

**PROCEDURE FOR THE PREPARATION AND FOLLOW-UP OF AN
AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY
(ATSDR) PUBLIC HEALTH ASSESSMENT**

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AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR) SITE VISIT FOR PUBLIC HEALTH ASSESSMENTS

Introduction

The first step in the Public Health Assessment Process is a Site Visit to the Activity. Preparations for the site visit and providing ATSDR with documents require the most time and planning. This Issue Paper provides detailed instruction on how to prepare for and conduct a site visit, how to provide documents to ATSDR, and how to respond to written ATSDR Reports. Helpful hints and suggested actions for the host activity are highlighted in red.

ATSDR will often look at programs and request information that does not fall under the Defense Environmental Restoration Program. Examples include lead in housing surveys and soil lead surveys associated with housing not conducted under the Installation Restoration Program. Other areas may include Occupational health issues, indoor air quality issues in residential housing, natural resource issues (hunting and fishing) and testing/treatment of potable water. Therefore, it is important to assemble a team representing the different organizations ATSDR may want to meet with during the site visit. Finally, during the site visit it is not uncommon for the ATSDR Public Health Assessors to meet with community members, restoration advisory board members, local and local government officials without Navy representation present. The meetings are a routine part of the site visit. The purpose of the meeting(s) is to get a “broader” understanding of the site and if applicable identify community health concerns related to site activities.

Superfund Law

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980 are referred to as the Superfund Law. By enacting this law, Congress established a fund to identify and clean up the nation's hazardous waste sites. EPA administers the Superfund program in cooperation with individual states, territories, and tribal governments. EPA's Office of Emergency and Remedial Response oversees management of the program.

The National Priorities List

EPA's National Priorities List for Uncontrolled Hazardous Waste Sites (NPL) is a published list of hazardous waste sites that are being addressed through the Superfund program. These Superfund sites are found throughout the United States and in several U.S. territories. The Web address is <http://www.epa.gov/superfund/sites>

Background:

Congress established The Agency for Toxic Substances and Disease Registry (ATSDR) as a separate agency from EPA to ensure that public health issues at Superfund sites would be addressed. ATSDR is mandated by Congress (Section 104(i) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA), as amended (42 U.S.C. §9604), and Section 2704 of Title 10, United States Code to conduct public health assessment activities at all sites on (or proposed for) EPA's National Priorities List for Uncontrolled Hazardous Waste Sites (NPL). Congress also directed ATSDR to establish a national registry of serious diseases and illnesses and a national registry of persons exposed to toxic substances. Any person, group, or agency can request ATSDR's assistance on any health-related issues concerning toxic chemicals released into the environment. A request for assistance almost always results in a site visit from ATSDR.

When a site has been placed on the NPL, or when assistance has been requested, ATSDR will contact the Technical Liaison Navy and Marine Corps Public Health Center (NMCPHC) with notification of their intent to conduct a public health assessment, or other public health activity. NMCPHC will notify the Program Administrator and contact the NAVFAC Restoration Program Manager, and the Activity Installation Restoration Program Manager. The points of contact will be established and forwarded to ATSDR. NMCPHC is available to assist the activity without cost in preparation for the public health assessment upon request. NMCPHC will visit the Activity upon request and provide a command brief on the Public Health Assessment process and/or assist in preparing for the site visit.

A command or activity should notify the Navy and Marine Corps Public Health Center, Technical Liaison to ATSDR and the NAVFAC ATSDR Program Administrator prior to contacting ATSDR. The purpose of notifying the Liaison and Program Administrator prior to contacting ATSDR is because a request for assistance will usually result in services outside of the agreed upon Annual Plan of Work. Therefore, any changes or modifications to the APOW have to be approved by the Program Administrator for scheduling and budgeting purposes.

