

PNL--7547

DE91 004917

INTEGRATION OF SITE-SPECIFIC HEALTH
INFORMATION: AGENCY FOR TOXIC
SUBSTANCES AND DISEASE REGISTRY
HEALTH ASSESSMENTS

A. M. Lesperance
M. R. Siegel

December 1990

Prepared for
the U.S. Department of Energy
under Contract DE-AC06-76RLO 1830

Pacific Northwest Laboratory
Richland, Washington 99352

MASTER

UH
DISTRIBUTION OF THIS DOCUMENT IS UNLIMITED

SUMMARY

The Agency for Toxic Substances and Disease Registry is required to conduct a health assessment of any site that is listed on or proposed for the U.S. Environmental Protection Agency's National Priorities List. Sixteen U.S. Department of Energy (DOE) sites currently fall into this category.

Health assessments contain a qualitative description of impacts to public health and the environment from hazardous waste sites, as well as recommendations for actions to mitigate or eliminate risk. Because these recommendations may have major impacts on compliance activities at DOE facilities, the health assessments are an important source of information for the monitoring activities of DOE's Office of Environmental Compliance (OEC).

This report, which has been prepared by Pacific Northwest Laboratory, provides an overview of the activities involved in preparing the health assessment, its role in environmental management, and its key elements.

The use of a summary page is recommended as a mechanism for extracting key information from the assessments. Because the information would be recorded in a consistent format, the summary page provides the additional benefit of allowing OEC to compare the consistency and completeness of information contained in the assessments of DOE sites.

CONTENTS

1.0 INTRODUCTION	1
2.0 ATSDR HEALTH ASSESSMENTS AND POLICY	3
HEALTH ASSESSMENTS	3
RELATIONSHIP OF HEALTH ASSESSMENTS TO REMEDIAL INVESTIGATION/FEASIBILITY STUDY PROCESS	3
GUIDANCE DOCUMENTATION	5
KEY ELEMENTS OF ATSDR HEALTH ASSESSMENTS	6
SUMMARY PAGE INFORMATION FROM HEALTH ASSESSMENTS THAT IS CRITICAL TO OEC	8
RELATIONSHIP OF ATSDR HEALTH ASSESSMENT TO OTHER STUDIES	10
3.0 REFERENCES	13

FIGURES

1	Organizational Chart for the Agency for Toxic Substances and Disease Registry	4
2	Overview of the ATSDR Process in Relation to the RI/FS Process	5
3	Health Studies that May Be Conducted at NPL Sites and Possible Outcomes of ATSDR Health Assessments	6
4	Prototype ATSDR Summary Page for the Hanford 100 Area	9
5	Possible Topics Contained Within the Health Issues Category of the OEC Prototype Summary Page	11

1.0 INTRODUCTION

The purpose of this report is to provide information regarding health assessments conducted by the Agency for Toxic Substances and Disease Registry (ATSDR). Pacific Northwest Laboratory (PNL)^(a) prepared the report at the request of the Office of Environmental Compliance (OEC) within the Office of Environment, Safety and Health, U.S. Department of Energy (DOE).

The primary mission of the OEC is to ensure DOE's compliance with applicable environmental statutes and regulations. In that capacity, OEC reviews site-specific documents and monitors compliance activities at DOE facilities.

At present, 17 DOE facilities (at 13 DOE sites) are listed or are being considered for inclusion on the Environmental Protection Agency's (EPA) National Priorities List (NPL). ATSDR is required to conduct health assessments for all these sites. Additional DOE facilities are expected to be proposed for or added to the NPL; ATSDR will be required to prepare a health assessment for these sites as well.

The ATSDR health assessments provide a qualitative description of public health impacts imposed by a hazardous waste site. The objectives of a health assessment are to

- evaluate the release of hazardous substances
- determine whether present or future impacts on public health are occurring or may occur
- develop recommendations
- identify actions and studies that are needed to prevent human health impacts.

An understanding of ATSDR health assessments will assist OEC in its oversight role. Because conclusions and recommendations from the health assessments may have major impacts on compliance activities at DOE facilities, this report identifies and reviews key information from guidance documents and ATSDR health assessments.

