

**SUPPORTING STATEMENT A
OF THE REQUEST FOR
OMB REVIEW AND APPROVAL OF**

**A Site Specific Modular Evaluation Instrument for
Behavior Outcome Measurement**

June 22, 2007

Project Officer: Susan J. Robinson, MS
Agency for Toxic Substances and Disease Registry (ATSDR)
Century Center, Building 1825, Room 3100
Atlanta, GA 30333
Susan.Robinson@ees.hhs.gov
404-498-0312 (phone)
404-498-0092 (fax)

Table of Contents

A. JUSTIFICATION

- A1. Circumstances Making the Collection of Information Necessary
- A2. Purpose and Use of the Information Collection
- A3. Use of Improved Information Technology and Burden Reduction
- A4. Efforts to Identify Duplication and Use of Similar Information
- A5. Impact on Small Businesses or Other Small Entities
- A6. Consequences of Collecting the Information Less Frequently
- A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
- A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency
- A9. Explanation of Any Payment or Gift to Respondents
- A10. Assurance of Security Provided to Respondents
- A11. Justification for Sensitive Questions
- A12. Estimates of Annualized Burden Hours and Costs
- A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
- A14. Annualized Cost to the Federal Government
- A15. Explanation for Program Changes or Adjustments
- A16. Plans for Tabulation and Publication and Project Time Schedule
- A17. Reason(s) Display of OMB Expiration Date is Inappropriate
- A18. Exceptions to Certification for Paperwork Reduction Act Submissions

List of Attachments

- A. ATSDR Cooperative Agreement Program Description
- B. ATSDR Vision, Mission, and Strategic Goals
- C. Government Performance Results Act of 1993 (GPRA)
- D. Authorizing Legislation – CERCLA
- E. Top 20 Substances Found in Completed Exposure Pathways (CEPS) at Hazardous Waste Sites, 2003
- F. Survey Items (by Contaminant Group and Example Modules)
- G. Additional Modules (Demographics, HRQOL, Stress, Intention to Change, Knowledge and Beliefs)
- H. General overview of the step-wise method for compiling and customizing a site survey and examples
- I.1 60-day Federal Register Notice
- I.2 Public Comments on the 60-day Federal Register Notice
- J. List of Reviewers
- K. ATSDR State Cooperative Agreement Partners
- L1. Sample Cover Letters for Pre- and Post-Intervention Evaluation
- L2. Sample Cover Letter for Post-Intervention Evaluation
- M. Sample Interviewer Scripts – Telephone and In-Person

A. Justification

A1. Circumstances Making the Collection of Information Necessary

In 1980, Congress created the Agency for Toxic Substances and Disease Registry (ATSDR) to implement the health-related sections of laws that protect the public from hazardous wastes and environmental spills of hazardous substances. The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), commonly known as the "Superfund" Act, provided the Congressional mandate to remove or clean up abandoned and inactive hazardous waste sites and to provide federal assistance in toxic emergencies. As the lead Agency within the Public Health Service for implementing the health-related provisions of CERCLA, ATSDR is charged under the Superfund Act to assess the presence and nature of health hazards at specific Superfund sites, to help prevent or reduce further exposure and the illnesses that result from such exposures, and to expand the knowledge base about health effects from exposure to hazardous substances.

ATSDR also works closely with state agencies to carry out its mission of preventing exposure to contaminants at hazardous waste sites and preventing adverse health effects. ATSDR provides funding and technical assistance for states to identify and evaluate environmental health threats to communities. These resources enable state and local health departments to further investigate environmental health concerns and educate communities. This is accomplished through cooperative agreements and grants. ATSDR currently funds 29 states (Attachment A). In addition to awarding direct funds and services to state agencies, ATSDR staff provides technical and administrative guidance for state-conducted site activities.

Evaluation is a critical component in ATSDR's site-related public health actions, both to ensure the successful application of site-specific/site-related intervention activities, and the effective management of resources. However, ATSDR does not currently have an agency-wide standardized measurement instrument to obtain, analyze and strategically examine the outcomes of its health education and health promotion activities. Those activities are primarily aimed at developing coping mechanisms to adopt that are appropriate for interrupting exposure until site clean-ups have occurred to a level where such behaviors are no longer necessary, and enhancing the mental and physical health of individuals living near hazardous waste sites. A standardized instrument to measure behavior outcomes associated with agency intervention efforts at a site helps strategically target and manage current programs and resources.