ATSDR will request background information prior to the site visit. Attachment (a) contains a detailed list of what type of documents ATSDR will usually request. Attachment (b) contains detailed instructions on how to deliver the requested documents. Following the site visit ATSDR will usually request additional documentation to fill data gaps. Attachments (a) and (b) also contain instruction on how to deliver documents, and what types of documents are normally requested after the site visit has been completed.

The Site Visit is the most time consuming aspect of a Public Health Assessment. The size of the facility and the complexity of site operations will ultimately dictate the level of effort required. The average site visit takes 2.5 days. Plan on the site visit lasting for 3 days. Attachment (c) contains a detailed example of a standard site visit schedule and instructions on how to plan and organize for the event. ATSDR will also

provide suggestions on their areas of interest to be included in the site visit. NMCPHC is also available to assist in the preparation of the site visit upon request. NMCPHC will also participate in the site visit to assist the Activity in providing ATSDR the information they need.

Overview of the Public Health Assessment Process

An Overview of the Public Health Assessment Process is provided below to assist the reader in understanding what ATSDR is looking for during the different stages of the process.

The Navy ATSDR Program Manager is Ms. Kim Parker Brown, NAVFAC: Phone Number: 202-685-1671; e-mail: Kim.Brown @Navy.Mil

The Navy ATSDR Technical Liaison is Mr. David F. McConaughy, NMCPHC: Phone Number: 757-953-0942; e-mail mcconaughyd@med.navy.mil

Objectives

There are two primary objectives of a public health assessment. These are:

1. To evaluate whether people in the community have, currently are, or could be exposed to hazardous chemicals that have been released into the environment.
2. To determine whether human contact with the chemicals might result in illness or other harmful health effects.

The public health assessment process differs from EPA's risk assessment process:

- Specifically, to determine the public health issues that need to be addressed at a site, ATSDR identifies places where human exposure occurs and the types of illnesses that might be associated with that exposure. ATSDR then makes recommendations for reducing or preventing exposure or for conducting other public health actions. EPA's risk assessment process is used to determine clean-up levels and develop site clean-up plans that will protect both the environment and public health.
- ATSDR is a public health advisory agency rather than a regulatory agency.
- ATSDR advises state and federal regulatory agencies on public health actions needed to reduce or prevent human exposure to hazardous substances. EPA is a regulatory agency with the power to enforce its decisions and regulations to protect the environment and public health. EPA is responsible for site cleanup.

Types of Assessments

ATSDR prepares different types of written reports to document public health assessment activities, results of evaluations, recommendations, and public health action plans. Following are descriptions of the four main types of these reports.

Public Health Assessment

A public health assessment document is written to report on the results of evaluation of all available information about a site and the communities that may be affected by it.

Health Consultation

A health consultation is written to respond to a specific question or request. The health consultation provides the results of data evaluation that answers the specific question.

Health Advisory

A health advisory is written to alert government agencies and the public about an immediate and significant danger to human health from the release of hazardous chemicals.

Exposure Investigation

An exposure investigation is written to report the results of analysis of environmental and biological samples that ATSDR has collected to verify human contact with a chemical. Exposure investigations are conducted when no data are available to verify human contact with a chemical, but contact is suspected.

The Process in Brief

The basic process for conducting a public health assessment is the same for all sites. The methods of evaluating site data and conditions are the same, even though the results of the evaluation may be presented in different types of written reports.

The first step in the public health assessment process is a site visit. The site visit plays a key role in the public health assessment process. A site visit includes an inspection of the area under investigation with an emphasis on determining whether all five elements of an exposure pathway are present. The site visit process includes: Identifying actual human contact (also called exposure) with chemicals in the environment, identifying the types of illnesses that might be related to contact with chemicals from the site, recommending health-based follow-up actions, such as an exposure investigation, and recommending ways to reduce or prevent exposures.

The site visit process does not include: performing medical examinations of individuals in the community, determining whether illnesses found in a community are actually associated with exposure to site-related chemicals, or establishing site clean-up levels.