The concept of a summary page to facilitate OEC's review of the health assessments is introduced. The summary page will allow OEC to ascertain the degree of consistency in the conclusions and recommendations for various sites.

To obtain information for this report, ATSDR guidance documents and regulations were reviewed and agency officials were interviewed. Health assessments from 70 sites were reviewed to evaluate the level of consistency in reporting. Of the health assessments reviewed, 18 were classified as full health assessments, 42 as preliminary health assessments, and 10 as draft health assessments.

(a) Pacific Northwest Laboratory is operated for the U.S. Department of Energy by Battelle Memorial Institute under Contract DE-AC06-76RLO 1830.

2.0 ATSDR HEALTH ASSESSMENTS AND POLICY

The ATSDR was established in 1980 by the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). It is a component of the Public Health Service, Department of Health and Human Services, and is responsible for carrying out various health-related activities under CERCLA and the Resource Conservation and Recovery Act (RCRA). In 1986, the Superfund Amendments and Reauthorization Act (SARA) expanded the scope of the agency's responsibilities. Among other activities, the agency is now required to prepare health assessments for all Superfund sites and to prepare toxicological profiles for hazardous substances. The divisions within ATSDR are indicated in Figure 1.

HEALTH ASSESSMENTS

ATSDR defines 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, to develop health advisories or other recommendations, and to identify studies or actions needed to evaluate and mitigate or prevent human health effects" (42 CFR 90).

ATSDR is required to conduct a health assessment within one year after a site is proposed for inclusion on the NPL [CERCLA 104(i)(6)(A)]. Initially, ATSDR requests all available documentation regarding the facility from EPA. ATSDR may establish additional contacts with the state departments of health and environment, as well as other federal agencies such as the National Oceanic and Atmospheric Administration; the United States Geological Survey; the Department of Defense; and the DOE, for site-specific information.

RELATIONSHIP OF HEALTH ASSESSMENTS TO REMEDIAL INVESTIGATION/FEASIBILITY STUDY PROCESS

EPA and ATSDR have signed a Memorandum of Understanding (MOU) that establishes policies for conducting health activities related to releases of hazardous substances. ATSDR is currently responsible for assessing the potential for existing or future exposure to hazardous substances; for developing health advisories; and if warranted, for conducting follow-up investigations to determine future health impacts (EPA 1986).

Congress expressed a preference that, to the "maximum extent possible," the health assessment be completed before the remedial investigation/feasibility study (RI/FS) is completed (42 U.S.C. 9604). Although EPA and ATSDR are responsible for conducting public health investigations, EPA has the final authority for risk management decisions based on the investigations (EPA 1986). Figure 2 provides an overview of the ATSDR process in relation to the RI/FS process.

Cooperative agreements have been signed between ATSDR and 22 states regarding the conduct of health assessments. However, in many of these agreements, there are no provisions for conducting health assessments at federal facilities. The following states have agreements with ATSDR to conduct health assessments:^(a)

California	Maryland	Pennsylvania
Colorado	Massachusetts	South Carolina
Connecticut	Missouri	Texas
Florida	Minnesota	Virginia
Illinois	New Hampshire	Washington
Indiana	New Jersey	Wisconsin
Iowa	New York	
Louisiana	Ohio	

(a) Personal communication with R. Gillig, ASTDR, June 1990.