In addition, in direct response to OMB's 2003 Program Assessment Rating Tool (PART) audit recommendations, ATSDR revised its goals and performance measures. There are now a total of five goals and eight measures (see Attachment B). The first three goals are intended to demonstrate significant progress in achieving intermediate and long-term, outcome oriented goals. In response to ATSDR Strategic Goal 3 ("Mitigate the risks of human health effects at toxic waste sites with documented exposures"), Performance Measure 4 of the OMB PART

Process requires ATSDR to use one of four outcomes to document the reduced occurrence or reduced risk of health effects for each Category 1 (urgent public health hazard) or Category 2 (public health hazard) site. The four outcomes are: (1) Comparative morbidity/mortality rates; (2) Biomarker Tests; (3) Levels of Environmental Exposures; and (4) **Behavioral Change of Community Members and/or Health Professionals.**

In order to measure and interpret behavior change of community members at sites, the agency and its partners in the cooperative agreement states need a standard, OMB-approved survey tool. This tool will permit ATSDR to collect pre- and post-intervention data. A standardized tool will also improve efficiency because it will allow ATSDR to gather survey data on behavior change for a large number of sites without having to secure OMB approval every time.

A set of standardized survey modules have been designed to measure individual beliefs, attitudes, knowledge, and behaviors at hazardous waste sites that may be influenced by agency health education and health promotion efforts. These modules will be used to determine knowledge improvements, attitude shifts, and behavior change following specific ATSDR program efforts and activities at a particular site. The modules are: (1) knowledge and beliefs; (2) behaviors; (3) stress; (4) health related quality of life; (5) intention to change; and (6) social demographics. The particular module(s) selected for use at a site will vary depending on the contaminant of concern, environmental media, environmental pathway, and education/health promotion actions taken in response to the site conditions. The surveys were intentionally designed in a modular framework to allow customization of the survey instrument at each site specific to contaminant(s), environmental media, and route(s) of exposure found at the site as well as potentially contributing factors.

To minimize the costs of survey activities, ATSDR would conduct the majority of surveys through its cooperative agreement partners, who are already working at the sites. ATSDR will encourage its partners to work with other agencies and programs, such as the Department of Fish and Wildlife, lead poisoning and prevention programs, and county health departments, to collect these data. ATSDR will develop detailed guidance for the agency and its partners in implementing the survey module framework.

This survey is in compliance with efforts to improve customer service in accordance with the 1993 Executive Order 12862 and the Government Performance and Results Act (GPRA) (Attachment C) requiring programs to evaluate the outcomes of their programs. Additionally, this survey is in keeping with the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) mandate to help prevent or reduce further exposure at hazardous waste sites and the illnesses that result from such exposures (Attachment D). CERCLA also provides the legislative authority to collect the information from this survey.

A2. Purpose and Use of Information Collection

ATSDR invests considerable resources – staff, materials, supplies, time, monies – to prevent exposures and mitigate adverse human health effects of hazardous substances from waste sites, unplanned releases and other sources of pollution present in the environment. A large percentage of these resources are directed toward activities and interventions (or, programs) designed to positively impact individual community members. It is critical that ATSDR have the capacity to answer whether or not these expenditures elicited the desired effects or impact.

Environmental public health activities and interventions are intended to facilitate change. Evaluation of ATSDR public health activities at sites currently focuses on (1) process or implementation evaluation, which answers the question “Did you do what you intended?” and (2) output evaluation, which answers the question “What and how many tangible products – services, materials – were produced?”. We do not have measurement tools or standard data collection procedures that allow us to assess changes at a site, which is a major gap in our capacity for evaluating the impact of our efforts.

The purpose of this survey, when implemented, is to address this evaluation gap. The information collected by the survey modules will produce data directly related to the desired results of site-related activities and interventions. Specifically, this survey would allow us to collect data from community members on knowledge and beliefs about environmental contaminants, level of stress, demographics, intention to change behaviors related to exposure and engagement in protective behaviors.

Analyses of the information collected will answer “What changes or impacts did community members experience following intervention by ATSDR at that site?”. In addition, results from these data are likely to assist us in answering more far reaching questions about a site, including: “Were the activities and interventions conducted or facilitated by ATSDR effective?” and “Did they produce the desired results?”; “Should ATSDR continue to use resources for these activities and interventions?” and “What improvements or revisions should be made, if any?”. Survey implementation and use of the information collected will substantially increase our impact evaluation capability at a site. However, site related data and results are not intended to be generalizable to a broader population or across sites with similar contaminants.

ATSDR staff work in diverse communities that are located near uncontrolled hazardous waste sites that are potentially contaminated by a wide range of chemicals (e.g., arsenic, lead, benzene, asbestos) in varying environmental media (e.g., air, water) and routes of exposure (e.g., inhalation, dermal). The behaviors that individual community members can take to interrupt exposures also vary by contaminant and media. Therefore, to reduce the response burden on respondents, a systematic approach was taken by agency staff responsible for this submission to

develop questionnaire modules for particular groups of chemicals, and to categorize by route of exposure and environmental media the behaviors that might put people at risk.