During the site visit ATSDR personnel observe current site conditions, observe ways that people use natural resources in the area, establish relationships with community members and others involved with work at the site, and collect first hand information about community health concerns.

During the site visit ATSDR collects information required to determine whether human contact with the chemicals from the site might result in illness or other harmful health effects. The information is collected before, during and after the site visit. Providing ATSDR with the correct information is the most important responsibility for the RPM/IRPM. ATSDR assumes a completed pathway is a potential public health concern until documentation shows otherwise. The most common cause for delayed Public Health Assessment Reports is due to ATSDR not receiving information.

Types of Information

Some types of information might be available from a site visit and other types of information would be gathered before or after a site visit. Again, it is critical that ATSDR receive the required information in a timely manner, prior to, during and after the site visit.

Following are some types of information collected from site visits:

- Community health concerns. Information about health concerns in the community is usually gathered at meetings held in association with site visits, meetings may be held throughout the public health assessment process.
- Visual confirmation of community size and composition.
- Visual sense of the land and natural resource uses.
- Visual idea about the movement of contaminants.

The following types of information would be available from other sources:

- Background and site history information is usually available in reports that are collected before or after the site visit.
- Environmental contamination information is usually available in reports that are collected before or after the site visit, unless the community and environmental agencies are able to provide it at the time of the site visit.
- Information contained in state databases about births, deaths, and diseases in the community's population is usually gathered after the site visit.

Reviewing and Evaluating Environmental Data

When analyzing exposure pathways, available laboratory analysis of soil, water, air, and food samples must be reviewed and evaluated. This "environmental data" should describe the amount of each chemical found, the number of samples collected, when and where each sample was collected, when each sample was analyzed, and any other information needed to evaluate the quality of the data. This information is used to select the chemicals that need further evaluation and to determine what additional data are needed. Environmental data are also used in defining the nature and extent of contamination.

As stated above, ATSDR does not collect data. It is thus important that the Navy RPM provides only appropriate data necessary for a public health assessment. That is, only

data used for conducting human health and ecological risk assessments under CERCLA should be sent without detailed explanation. For example, if a Public Works lead in soil survey is forwarded to ATSDR, a detailed explanation should be attached explaining why and how the data was collected.

If ATSDR believes that available environmental data are inadequate for evaluating exposures, the assessor will evaluate the data available and also decide what additional data (they feel) are needed. The health assessor will request the needed data from the appropriate person or agency responsible for collecting it, and evaluates additional data as available, while keeping all parties informed about results. It is very important for the RPM and/or IRPM responsible for providing ATSDR information to immediately respond as to whether the Facility concurs with the request for collecting additional information.

Reviewing Background Data

Background data describe natural levels of chemicals in the environment (such as metals in soil). Also, levels of chemicals in the environment introduced through human activity (such as pesticides from mosquito control spraying) may be considered background data. Site environmental data are compared with background data.

The ATSDR must alert people to the presence of any chemical they may be in contact with at levels that may harm them. If the source of the chemical is not from the site under investigation, the health assessor is required to clearly state that. Therefore it is important for the RPM to ensure accurate background information is forwarded to the health assessor. If required, background information would most likely be sent following the site visit in response to the health assessor's public health concerns.

Using Comparison Values

Comparison values are levels of chemicals in the environment that are considered safe for human contact. Comparison values are derived from scientific studies and modified by safety factors to be more protective of human health.

The ATSDR has their own comparison values developed for a specific chemical in each of three environmental media: air, soil, and drinking water. If a chemical is found at a level above the comparison value and people can contact the chemical, the health assessor selects the chemical for further evaluation. Also, if a chemical is found that people are potentially exposed to but there is no comparison value for that chemical, it is also selected for further evaluation. Chemicals found at levels below comparison values are not selected.