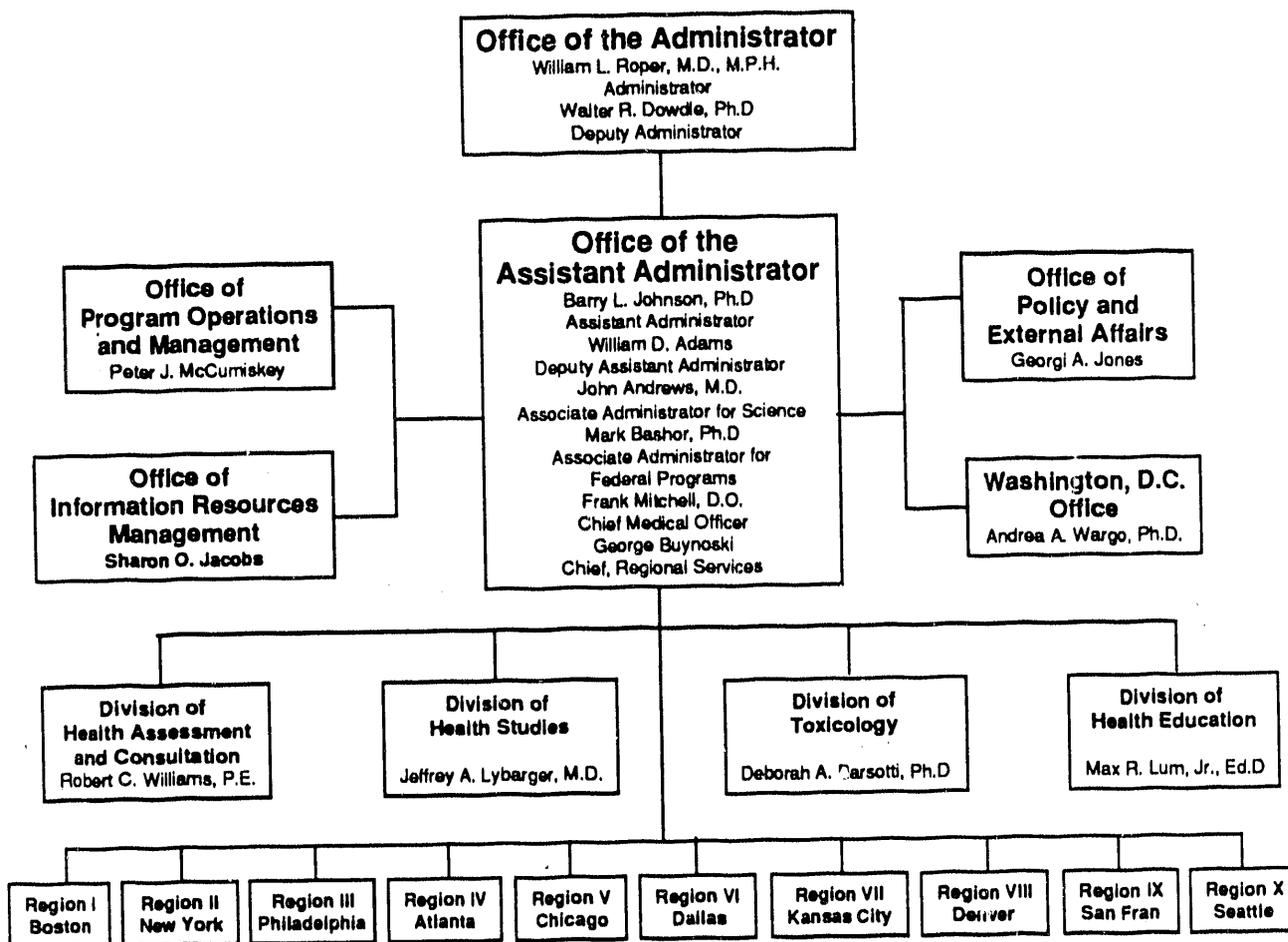


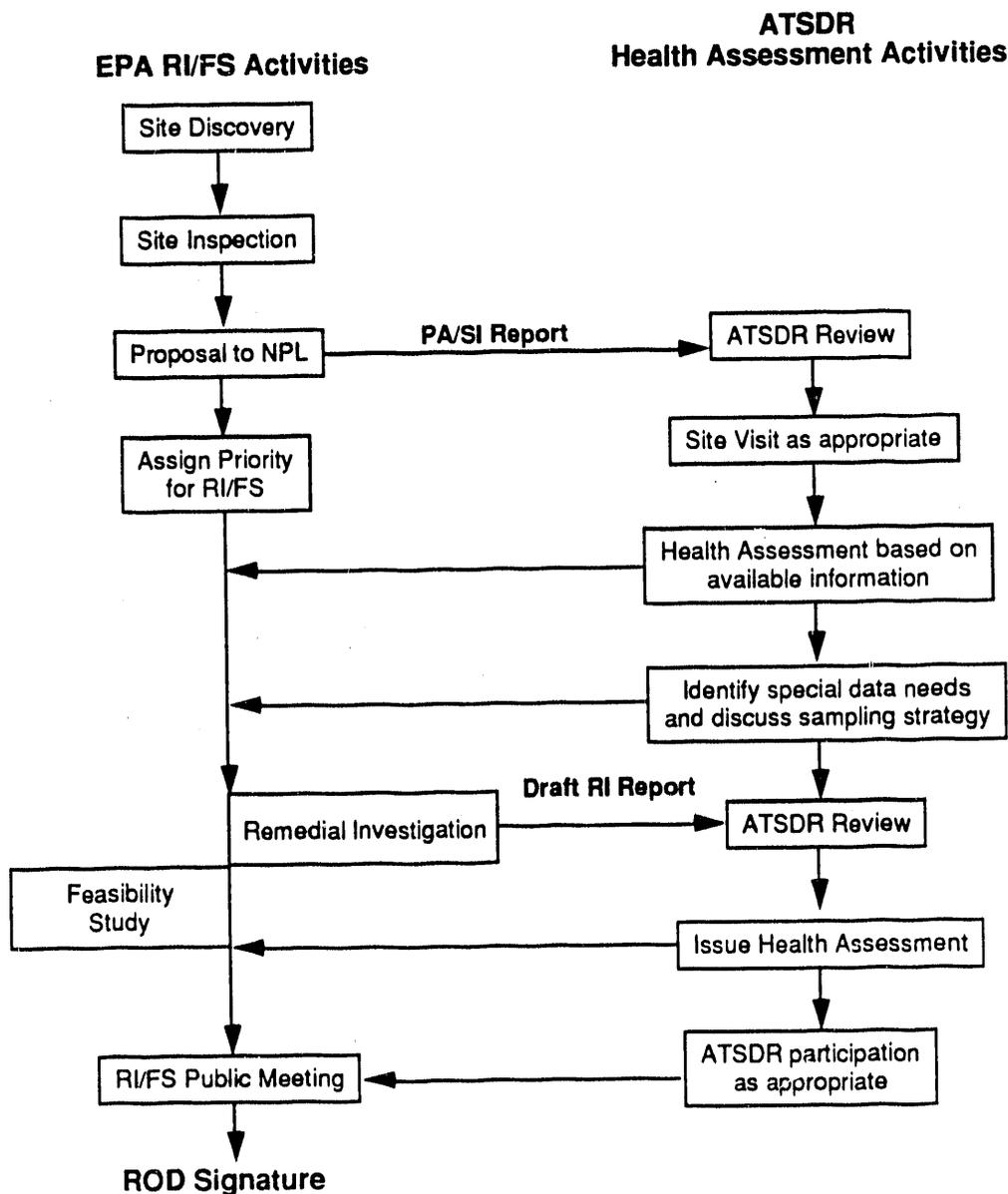
Figure 1. Organizational Chart for the Agency for Toxic Substances and Disease Registry

Health assessments are released either as full health assessments, preliminary health assessments or draft health assessments. Preliminary health assessments are conducted at sites where the site characterization process has not yet been completed. Full health assessments are based upon a completed RI/FS. As the RI/FS data are gathered by the responsible agency, they are forwarded to ATSDR for review and possible followup. Full health assessments and preliminary health assessments may be released in draft form.

Additional health studies may be initiated based upon the conclusions of an ATSDR health assessment (Figure 3). A *pilot study* of the health effects of hazardous substances may be conducted on selected groups of the exposed population to

determine whether a larger epidemiological study or health effects study is warranted. A second study, an *epidemiological study*, tests a specific hypothesis regarding the relationship between a hazardous substance and a health outcome. Another study that may be conducted, depending on the outcome of a health assessment, is a *health surveillance/registry study*. A health surveillance study uses screening techniques to identify specific biological markers or disease (ATSDR, undated).

DOE and ATSDR are currently negotiating a MOU that will, among other things, allow inter-agency agreements (IAGs) to be established for specific sites. The IAGs will define each agency's specific responsibilities in the health-related studies by ATSDR. To date, an ATSDR role has been



Source: EPA, Office of Solid Waste and Emergency Response, March 1987, Dir. No. 9285.4-02

Figure 2. Overview of the ATSDR Process in Relation to the RI/FS Process

defined in at least one agreement, i.e., the Federal Facility Agreement (FFA) at the Hanford Site in Washington State.

professionals who are responsible for preparing health assessments.^(a) Since 1988, health assessments have been conducted using this guidance manual.