To begin with, the agency staff developed a table of the Top 20 Substances Found in Completed Exposure Pathways (CEPs) at Hazardous Waste Sites in relation to 2003 CERCLA Priority List of Hazardous Substances and Chemicals (see Attachment E). The purpose of this table was to prioritize ATSDR survey efforts toward those contaminants most likely to be found at hazardous waste sites and of greatest concern for potential health effects as a result of exposure. In addition to prioritizing based on information about the contaminants to which people have been exposed, it was also important to ascertain if there were any contaminants of more recent importance. This led to a review of the list of ATSDR Focus Sites as found on the ATSDR intranet web site. A Focus Site is a high priority site of current interest which involves extensive resources to address the public health concerns and other site complexities. As a result of this review, asbestos was included as a chemical of concern because of its recent importance.

ATSDR's Hazardous Substance Release and Health Effects Database (HazDat) is the agency's scientific and administrative database developed to provide access to information on the release of hazardous substances from Superfund sites. HazDat provided information on the types of activities reported likely to be associated with exposures to the top 20 substances found in completed exposure pathways. The information obtained from HazDat for each chemical included the frequency reported of the following:

- pathway (inhalation, oral, dermal, other)
- media (e.g., air, soil, water) and
- associated activities (e.g., recreational, trespassing, ingestion).

Many of the substances listed in the top 20 CEP share similarities in chemical property and exposure pathway. Thus, the substances were grouped into major categories based on the properties of the chemical and similarities in completed exposure pathways. The results are as follows.

- **Metals** (Lead, Arsenic, Cadmium, Chromium, Manganese, Zinc, Copper, Nickel). Metals generally have similar physical properties (strong and resistant to different stresses) and are therefore available for uptake in similar scenarios.
- **Volatiles** (TCE, PERC, VOCs, Benzene, Chloroform, Methylene Chloride, 1,1,1-Trichloroethene, 1,1-Dichloroethene). As a group, volatiles possess similar properties and are available for uptake via similar routes.
- **PAHs, Benzo(a)pyrene**. Polycyclic aromatic hydrocarbons (PAHs) and benzo(a)pyrene (B(a)P) are included in the next "grouping." PAHs represent a group of over 100 chemicals that are formed as a result of incomplete combustion. B(a)P is the most common PAH, and is therefore considered to be in the same grouping.
- **Polychlorinated biphenyls (PCBs) and Mercury**. PCBs and mercury are similar in several potential exposure scenarios, but have very different properties. **PCBs** are mixtures of up to 209 individual chlorinated compounds (known as

congeners). **Mercury** has several forms: metallic, inorganic (salts), and organic (methylmercury). In its metallic form, mercury acts much like other metals. In its methylated form, mercury acts much like PCBs in its potential for bioaccumulation, lipophilicity, and desire to bind to soil. For these reasons, PCBs and mercury are considered individually.

- **Asbestos.** Asbestos is a mineral that occurs naturally in the environment and therefore must be considered separately. Asbestos has unique properties and, in many circumstances, poses unique exposure scenarios.
- **Dioxin.** Chlorinated Dibenzo-*p*-dioxins (CDDs) are a family of 75 chemically related compounds, commonly referred to as dioxins. Dioxins are a broad group of chemicals with varying health effects and toxicities. Although some dioxins are similar to several PCB congeners, the broad nature of dioxins disallows grouping with PCBs or with other environmental contaminants.

A series of tables were created using data from HazDat and other sources (e.g., ATSDR's Case Studies in Environmental Medicine) to summarize information on potential *Activities* by *Pathway* and *Media* for the Grouped Chemicals. Survey items were then developed and assigned to contaminant groups based on those activities. Various sources were used to help develop questionnaire items. These included previous items developed by ATSDR, CDC's Behavioral Risk Factor Surveillance System (BRFSS), and other environmental surveys. Most items in the behavior survey were developed for this behavior survey.

A number of subject matter experts provided input on the items included in a module for a specific contaminant group, environmental media, and pathway. Following internal and external review, the survey modules were finalized. The final set of survey items in the modules represent our best professional judgment of the behaviors most likely to be addressed by site interventions.

Attachment F1 is an overview, in table summary form, of behavioral survey questions by contaminant group. Attachment F3 is the Contaminant Group, Environmental Media, and Environmental Pathway Module (CEEPM) which expands the table by specifying the applicability of survey questions according to environmental media and environmental pathway, as well as contaminant group. We anticipate that one or more of the CEEPMs will be used at a site depending on the contaminant(s) present, environmental media, and route(s) of exposure. If exposure could occur by multiple media and pathways, the survey form will not repeat a question that is found in both CEEPMs.

We anticipate that there may be occasions where site teams will want to add a behavior survey item to a CEEPM that is listed with a different CEEPM in this submission package. This could occur when the intervention selected by the site team addressed a specific behavior that, in their professional opinion, is better assessed using one or more items from the overall library of

behavioral survey items as included in this submission package. As our data collection efforts mature, we will be in a better position to improve the individual modules.