Identifying Pathways for Further Evaluation

After selecting the chemicals that need further evaluation, ATSDR's next step is to determine whether people are actually coming into contact with the chemicals in a way that can harm them.

Preparing for Exposure Evaluation

During this step ATSDR evaluates whether people who are in contact with the selected chemicals could get sick from exposure to the chemical(s).

To do this, ATSDR conducts the following:

- Calculate site-specific doses
- Review chemical-specific toxicity data
- Use a weight-of-evidence approach to decide whether people might get sick

Site-specific doses: A site-specific dose is an estimate of the amount of a chemical that enters a person's body in a specific way and for a specific period of time.

Review chemical-specific toxicity data: Chemical-specific toxicity data provide information on the type of health effects associated with exposures to various levels of a specific chemical. These data are based on studies of animals and people. In the public health assessment process, a toxicological evaluation includes reviewing information on:

- how the chemical gets into the body
- what happens to the chemical after it gets into the body
- what effects are associated with the chemical and at what levels

Use a weight-of-evidence approach to decide whether people might get sick: The weight-of-evidence approach is an assessment method that includes reviewing site-specific doses, epidemiological studies, and chemical-specific toxicity data to evaluate exposures and potential health effects in a community.

Children and Health Effects

Potential health effects to children are of particular concern to the ATSDR because the exposure pathways and sensitivities may be different than for adults. The health assessor will carefully evaluate how children might contact chemicals at a site.

Children are often more sensitive to the effects of chemical exposure than adults. Their play activities often result in longer lengths of exposure than adults. Exposure to some chemicals may have a permanent effect on their developing body systems. Prior to the site visit contact day care providers/facilities to notify them what is taking place, why it is taking place and what to expect. ATSDR will most likely visit such facilities that are located on the activity as a routine function of their health assessment process. The ATSDR will request information on lead based paint sampling both for the playground soil and the building as appropriate. They may also ask for information on asbestos

insulation if the building was constructed prior to 1970. They will look at the condition of the building paint and ask what if anything the building has been used for in the past. Having the information available during the site visit will make the post site visit follow-up much easier. If there are no environmental concerns it also allows ATSDR to remove the location from their area of concern. Also if there are restricted or fenced off areas adjacent to outside play areas make sure the signage and fences are intact and in place. Note: The activity should have an established inspection/maintenance program in operation where this type of situation exists.

Written Public Health Assessment Reports

The results of the public health assessment are reported in a written document. Other types of reports may be prepared depending on the needs of the community or agency requesting help and on the conditions at the site.

There are three separate Public Health Assessment Reports published by ATSDR. They are in order of publication:

- Data Validation Public Health Assessment Report
- Public Comment Public Health Assessment Report
- Final Public Health Assessment Report

The first written report (Not a Public Health Assessment Report) issued by ATSDR will be a short Site Visit Summary Report (usually electronically) sent to the host command outlining their findings, or summarizing the items discussed during the exit brief. Comments are not requested on the Site Summary Report, but it is appropriate and recommended for the Activity to respond by letter if they have concerns or questions on what was said. If there are no questions or concerns it is recommended a response letter be sent acknowledging the receipt of the site summary report. If the Program Manager and NMCPHC are not on the distribution list for the Site Summary Report, a copy of the report should be forwarded for their review.

The first Public Health Assessment report is a Draft Validation Public Health Assessment Report. The Draft Validation Report is sent to the Activity, NMCPHC, Regulatory Community, and other Navy officials as designated by the Navy. It is very important to review and comment on the Data Validation Report by the requested due date. ATSDR will consider comments received on the Data Validation Report and incorporate changes as appropriate into the Public Comment Public Health Assessment Report. NMCPHC reviews every ATSDR documents and coordinates comments with the host activity. Navy comments should be submitted in a single electronic package to the public health assessor. The following persons should be copied on all comments/correspondence with the public health assessor:

