



Health Assessments and Other Activities of the Agency for Toxic Substances and Disease Registry

BACKGROUND:	The Agency for Toxic Substances and Disease Registry (ATSDR) is responsible under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) for conducting health assessments at all sites on or proposed for the National Priorities List (NPL). The ATSDR also has a number of other health-related responsibilities under both CERCLA and the Resource Conservation and Recovery Act (RCRA). Accordingly, the ATSDR will have a significant role to play at DOE sites undergoing environmental restoration activity. DOE and ATSDR have jointly issued a Memorandum of Understanding (MOU) to facilitate ATSDR activities at DOE sites.
STATUTES:	Comprehensive Environmental Response, Compensation, and Liability Act, 42 USC 9604(i); Resource Conservation and Recovery Act, 42 USC 6939a.
REGULATION:	42 CFR 90.
REFERENCES:	<i>Health Assessments and Other Activities of the Agency for Toxic Substances and Disease Registry</i> , U.S. DOE Office of Environmental Guidance, RCRA/CERCLA Division (EH-231), DOE/EH-0179, March 1991; <i>Health Assessment Guidance Manual</i> (Draft), ATSDR, July 1990; "Interim Guidelines for Public Comment on Health Assessments," ATSDR, 56 FR 11221, March 15, 1991; "Memorandum of Understanding Between ATSDR and DOE on the Development of Toxicological Profiles for Hazardous Substances and Health Assessments and Related Activities at DOE Facilities," October 10, 1990; Letter from Director, DOE Office of Environmental Guidance to Director, ATSDR Division of Health Assessment and Consultation, April 29, 1991.

What is the ATSDR?

The ATSDR, headquartered in Atlanta, Georgia, is an agency of the U.S. Public Health Service (PHS) within the Department of Health and Human Services. (Other PHS agencies include the Centers for Disease Control (CDC), the National Institutes of Health, and the Indian Health Service.) Although the ATSDR is not part of the U.S. Environmental Protection Agency (EPA), it has representatives located in each of EPA's ten regional offices. In carrying out its environmental health mandates, the ATSDR works closely with both EPA and CDC in its primary responsibility of assessing the health effects associated with hazardous waste sites. The ATSDR was established by CERCLA, but also has duties under the RCRA. The ATSDR's responsibilities were greatly expanded in 1986 when CERCLA was amended by the Superfund Amendments and Reauthorization Act (SARA).

What is a health assessment?

The ATSDR is required by CERCLA to conduct a health assessment for every site proposed to be included on the NPL. ATSDR regulations (42 CFR 90.2) define a health assessment as "the evaluation of data and information on the release of hazardous substances into the environment in order to assess any current or future impact on public health, develop health advisories or other recommendations, and identify studies or actions needed to evaluate and mitigate or prevent human health effects."

The ATSDR's health assessments are not the same as EPA's risk assessments performed as part of the CERCLA Remedial Investigation/Feasibility Study (RI/FS) at NPL

sites. A health assessment is generally a *qualitative* description or statement of the public health impacts of a site. A risk assessment is a more *quantitative* assessment containing a numerical estimate of the likelihood that the contaminant exposures at a site will result in specific undesirable consequences.

How does the ATSDR conduct health assessments?

CERCLA Section 104(i)(6)(A) [42 U.S.C. 9604(i)(6)(A)] requires that ATSDR conduct a health assessment within one year after a site is proposed for the NPL. The two types of ATSDR health assessments are preliminary and full. Preliminary health assessments are conducted at sites where the site characterization process has not yet been completed. Therefore, most newly proposed NPL sites will be the subject of a preliminary health assessment. These health assessments typically are based on data gathered as part of the Preliminary Assessment/Site Investigation process, or other available data. Full health assessments are based upon completed RI/FS data.

ATSDR regulations found at 42 CFR 90 outline the general procedures for conducting health assessments and health effects studies. Detailed procedures and methodologies for conducting health assessments are contained in ATSDR's draft *Health Assessment Guidance Manual*. Health assessments usually contain the following elements: background, including site characterization; history demographics and land use; community health concerns; environmental contamination; pathways analysis, including environmental and human exposure pathways; public health implications; conclusions; and recommendations. As part of

the health assessment process, the ATSDR representatives responsible for preparing a health assessment will usually conduct a site visit, which typically includes a site tour and discussions with individuals knowledgeable about site activities and conditions.