As demonstrated by public health intervention efforts toward behaviors such as smoking cessation and substance abuse prevention, behavior change is not necessarily a simple process of an intervention leading directly to an outcome. There are a number of antecedent, intermediate, and intervening factors that are potentially critical to understanding and interpreting behavior change results. For example, the “Stages of Change” model emphasizes that behavior change is a process in which individuals begin at various stages of readiness to change (Prochaska and DiClemente, 1982). Behavior change is usually gradual and often nonlinear with frequent relapses. Few studies have been conducted of behavior change related to environmental hazards. However, there is some empirical evidence of the importance of intermediate endpoints as related to behavior change. Bowler and Schwarzer (1991) found that a certain degree of environmental worry is needed for translation into readiness to take action. In a study on childhood lead poisoning preventive behaviors, Bland et al. (2004) demonstrated that self-efficacy was positively related to hand-washing and damp-dusting behaviors. Finally, Seguin, Pelletier, and Hunsley (1999), suggest that levels of self-determined motivation toward the environment predict engagement in environmental behaviors. We also need the ability to measure those factors that will help to interpret the behavior outcomes. The following survey modules, grouped together in Attachment G, are intended to measure concepts that have been suggested in the literature as antecedent to and to possibly impact successful behavior change:

- Stress
- Intention to Change
- Knowledge and Beliefs
- Social Demographics

In addition to acting as modifiers of behavior, we may also want to **directly** target these constructs for health education and promotion interventions. For example, an intervention aimed at reducing stress levels may be of great importance at sites where the community perceives that a considerable hazard exists but completed exposure pathways linking the hazard to the population do not exist.

Finally, Attachment G includes an additional survey module with ten items (CDC, 2000) to measure Health-Related Quality of Life (HRQOL). The HRQOL is widely used as a measurable outcome of physical and mental health and function. For example, four of the HRQOL measures have been part of the

full sample CDC BRFSS core since 1993 and were added, beginning in 2000, to the examination component of the National Health and Nutrition Examination Survey (NHANES). By including the HRQOL as a module, ATSDR will be able to assess changes in perceived quality of life in an environment of potential toxins.

Attachment F2 is an example survey which illustrates how survey items can be drawn from the reference modules (Attachments F3 and G) and combined to produce a site-specific evaluation instrument.

A3. Use of Improved Technology and Burden Reduction

We anticipate that for approximately 75% to 80% of the sites where the survey will be used, data from respondents will be collected via 1) interviewer/self-administered surveys at a number of venues that generally will include public availability sessions, community meetings, and the residences of the site community, or 2) telephone. To estimate the length of time it would take to complete a survey, we developed two sample surveys around a single site scenario – personal interview and self administered (see Attachment H for an overview of the step-wise method for compiling and customizing a survey, the sample site scenario and the surveys). In administering the sample surveys to a total of 9 people (four personal interviews and 5 self administered), we believe that, in the general population, the survey will take on average 20 minutes to complete.

In certain circumstances such as where resources are limited, the population is very large and widely dispersed, and obtaining telephone numbers is cost or technologically prohibitive, we may rely on mail surveys. In addition, in certain situations where it has been determined that the population to be surveyed has internet access, and/or prefers a web or email based communication strategy, the surveys will be converted to web format to allow for easier completion by those respondents. We anticipate using a mail, internet, or web format infrequently. In all cases, we will select the most appropriate method to make the collection as easy on the respondents as possible while using available technology where possible.

As noted previously, the surveys were designed in a modular framework to allow tailoring of the survey instrument at each site specific to contaminant(s), environmental media, and route(s) of exposure found at the site as well as potentially contributing factors. This will reduce the burden on respondents by avoiding asking unnecessary questions. The data will most likely be maintained in a spreadsheet (e.g., Microsoft Excel) or relational database (e.g., Microsoft Access). Simple statistical analyses can also be performed using these software products.

We envision that in subsequent years, we will build a database program (e.g., Microsoft Access based) wherein survey items are selected from a series of drop down menus and a survey instrument in a report format is automatically generated for each site. Depending on resources, it may also be possible to have an electronic version of the survey on a lightweight laptop or

palm pilot-like device where an interviewer can input the responses directly into the database. This would facilitate data collection efforts and minimize errors that may result by inputting data from a paper and pen survey into an electronic database.

A4. Efforts to Identify Duplication and Use of Similar Information

ATSDR has a unique mission as it is the only federal agency dedicated to preventing and mitigating exposure and adverse human health effects of hazardous substances from waste sites, unplanned releases and other sources of pollution present in the environment. To our knowledge, data collection on individual behaviors at hazardous waste sites following intervention is not occurring.