GUIDANCE DOCUMENTATION

An ATSDR document details the format, guidelines and methodologies that will be used by ATSDR staff and state and local health

(a) Agency for Toxic Substances and Disease Registry. Undated draft. "Health Assessment Format, Guidelines and Methodology."

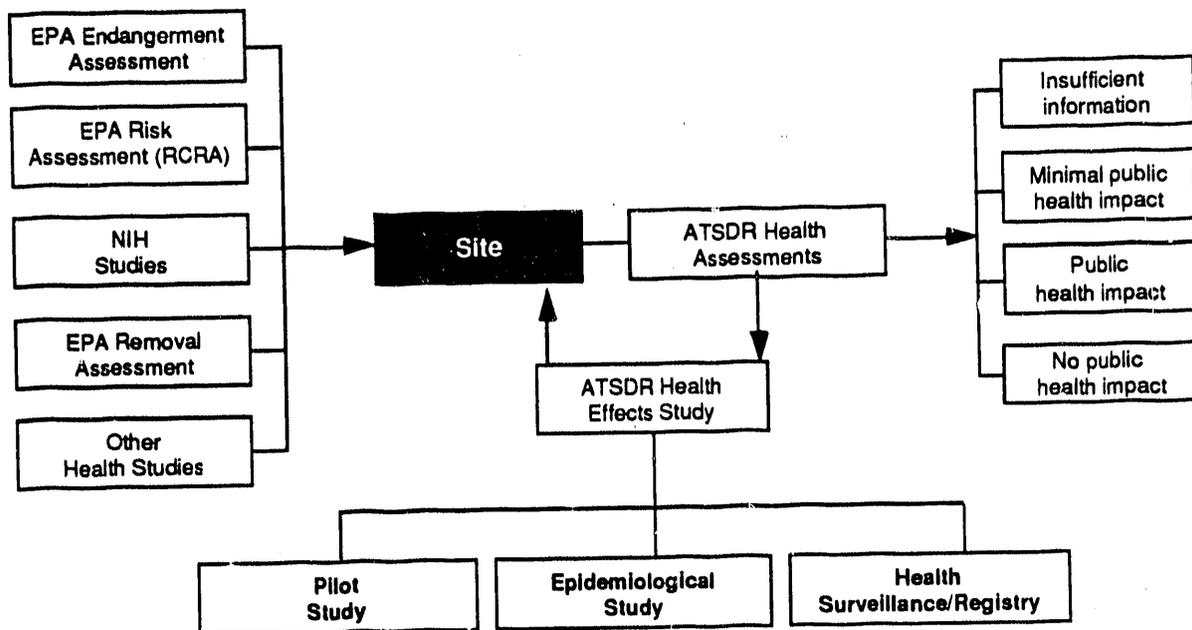


Figure 3. Health Studies that May Be Conducted at NPL Sites and Possible Outcomes of ATSDR Health Assessments

A second manual entitled the *Health Assessment Training Manual* highlights information for staff who are responsible for preparing a health assessment. This document is important for ensuring consistency in reporting among the various health assessments.

On February 13, 1990, ATSDR promulgated final regulations that govern the conduct of health assessments and related health effects studies (42 CFR 90). It is anticipated that ATSDR will issue guidance related to public comment periods for health assessments, public health advisories, and additional health effects studies.

KEY ELEMENTS OF ATSDR HEALTH ASSESSMENTS

Before 1988, the content of health assessments varied because of a lack of formal guidelines. Now that a guidance documentation which addresses

specific reporting requirements has been issued, the health assessments are more consistent.^(a)

Depending on the availability and comprehensiveness of the information contained in the prior studies, the final format of the pre-1988 health assessments may vary in detail. Nonetheless, the following discussion addresses the common elements of health assessments conducted after draft guidance was issued. These elements include

- site characterization
- demographic characteristics
- contaminants of concern
- environmental and human pathways
- human exposure considerations

(a) Agency for Toxic Substances and Disease Registry. Undated draft. "Health Assessment Format, Guidelines and Methodology."