What other health-related activities does ATSDR carry out?

Other ATSDR health-related activities include:

- Health consultation** - a response from ATSDR to a specific question or specific request for information pertaining to hazardous substances or to a facility with hazardous waste sites.
- Pilot study** - a limited study of the health effects of hazardous substances on selected exposed populations at specific sites to determine, among other things, the need to conduct a larger epidemiological study.
- Epidemiological study** - a study testing a specific hypothesis regarding the relationship between exposure to a hazardous substance and a health outcome.
- Registry** - the identifying and following of persons exposed to defined hazardous substances at selected sites to facilitate the development of new scientific knowledge. Registries generally will serve as a resource for other health effects studies.

The ATSDR also produces toxicological profiles on hazardous substances commonly found at hazardous waste sites. These documents describe health effects associated with the specific substance and summarize the available studies on the substance in question.

What are ATSDR's responsibilities at DOE sites?

The ATSDR's mandate to conduct health assessments at all NPL sites includes federal facilities on or proposed for the NPL. An MOU between DOE's Office of Environmental Restoration and Waste Management (EM) and ATSDR describes the role that ATSDR will play in DOE's environmental restoration program. The MOU provides for: (1) the conduct of health assessments by ATSDR at DOE environmental restoration sites under the purview of EM; (2) the preparation of toxicological profiles by ATSDR on request by DOE; and (3) the conduct of other health-related activities.

The health assessments will help determine the need for other, more in-depth health studies at the various DOE sites. These additional studies would normally be carried out by ATSDR directly or by other groups, such as the CDC or state health departments, under agreements with the ATSDR. Other studies of health effects possibly related to past exposures, such as those associated with dose reconstruction studies at several DOE sites, may be conducted independently of the ATSDR by other health agencies such as the CDC.

How will ATSDR carry out its responsibilities at DOE sites?

The DOE-ATSDR MOU provides that the individual DOE Field Offices will enter into Interagency Agreements (IAGs) with the ATSDR. DOE-EM and the ATSDR are currently preparing a revised model IAG to be used by the

Field Offices. It is expected that the individual Field Offices will negotiate IAGs that will detail the responsibilities of DOE and the ATSDR for site-specific activities and establish a mechanism for support of ATSDR activities [such as, full-time equivalents (FTEs) and funding of ATSDR studies].

What opportunity will DOE have to review and comment on health assessments and other ATSDR health studies?

The ATSDR's current practice is to release initial draft health assessments to EPA and affected states for a 30-60 day review and comment period. DOE will not be included in this review and comment cycle. A second draft of the health assessment will then be released to the public for a 30-day review and comment period. DOE will be included in this second round of review and comment. DOE has suggested that all parties will be better served by DOE's early involvement in the review process and has requested that the ATSDR reconsider its present policy.

In addition, ATSDR health effects studies, such as pilot and epidemiological studies, will undergo a public review and comment period before being finalized. The length of this public comment period will vary, but will typically last 30-60 days. Under current ATSDR policy, DOE review will be limited to this public comment period.

Can private individuals ask the ATSDR to conduct health assessments at specific sites?

Yes. CERCLA Section 104(i)(6)(B) [42 USC 9604(i)(6)(B)] allows individuals to petition the ATSDR to conduct health assessments at sites where individuals may have been exposed to a release of hazardous substances from a site, even if that site is not on the NPL. Although not required to do so, the ATSDR will probably notify DOE if one of its sites is the subject of a health assessment petition. The ATSDR will also notify DOE if it decides to conduct a health assessment at a DOE site in response to a petition.

How can ATSDR assist in DOE community relations activities?

Appropriate ATSDR involvement in DOE's community relations program can enhance the acceptability to the public of health statements made about DOE sites. ATSDR health judgements can be used to help clearly communicate to the public any current or future health risks that may be associated with DOE sites. ATSDR representatives, especially those located in each of the EPA regional offices, may be available to attend public meetings or otherwise support DOE's efforts to provide the public with health-related information.

Questions of policy or questions requiring policy decisions will not be dealt with in EH-231 Information Briefs unless that policy has already been established through appropriate documentation. Please refer any questions concerning the subject material covered in this Information Brief to John Bascietto, RCRA/CERCLA Division, EH-231, (202) 586-7917.