the event involve an acute environmental incident (chemical, radiological, nuclear, explosion, natural disaster) that may cause acute human health effects? [ ] Yes [ ] No
Did the event involve reports of people with acute health effects consistent with health effects of the acute environmental incident in question? [ ] Yes [ ] No
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)? [ ] 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? [ ] Yes [ ] No
Is the ACE investigation restricted to the ACE authorizing legislation? [ ] Yes [ ] No
Will one or more CDC/ATSDR staff (including trainees and fellows) be deployed to the field? [ ] Yes [ ] No
Will the data collection be completed in 90 days or less? [ ] Yes [ ] No

Did you select "Yes" to <u>all</u> 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: [insert]

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Acute environmental incident to be Investigated:
   [Insert]

2. Characteristics of the Assessment:
   [ ] Standard approval (up to 5 days) is requested for this assessment
   [ ] 72 hour approval is requested for this assessment
   [ ] 24 hour approval is requested for this assessment
   [Insert justification for requesting 72 or 24 hour approval]

3. Location of the Investigation:
   [Insert]

4. Agency Requesting Epidemiological Assistance/Name and Title of Requestor:
   [Insert]

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

6. Method of Data Collection (Check all that Apply):
   [ ] Questionnaire (specify mode)
      [ ] Face-to-Face Interview
      [ ] 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:
   (Indicate the modules that questions are being pulled from. If any question from a module is being modified, please indicate in the box below.)

Section A: Exposed Individuals (refers to Appendix 2 - General Survey)

	Adult	Child	Questions used (e.g. A1, G2, etc.)	Question(s) have been modified (indicate with a * below)
Module Location/exposure information	[ ]	[ ]		
Module : Health status	[ ]	[ ]		
Module : Medical care received	[ ]	[ ]		
Module : Occupational history	[ ]	N/A		
Module : Medical history	[ ]	[ ]		
Module G: Personal protective equipment worn by emergency responders	[ ]	N/A		
Module : Communication/information and instructions	[ ]	N/A		
Module : Needs resulting from the incident	[ ]	N/A		
Module : Other people exposed with the respondent during the release	[ ]	N/A		
Module: Demographic and contact information	[ ]	[ ]		
Specimen/lab information	[ ]	[ ]		

Section B – Households (refers to Appendix 4 - Household Survey)

		Questions used (e.g. A1, B2, etc.)	Question(s) have been modified (indicate with a * below)
Module A: Contact information	[ ]		
Module B: Demographics	[ ]		
Module C: Location/Exposure and Communications	[ ]		
Module D: Health Status	[ ]		
Module E: Medical Care Received	[ ]		
Module F: Needs	[ ]		
Module G: Other, please specify: [insert]	[ ]		

Section C – Health Care Facilities (refers to Appendix 5 - Hospital Survey)

		Questions used (e.g. A1, B2, etc.)	Question(s) have been modified (indicate with a * below)
Part A: Surge	[ ]		
Part B: Response	[ ]		
Part C: Decontamination	[ ]		
Part D: Lessons learned	[ ]		
Other, please specify: [insert]	[ ]		

8. Burden Estimate for Data Collection:

	Minutes
Exposed individuals	
Households	
Health care facilities	
Other respondents: [insert]	

(If data collection using a survey is longer than 30 minutes, please provide a justification for this burden.)
[Insert]

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

CDC/ATSDR SPONSORING PROGRAM:
[Insert]

NAME, TITLE, AND CONTACT INFORMATION OF PROGRAM CONTACT:
[Insert]

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:

REQUESTED APPROVAL DATE:
[insert]

DATE REQUEST SUBMITTED TO THE INFORMATION COLLECTION REQUEST LIAISON:
[insert]

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

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

DESCRIPTION OF THIS SPECIFIC COLLECTION:

1. Acute 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 Affected 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 affected 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.