- public health implications
- recommendations and conclusions.

The health assessment report begins with a general *site characterization*. The site characterization may include a brief description of the site, the size of the site, a general description of past and present site operations, a description of the site boundaries, a history of the hazardous waste dumping, and the status of the RI/FS. Also included may be a brief statement describing the geographic and physical characteristics of the site. A list of the documents reviewed during the preparation of the health assessment may also be included.

A separate section of the health assessment addresses the *demographic characteristics* of the area surrounding the facility. Information may include the size of the town (number of residents within various distances from the site), the sources of drinking water, and the number of private and residential wells.

The *contaminants of concern* located on site are listed in the assessment. Using screening values, ATSDR determines whether a contaminant poses a potential threat to the public beyond the boundaries of the facility. The information in this section includes the media in which the contaminant was found and the concentration ranges. If possible, the contaminants are classified as onsite or off-site contaminants. This section may also address the migration of contaminants offsite. If available, a list of the state recommended allowable limits for the contaminants and their background concentration levels will be included. A brief statement that addresses the presence or absence of physical hazards is also incorporated in this section.

The subsequent section of a health assessment involves the *identification of the environmental and human pathways*. The purpose of this section is to evaluate the potential for contaminants to migrate to humans and to assess the possibility of humans being exposed via specific pathways. The contaminated media, the environmental pathways, and the site-specific factors that influence the migration of

the contaminants are addressed in this section. Environmental pathways include groundwater, surface water, soil, air, and irrigation practices. Human pathways identified in the health assessments are consumption (drinking and eating), dermal absorption, ingestion, inhalation, and bathing.

The purposes of the section that address the *evaluation and discussion of the human exposure consideration* are to determine the significance of the exposures to humans and to assess whether other studies or research is necessary to make a final assessment. Examples of some of the topics that have been mentioned in this section include an evaluation of volatile organic compound (VOC) concentrations in a quarry, air emissions from a landfill, status of the offsite contamination, nearby hunting and fishing practices, and the possibility of exposure to onsite workers and the community. If not provided previously, an estimate of the population surrounding the facility is provided. Subgroups or sensitive populations that may be at a potentially higher risk than the general population are identified. In general, this section integrates and discusses the site characteristics, environmental pathway(s) and human exposure pathway(s).

After information about the site, the contaminants of concern, and the potential for human exposure has been integrated, a statement of the *public health implications* of the site is formulated. A range of implications may be identified (e.g., no public health implications, public health concern, insufficient information to provide an assessment).

Recommendations and conclusions are made in the final section of the health assessment. If it is determined that additional data are needed to completely characterize a site, specific steps are recommended. For example, recommendations may be made to conduct additional groundwater monitoring, to characterize the extent of the groundwater contamination, to restrict access to the site, or to conduct an epidemiological study. Because many of the preliminary health assessments are conducted before the RI/FS is completed, a frequent recommendation in this section is completion of the RI/FS.

SUMMARY PAGE INFORMATION FROM HEALTH ASSESSMENTS THAT IS CRITICAL TO OEC

The summary page is intended to capture key information that can be extracted easily from health assessments and that will be most beneficial to OEC as it reviews health assessments for DOE sites.

The summary page will also allow OEC to ascertain the degree of consistency in the conclusions and recommendations made among sites with similar issues and contaminants as those found at DOE sites. For example, OEC may be reviewing a health assessment for a DOE site where chromium was a concern. OEC may then want to access and identify other sites where chromium has been detected. By consulting the summary pages, the OEC can review the concentration of the chromium, the public health implications, the conclusions, and the recommendations for those sites.

Health assessments were reviewed and evaluated for their agreement with ATSDR guidance documentation. Although not all health assessments completely adhered to the guidance material, major consistent elements were identified. A list of these major elements and the types of information found in guidance documentation and health assessments was recorded and used in the design of a summary page.

To test the design and the value of a summary page, a prototype was constructed for the 100 Area on the Hanford site. This prototype is shown in Figure 4.