As noted in section A.2., HazDat is the agency's scientific and administrative database developed to provide access to information on the release of hazardous substances from Superfund sites or from emergency events and on the effects of hazardous substances on the health of human populations. It is ATSDR's primary site-related database. Data sources for HazDat include ATSDR's public health assessments, ATSDR's toxicological profiles, and data from the U.S. Environmental Protection Agency's CERCLIS database. While these data can answer questions about the site community and the extent of exposure, they are unable to answer questions about key behavioral outcomes related to risks of exposure. Until recently, ATSDR also collected site related information in a separate database titled the Site Tracking and Reporting System (STARS). However, the system is no longer being supported, no new data are being input, and existing data will be integrated into HazDat. STARS was designed to track agency site-specific activities in the health assessment process. A review of the STARS database reports shows that there have been few attempts to systematically measure and track behavior change in response to health intervention efforts at hazardous waste sites. Thus, ATSDR currently does not collect nor has a database in which to capture behavioral and other outcomes. Since HazDat is the Agency's primary site-related database, we will work with the agency staff to integrate the new proposed site-specific data collection effort into HazDat.

A5. Impact on Small Businesses or Other Small Entities

Site community respondents will be responding as individual members of the community, although some may be proprietors of small businesses. Every effort has been made to ensure that burden on these respondents is minimal. On average, a survey will take 20 minutes to complete.

A6. Consequences of Collecting the Information Less Frequently

ATSDR's ability to meet the program evaluation requirements of GPRA, CERCLA and the 2003 OMB Part audit would be hampered without approval of this OMB submission. The

behavioral survey items in Attachment F3 clearly relate to behavioral outcome measures. The items included in Attachment G are required to better understand and interpret the results from the behavioral outcome measures. As such, these items contribute to a subtler measure of program effectiveness. Since this is a new area for outcome data collection, it is important that we include factors which are antecedent explanatory variables (e.g., socio-demographics), potentially intermediate endpoints to behavior change (e.g., intention to change, knowledge and beliefs), and constructs that may be targeted for intervention (stress and other mood measures).

The timing of the data collection will vary by site, intensity of ATSDR activities, and whether the site is new or one at which ATSDR has been actively engaged for some time. In general, at a new site, we would aim for two data collections: one at baseline before ATSDR's health education and health intervention activities have begun and one after a sufficient period of time has elapsed for ATSDR activities to have had an impact. The decision about when to initiate a post-intervention data collection will be determined by the ATSDR team assigned to the site; site teams are generally comprised of staff scientists in a variety of disciplines relevant to the public health assessment process including epidemiologists, toxicologists, environmental health scientists, and health educators. Criteria will be developed to guide the team on when and how to administer the survey instrument. By definition, a baseline data collection cannot be implemented in sites where ATSDR has been operating for some time. At these sites, a single data collection is envisioned. Again, the decision about when to initiate data collection will be determined by the site team. The questions have been formatted to be used in a pre- and post-intervention design for new sites, and a post-intervention only design for current sites.

Since only one pre- and one post-intervention data collection are envisioned for new sites, collecting information less frequently at new sites would result in no baseline data or no follow-up data. On existing sites, only one data collection is currently envisioned and is, by definition, the minimum that can be undertaken. In this case, we can only measure whether individuals report behaving in ways that are likely to prevent exposure. The assumption is that the greater the frequency of individuals reporting acting in a preventive manner, the more likely it is that exposures are reduced. In so doing, we are more likely to assess agency impact than relying on process measures alone. There are no legal obstacles to reduce the burden.

A7. Special Circumstances relating to the Guidelines of 5 CFR 1320.5

This data collection fully complies with the guidelines of 5 CFR 1320.5.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

8.A. A 60-day notice was published in the Federal Register on November 7, 2006, page 65116, Vol. 71, (Attachment I-1). There was one request for information on the instrument (Attachment I-2).

8.B. A wide range of individuals served as consultants and/or content reviewers on the development of the modules regarding the appropriateness of content, intelligibility and wording. A list of these persons is found in Attachment J.

The draft survey was sent internally to ATSDR staff for review including Senior Management (e.g., Agency and Division Directors and Deputy Directors), Associate and Assistant Directors of Science, Division Branch Chiefs, and other selected individuals. We also sent the draft survey and modules to the 29 funded partner organizations (Cooperative Agreement Partners – see Attachment K for a list of staff). As noted in section A.1., ATSDR provides these grants through a Cooperative Agreement funding mechanism and this program helps build the capacity of governmental jurisdictions to assess and respond to public health issues related to human exposure to hazardous substances in the environment. Input from our Cooperative Agreement Partners was critical since they will also be conducting some of the survey data collection. Therefore, we had multiple conference phone calls with them to receive feedback, answer questions, and address concerns.

As a result of these efforts to receive comments, additional items were added, some were eliminated (e.g., items addressing wearing a filter face mask during various activities), the wording of some items was changed, and a “don’t know/not applicable” response category was added.

A9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be provided to survey respondents.

A10. Assurance of Confidentiality Provided to Respondents

The CDC/ATSDR Privacy Act Officer has reviewed this OMB application and has determined that the Privacy Act is applicable. The applicable system notice is 09-19-001, Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances.

