

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

(Part B: Collections of Information Employing Statistical Methods)

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Point of Contact:

Mary Anne Duncan, DVM, MPH
Epidemiologist, Surveillance Team
Environmental Health Surveillance Branch
Division of Toxicology and Human Health Sciences
Agency for Toxic Substances and Disease Registry
4770 Buford Hwy NE, MS F-58
Atlanta, GA 30341
Phone: 770-488-3668
Email: maduncan@cdc.gov

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

TITLE OF INFORMATION COLLECTION: Methyl Bromide Release at a Condominium Resort

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

Respondents selected for this ACE investigation include persons who might have been exposed to methyl bromide on St. John, U.S. Virgin Islands; including, but not limited to:

- residents, visitors, and employees of condominium complex and other locations where this chemical was released
- pesticide company employees, and
- emergency responders.

We will attempt to interview all people who may have been exposed; sampling will not be employed.

2. Procedures for the Collection of Information

Potentially exposed persons who are available will be interviewed in person. Persons who are not available for in-person interviews, including vacationers who are no longer on St. John, will be interviewed over the telephone. Medical charts will be pulled by staff at the health care facilities (3 facilities are known at this time) abstracted by CDC and ATSDR personnel for persons who received medical care after being exposed to methyl bromide (Attachment C). Interviews and medical chart reviews should be completed in less than 2 weeks.

The lead Epidemic Intelligence Service Officer (EISO) or team lead from the requesting agency has the primary responsibility for the data analysis. Descriptive statistics (including frequencies, means, and ranges) will be calculated to describe the demographics of the respondents and their potential exposure levels. Frequencies will be calculated for other types of data such as reported acute signs/ symptoms indicative of exposure and types of medical care received. Additional bivariate and multivariate analyses may be conducted to identify risk factors for injuries. Statistical analysis beyond descriptive statistics will be conducted in consultation with a statistician/data analyst from the requesting organization, CDC, or ATSDR.

3. Methods to Maximize Response Rates and Deal with Nonresponse

The ACE team will engage in several activities to maximize response rates. We will be working with the Virgin Islands Department of Health and U.S. Environmental Protection Agency and will strategize on ways to locate participants and encourage them to participate. Appointments will be made to speak with emergency responders or businesses, which will be scheduled at their convenience. If the first attempt to reach prospective respondents is unsuccessful, repeat visits to their homes, telephone calls, or letters may be employed in an attempt to gain their participation. A toll-free telephone number may be arranged for individuals to return calls, if needed.

Before collecting information, investigators will inform respondents that participation is voluntary, that respondents will not be personally identified in any published reports of the study, and that their privacy will be protected to the extent allowed by law.

4. Tests of Procedures or Methods to be Undertaken

The ACE surveys were originally developed in 2010, based on surveys used to investigate earlier chemical incidents (conducted under 0920-0008 OMB approval). They were used in the field to investigate three incidents, then, in 2011, the general survey was revised to improve clarity and ease of use and pilot tested by a contractor.

Sections of the General Survey will be utilized for this investigation. The exposure questions have been tailored for this incident. The changes are described on the table in Question 7, Section A of the Request for ACE Investigation form (Attachment A). A copy of the survey which is planned is attached (Attachment B); along with a consent form (Attachment D).

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

The investigators leading the ACE investigation field responses and analyzing the data are trained in biostatistics and epidemiology. Investigators will collaborate extensively with health officials of the Virgin Island Department of Health throughout the process of data collection and analysis. The investigation will be supervised by ATSDR and CDC's experienced epidemiologists. Additional statistical resources are available at both ATSDR and CDC.

Because the investigation is a public health response and not a planned research study, the analysis will be descriptive. Statisticians will be consulted if sampling or a more complicated analysis is needed.