

**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
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: Methyl Bromide Release at a Condominium Resort

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Chemical incident to be Investigated:

A family of four vacationing at a Condominium Resort developed neurological symptoms consistent with chemical exposure. It was learned that methyl bromide, a highly toxic pesticide, was used on March 18 inappropriately to fumigate the condominium below the unit that the family occupied. All four family members were hospitalized and transferred to hospitals in Delaware and Pennsylvania, where they currently remain in serious condition. The paramedics who transported them also developed symptoms. Other vacationers, resort staff, pesticide company applicators, and emergency responders may also have been exposed and this pesticide may have been used inappropriately in other locations. Exposed persons may be experiencing symptoms of toxicity, but not know the cause of their symptoms. We estimate that this investigation may have approximately 40 respondents associated with the current and recent pesticide applications.

The U.S. Environmental Protection Agency is currently investigating the release and is performing environmental sampling. The Virgin Islands Department of Health is also involved in the response. Both agencies have requested assistance from the ATSDR Assessment of Chemical Exposures (ACE) team to investigate the incident. The investigation will be undertaken to:

- Identify persons who might have been exposed to the methyl bromide including: residents, visitors, and employees of condominium complex and other locations where this chemical was released, pesticide company employees, and emergency responders
- Interview these persons to determine exposure, acute health effects, and medical care received
- Provide information about methyl bromide to those who were potentially exposed
- Perform medical chart reviews for those persons receiving medical care following the exposure

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

The main purpose of the investigation is to identify persons who have potentially been exposed to methyl bromide, a very toxic substance, then determine if they are experiencing symptoms and provide them with information on the substance and how they can get help. This is an urgent request seeking expedited approval from OMB since people may be experiencing toxicity and not know the cause of their symptoms. The information obtained in this investigation is needed to support public health actions required by the health department to immediately stop further human exposure to methyl bromide, provide information to those who have been exposed, and to document and stop unauthorized pesticide application practices.

3. Location of the Investigation:

St. John, United States Virgin Islands

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

U. S. Virgin Islands Department of Health/Duane Howell, Acting Commissioner of Health

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)
 - Veterinary Facility Staff
 - 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)

	<u>Adult</u>	<u>Child</u>	<u>Questions used (e.g. A1, G2, etc.)</u>	<u>Questions that have been modified</u>
Module A: Location/exposure information	[X]	[X]	A1, A2, A3, A6, A7	A1, A2, A3, A7 child New question: A11–A15
Module B: Health status	[X]	[X]	B1,B2	B1,B2
Module C: Injuries from fire/explosion	[]	[]		
Module D: Medical care received	[X]	[X]	D1–D18, D20	D1, D2, D8, D15
Module E: Occupational history/exposure to chemicals at work	[]	N/A		
Module F: Medical history	[X]	[X]	F1, F4–F8	F1, F7, F8 New question: F1.o, F9
Module G: Personal protective equipment worn by emergency responders	[]	N/A		
Module H: Communication/information and instructions	[]	N/A		
Module I: Needs resulting from the incident	[]	N/A		
Module J: Other people exposed with the respondent during the release	[X]	N/A	J1,J2	J1,J2
Module K and Pet Survey: Exposure and health status of pets	[X]	N/A	K1,K2 Pet survey 1–7, 9–14	K1,K2 Pet survey 1,7,9,10
Module L: Demographic and contact information	[X]	[]	L1–L2, L4–L9	New question: L11
Module M: Other, please specify: [insert]	[]	[]		
Module N: Conclusion statements	[]	[]	N1, N2, N3	N1, N2, N3
Specimen/lab information	[]	[]		

8. Burden Estimate for Data Collection:

	Minutes
Exposed individuals (40 X 25 min)	1000
Households	
Health care facilities	
Other respondents: [insert]	

INVESTIGATION LEAD:

Name: Esther M. Ellis

Title: Territorial Epidemiologist

Affiliation: U. S. Virgin Islands Department of Health

CDC/ATSDR SPONSORING PROGRAM:

Assessment of Chemical Exposures (ACE) program

NAME, TITLE, AND CONTACT INFORMATION OF PROGRAM CONTACT:

Mary Anne Duncan, DVM, MPH, Dipl. ACVPM
CDR, US Public Health Service
Epidemiologist, Environmental Health Surveillance Branch
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CERTIFICATION:

I, Mary Anne Duncan 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:



4/2/15

REQUESTED APPROVAL DATE:

04/03/2015

DATE REQUEST SUBMITTED TO THE INFORMATION COLLECTION REQUEST LIAISON:

04/02/2015