Respondents will be asked to provide name and address. Personal identifiers will be kept for two years. Identifying information is necessary for possibly re-contacting respondents in a pre- and post-intervention design framework. In addition, this information is needed in order to map the location of the respondent in relation to the area of exposure for both the pre- and post-intervention design and post-intervention only design. This will be done through geocoding of addresses using geographic information systems (GIS) hardware and software. Mapping of the

respondent's address will allow the agency to ascertain the relationship between possible reduction in risk behaviors and location in the area(s) of exposure. This is especially important if the data collection venue is a public availability session or community meeting. These meetings are open to the public and are attended by people concerned about the hazardous waste site. It is often the case that some of the people attending the meeting, while concerned about the site, do not live in the vicinity of the exposure pathway area (e.g., a person may have lived in the area in the past but has since moved or grew up as a child in the area but has since moved). These respondents are less likely or not expected to engage in behaviors that interrupt exposure. By asking for the respondent's address, we will be able to examine these responses independently or exclude them from some analyses.

To safeguard the privacy of responses, respondent names and addresses will be separated from the survey immediately following the assignment of a code number to the survey. This code number will become the link between the removed names and the responses where re-contacting of respondents is necessary. In addition, geocoded address data will not be identified using a latitude and longitude value but rather, following geocoding, by assigning a proximity category. This category will be assigned to the survey such as "in the exposure pathway" or "not in the exposure pathway," or "within ¼ mile of the site," "greater than ¼ mile but less than ½ mile of the site," or "greater than ½ mile from the site." These are examples. The latitude and longitude values will be deleted from the database.

No data will be reported or mapped for public use by name, address, or if mapping permits the identification of a particular residence (e.g., sparsely populated area). Respondents will be advised of the privacy of their responses in the cover letter accompanying the survey. Respondents will be told that they are not required to respond to each question and that they may leave blank any question. All surveys will be kept in a secure locked file cabinet with limited access at the agency or health department (if conducted by ATSDR's cooperative agreement partners).

Data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. The paper document containing personal identifiers will be kept in locked file cabinets at CDC/ATSDR or the State Health Department. Access to computer files will be password-protected and access will be limited to authorized personnel. All staff working on the project will agree to safeguard the data and to not make unauthorized disclosures. Data will be safeguarded in accordance with applicable statutes. Responses in published site reports will be presented in aggregate form and no individuals will be identified by name.

CDC has determined that this program evaluation activity does not require review and approval by the IRB.

A11. Justification for Sensitive Questions

The Demographics Module includes questions about Race and Ethnicity, which may be considered sensitive by a portion of respondents. The Privacy Officer has determined that the following survey items are sensitive or potentially sensitive: pregnancy status, depression, anxiety, other mood issues interfering with daily functions, activity limitations, inability to work, and education level <high school. The use of these items is intended to assist the agency in its site specific program evaluation efforts.

- Occasionally, we may ask a question on pregnancy. Under certain circumstances (e.g., methyl mercury and fish consumption), pregnant women may be advised to take additional behavior precautions to avoid exposures.
- Education level<high school will be used to help interpret our results and to determine if there are problems with our intervention materials for program evaluation purposes.
- Question items related to mood (depression, anxiety, and other mood issues interfering with daily functions) and activity limitations are included in that some studies (e.g., Bowler and Schwarzer, 1991) have suggested that a certain degree of environmental worry is needed for translation into readiness for action. In addition, due to expressed community concerns, the agency may conduct intervention strategies to mitigate high stress, worry, and other mood issues that may interfere with daily functions. For example, in terms of stress effects, based upon the findings of several qualitative investigators, residents who believe they were exposed to contamination experience a high degree of stress (Edestein, 1988; Vyner, 1988) and display specific signs of stress elevations. Quantitative studies at hazardous waste sites tend to support the stress implications suggested by the qualitative research (Baum, 1987; Bowler and Schwarzer, 1991; Gatchel and Newberry, 1991; Gibbs, 1989). As noted in Section A.2, HRQOL items will be used to assess changes in perceived quality of life in an environment of potential toxins.

Respondents will be told that their participation in the survey is voluntary and they may refuse to answer any of the questions at any time. Social security numbers will not be collected as part of this data collection.

A12. Estimates of Annualized Burden Hours and Costs

A.12.A. Depending on the resources available to the agency and its partners, the site-specific survey module instrument will be administered at Category 1 (urgent public health hazard) and Category 2 (public health hazard) sites where behavior change is the selected outcome to document the reduced risk of health effects.

In addition, depending on resources, the site-specific survey module instrument may be administered at other sites where the agency determines that health education and promotion

intervention efforts are needed to bring about knowledge improvements, attitude shifts, and/or behavior change. This is most likely to be the case for sites where the lack of data precludes drawing a conclusion about the public health hazard of the pathway. This hazard category may still suggest health education and promotion interventions to empower community members to take prudent public health actions to avoid potential health effects.