- Ms. Kim Parker Brown, NAVFAC, kim.brown@navy.mil

- Mr. David F. McConaughy, NMCPHC, david.mcconaughey@med.navy.mil
- Mr. Gary Campbell, ATSDR Federal Facilities Branch Head, ghc1@cdc.gov

The second Public Health Assessment report is a Public Comment Public Health Assessment Report. ATSDR will request from the Activity where and to whom the report should be sent. The report will be posted on their Web page and automatically sent to designated repositories. ATSDR will also send copies of the report to organizations such as Restoration Advisory Boards upon request. It is very important to review the document and submit comments by the designated due date. All comments submitted on the Public Comment Report must be addressed by ATSDR in the Final Report. All Navy comments should be submitted in a single electronic package to the public health assessor with copies to the persons listed above.

The last report published is the Final Public Health Assessment Report. The Final Public Health Assessment Report is provided to the same locations as described in the Public Comment section above. Comments on the Final Public Health Assessment will not be addressed by ATSDR. If the facility does not agree with the conclusions or recommendations presented in the Final Report it is appropriate to respond to ATSDR in the form of a letter. The letter should list the concern(s) and supporting comments. A copy of the letter should be provided to the persons listed above under the Draft Validation Section.

The type of document ATSDR issues depends upon the needs of the community or on the needs of the agency that requested help. Following are descriptions of some of the primary documents that ATSDR produces.

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A public health assessment document is written to report on the results of evaluation of all available information about a site and the communities that may be affected by it.

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Listed below are the definitions of each public health category. Each completed exposure pathway identified will be categorized as defined below. It is very important to review the category assigned for each identified pathway. During the document review process it is appropriate to state whether the review person agrees or disagrees with the category classification. If there is a disagreement provide supporting documentation.

- Category A
Category A is urgent public health hazard. Actions must be taken quickly to end or prevent contact with chemicals from the site because short-term contact could cause harm or physical hazards present at the site could cause serious injury or death. For sites in this category, the health assessor does not need to complete all public health assessment activities before taking action.
- Category B
Category B is public health hazard. Contact with chemicals from the site might cause harm if contact continues over time or a physical hazard could cause injury if people are on the site.
- Category C
Category C is indeterminate public health hazard. More information is needed before conclusions can be made about the health impact a site may have on the community.
- Category D
Category D is no apparent public health hazard. People might be coming in contact with chemicals from the site, but the levels are too low to cause harm.
- Category E
Category E is no public health hazard. No one is coming in contact with chemicals from the site, and no one is likely to ever come in contact with site chemicals in a way that could harm them.

Recommendations

Many recommendations about actions that are needed at a site logically follow conclusions. For instance, if people are coming in contact with chemicals at a site in a way that could harm their health, a recommendation is needed to stop contact with the chemicals. If data are missing to evaluate whether chemicals are present at levels that could cause harm, then a recommendation should be made to gather that information. It is very important to review each recommendation, particularly during the Data Validation Report document review. ATSDR will assume the Navy agrees with their recommendation unless otherwise directed. Once a recommendation is presented to the public in the Public Comment Public Health Assessment Report, it may be very difficult to change or remove the recommendation due to public perception.

Public Health Action Plans

Whenever conclusions about a site result in recommendations to protect public health, an action plan will be included in the Public Health Assessment Report so that everyone interested in the site knows who has agreed to carry out the recommendations.

Often, recommendations are carried out before completion of the public health assessment report. Information on actions that have been completed, including who did the work and when, should be provided to ATSDR during the document review process. It is also important to review who is being recommended for what action. For example, ATSDR may recommend that the Navy sample private wells within a certain distance of base property. Although it is appropriate to have the wells sampled it may not be appropriate for the Navy to conduct the sampling. Therefore a comment would need to be submitted stating that the state health agency should collect the samples, not the Navy.

Note: A public health action plan will always be included if a site is categorized as an urgent public health hazard, a public health hazard, or as an indeterminate public health hazard.