Annually, ATSDR (including its State Partners) conducts public health education and promotion activities at approximately 250 sites. About half of those sites are new sites. In addition, we anticipate conducting new interventions at about half the existing sites. New interventions would allow for two data collection periods. Thus, almost three-quarters of our sites will have two data collection periods, baseline and post-intervention. At existing sites where ATSDR interventions have been completed, we would collect data once, post-intervention activity. We estimate that at 90% of the sites the exposed or potentially exposed population in a pathway is less than 10,000 (see Section B). The survey should take approximately 20 minutes to complete.

Approximately 10,750 respondents at sites with prior intervention programs will be asked to participate in post-intervention data collections $[(55 \text{ sites} * 150 \text{ respondents/site}) + (5 \text{ sites} * 500 \text{ respondents/site})]$. Approximately 35,500 respondents at sites with planned intervention programs will be asked to participate in pre- and post-intervention data collections $[(170 \text{ sites} * 150 \text{ respondents/site}) + (20 \text{ sites} * 500 \text{ respondents/site})]$. See Section B.1, Table B.1.B, for additional information on sites, site characteristics as they relate to the intervention and evaluation plan, and the number of respondents per site.

Since this is a new project, this represents our best estimate of a potential response rate. Once the survey has been conducted for 2 to 3 years, we can adjust these figures, as needed. An estimate of the total annual burden for the survey is shown in Table A.12.A.

Table A.12.A: Estimated Annual Burden Hours

Type of Respondents	Form Name	Number of respondents	Number of sites annually	No. of responses per respondent	Average burden per response (in hours)	Total annual burden (in hours)
General Public at Existing Sites with Exposed Populations of 10,000 or Less	Site-Specific Evaluation Instrument (post-evaluation only)	150	55	1	20/60	2,750
General Public at Existing Sites with New Interventions or New Sites with Exposed Populations of 10,000 or Less	Site-Specific Evaluation Instrument (pre- and post-evaluation)	150	170	2	20/60	17,000
General Public at Existing Sites with Exposed Populations of 10,000 or More	Site-Specific Evaluation Instrument (post-evaluation only)	500	5	1	20/60	830
General Public at Existing Sites with New Interventions or New Sites with Exposed Populations of 10,000 or More	Site-Specific Evaluation Instrument (pre- and post-evaluation)	500	20	2	20/60	6,670
Total						27,250

A.12.B. There are no direct out-of-pocket costs to the respondents for their participation in the survey. To calculate the estimated annual respondent cost, we used the mean hourly wage rate for all workers as determined by the Bureau of Labor Statistics National Compensation Survey, July 2004 (\$18.09). We selected this wage rate because we will be interviewing a wide range of people (e.g., blue-collar, white-collar, full-time, part-time, union, nonunion) across all geographic locations. The respondent costs would total \$492,953 as is shown in Table A.12.B.

Table A.12.B: Estimated Annual Respondent Cost

Type of Respondents	Number of respondents	Number of sites annually	No. of responses per respondent	Average burden per response (in hours)	Average hourly wage rate	Respondent Cost
General Public at Existing Sites with Exposed Populations of 10,000 or Less	150	55	1	20/60	\$18.09	\$49,748
General Public at Existing Sites with New Interventions or New Sites with Exposed Populations of 10,000 or Less	150	170	2	20/60	\$18.09	\$307,530
General Public at Existing Sites with Exposed Populations of 10,000 or More	500	5	1	20/60	\$18.09	\$15,075
General Public at Existing Sites with New Interventions or New Sites with Exposed Populations of 10,000 or More	500	20	2	20/60	\$18.09	\$120,600
Total						\$492,953

A13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs (capital, start-up, etc) for respondents to participate.

A14. Annualized Cost to the Government

The estimated annual cost to the federal government would be \$275,374. Staff salary estimates are based on the average full time salary for Atlanta based staff at the GS-13, Step 5 level (\$85,874). The breakdown of the cost is as follows:

\$ 43,000	Staff salary for programming, updating, and maintaining Microsoft Access database for survey module pick list (50% FTE)
-----------	---

\$ 64,500	Staff salary for developing survey guidelines and training on the use of the survey modules (75% FTE)
\$ 85,874	Staff salary for conducting surveys, management of data collection, compiling data, and analyzing data (100% FTE)
\$ 52,000	Staff travel for training of ATSDR Cooperative Agreement Partners on survey modules (26 trips x \$1,000 – two staff members above)
\$ 21,500	Technical support and consultation (25% FTE)
\$ 8,500	Supplies (Paper, training manuals, compact discs, mailing)
\$275,374	Total estimated costs

A15. Change in Burden Hours

This is a new information collection.

A16. Plans for tabulation and Publication and Project Time Schedule

Tabulation

The assessment of behaviors at sites is intended to be an ongoing agency activity. Tabulation plans differ slightly for new sites and existing sites. Data will most likely be analyzed in SAS, Microsoft Access, and/or Microsoft Excel using primarily descriptive statistics (e.g., frequency counts, measures of central tendency, and cross-tabulations), and graphical display. Site related data and results are **not** intended to be generalizable to a broader population or across sites with similar contaminants. The following table shells are samples of possible layouts for presenting the results from the analysis of aggregate site data.

Sample 1: “Follow Fish Advisories”

	Frequency	Percent of Total
Always Do This		
Sometimes Do This		
Seldom Do This		
Never Do This		
Don’t Know/Not applicable		
Total		

Sample 2: “Follow Fish Advisories” by “Age categories”

	18-30	31-50	50-65	66 and older	Total
Always Do This					
Sometimes Do This					
Seldom Do This					

Never Do This					
Don't Know/Not applicable					
Total					

Sample 3: “Damp dust home” by “Wash children’s toys”

		Wash children’s toys				Total
		Always Do This	Sometimes Do This	Seldom Do This	Never Do This	
Damp dust home	Always Do This					
	Sometimes Do This					
	Seldom Do This					
	Never Do This					
	Total					

Existing sites – Post-intervention only design

At existing sites with no new interventions planned, it will not be possible to measure a pre-post intervention behavior change. However, we will be able to measure whether individuals at a site report behaving in ways that are likely to prevent exposure. The assumption is that the greater the frequency of individuals reporting acting in a preventive manner at a site, the more likely it is that exposures are reduced.

New Sites/Existing Sites with New Intervention – Pre-and Post-intervention Design

Behavior change will be evaluated with the use of a pre- and post-intervention design at new sites or at existing sites with new planned interventions. Within a specified time period of ATSDR acquiring a new site and identifying the completed or potential exposure pathway area(s), a pre-intervention set of survey modules will most likely be given to residents in or near the exposure pathway or to those individuals attending a public availability session or community meeting about the site. Also, within a specified time period following ATSDR intervention efforts, depending on how the initial survey modules were administered, we will attempt to either 1) administer a post-intervention questionnaire to the same group of respondents who answered the pre-intervention or 2) administer a post-intervention questionnaire to a similar group of respondents such as those who attend a subsequent public availability session or community meeting.

In using a pre-post intervention design, we cannot attribute any changes in behavior directly to ATSDR intervention activities. However, we can assess what changes have occurred and interpret the data in light of ongoing activities at the site using the pre-post comparisons. This is important site related program feedback that is not currently collected by the agency.

Publication

Since this data collection effort is not for purposes of research and generalizable knowledge, publications will be limited to site related documents and internal reports that address program improvement at a site. In addition, data collection is being undertaken in response to the OMB PART Process requirement to document behavior change outcomes for Category 1 or Category 2 sites. Therefore, results may be included in reports to OMB. These publications will focus on the implications of this effort for site related program improvement.

Project Time Line

Resources permitting, the estimated project time line is below.

Project Time Line

Project Time Schedule	
Year 1	
Activity	Time Schedule
Develop Guidelines for Administering Single Data Collection at Sites	1-2 Months after OMB approval
Develop Guidelines for Administering Pre- and Post-Intervention Instruments	1-2 Months after OMB Approval
Hire Database Programmer to Program Survey Modules & Database to Hold Data Collected	2 Months after OMB Approval
Develop Training Materials	2-4 Months after OMB Approval
Train Agency Staff	5-6 Months after OMB Approval
Train State Partners	6-8 Months after OMB Approval
Identify Existing Sites For Administering Single Data Collection Effort	7-8 Months after OMB Approval
Identify Sites (New or Existing Sites with new interventions) for Administering Pre- and Post-Intervention Instruments	7-8 Months after OMB Approval
Administer Survey Module(s) at Selected Single Data Collection Effort Sites	8-10 Months after OMB Approval
Administer Pre-Intervention Survey Module(s) at Selected Sites	8-10 Months after OMB Approval
Initial Data Analysis of Survey Modules for Quality Assurance and Control	10-12 Months after OMB Approval
Analyze Site Data for Impact and Report Results	10-12 Months after OMB Approval
Years 2 and 3	
Activity	Time Schedule
Train Newly Hired Agency Staff	On-going as Needed

Train Newly Funded/Hired State Partner Staff	On-going as Needed
Identify Sites For Administering Single Data Collection Effort	On-going from Year 1
Administer Survey Module(s) at Selected Single Data Collection Effort Sites	On-going from Year 1
Identify Sites for Administering Pre- and Post-Intervention Instruments	On-going from Year 1
Administer Pre-Intervention Survey Module(s) at Selected Sites	On-going from Year 1
Administer Post-Intervention Survey Module(s) at Pre-Post Data Collection Sites	On-going from Year 1 after Interventions Concluded at Sites
Initial Data Analysis of Survey Modules for Quality Assurance and Control	On-going from Year 1
Analyze Site Data for Impact and Report Results	On-going from Year 1

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed on the data collection instrument.

A18. Exceptions to Certification for Paperwork Reduction Act Submission

No exceptions are being requested or pursued.