The summary page begins with the title of the site, as it is identified in the NPL list. This is necessary because some large and complex sites may have more than one health assessment. For example, four separate areas of the Hanford site are listed on the NPL. As a result, four separate health assessments will be performed. Other information on the site summary page includes the location of

the site (city and state), the type of health assessment completed (full or preliminary), the date DOE received the health assessment, the date the site visit began, the names of the agencies responsible for preparing the health assessment (ATSDR or state), and a listing of the sources of information consulted during preparation of the health assessment.

Demographic information is given to indicate the potential for human exposure to the contaminants. The population within various distances from the site may be identified. The year of the census data is indicated in parentheses.

The presence or absence of physical hazards is indicated in the health assessment and is included on the summary page. The hazard or the measures taken to mitigate the public exposure to the hazard are briefly described.

The next section of the summary page categorizes the contaminants of concern. Contaminants are categorized according to their proximity to the site and whether they are onsite contaminants or offsite contaminants. At some facilities, a contaminant may have been detected both onsite and offsite. (It is important to emphasize that ATSDR may identify a compound by numerous names. For example, methyl chloroform is also known as 1-1-1 trichloromethane and TCA. Synonyms become important when comparisons or trends are to be developed among numerous summary sheets.)

Also included in this section are the concentrations of the contaminants and the environmental pathways in which they were detected. For example, concentrations for the Hanford 100 Area were recorded in various ways: ranges, discrete variables, non-significant (NS), or not available (NA). Although screening values exist for water, soil and air, some contaminants were reported as NS in the Hanford 100 Area health assessment and were reported to be below the DOE derived concentration guides. Although the screening values assist in

NPL Site: Hanford 100 Area
DOE Facility: Hanford Reservation
Location: Richland, Washington

Assessment Type: Preliminary Health Assessment
Date Received by DOE: _____
Date Site Visit Began: April 17, 1989

Agency(s) Conducting HA: ATSDR/State of Washington
Documents Viewed: 1987 Environmental Monitoring Report
1987 Westinghouse Hanford Environmental Surveillance Report

Demography: 340,148 within 50-mile radius (1980); 6,270 within 20-mile radius; 251 within 10-mile radius
Physical Hazards: No physical hazards. Radiation zones are controlled. DOE ground and air forces.

ON -SITE CONTAMINANTS:

Contaminants	Concentration	Pathway
Nitrates	636 - 592,000 ppb	Groundwater
Chromium	<10 - 1,610 ppb	Groundwater
Carbon tet	2 ppb	Groundwater
Mercury	NA	Groundwater
Strontium 90	NA	Groundwater
Manganese-54	NS	Air
Cobalt-60	NS	Air
Ruthenium-103	NS	Air
Iodine-131	NS	Air
Cesium-137	NS	Air

OFF-SITE CONTAMINANTS:

Gross alpha-beta	NS	Surface water
Strontium-89/90	NS	Surface water
Tritium	NS	Surface water
Uranium species	NS	Surface water
Cobalt-60	NS	Surface water
Iodine 129/131	NS	Surface water
Niobium/zirconium-95	NS	Surface water
Iron	8 ppb (NS per state)	Surface water
Chromium	<7 ppb (NS per state)	Surface water
Dissolved oxygen	11.3 ppm (NS per state)	Surface water

HUMAN EXPOSURE PATHWAYS:

Pathway	Source
Ingestion	Surface water
Ingestion	Food chain
Dermal absorption	Surface water
Inhalation	Soil

PUBLIC HEALTH IMPLICATIONS:

ATSDR believes this site may have posed a public health risk in the past. Until past documentation becomes available, ATSDR cannot adequately address this location. When additional data from the RI/FS become available, it will be incorporated into the health assessment.

CONCLUSION:

Current information is not sufficient to adequately assess the pH concerns associated with this area. Wastes generated by the facility have entered the atmosphere and the Columbia River, possibly resulting in past exposures to the downstream populations. ATSDR views the site as being potentially hazardous to onsite remediation workers. Because of the remoteness and security associated with the 100 Area, ATSDR does not consider this location to be a hazard to an inadvertent intruder.

RECOMMENDATIONS:

1. Complete the RI/FS.
2. Richland City, State of Washington, USGS, and DOE should continue monitoring the groundwater and public water.

During the course of the RI, the following monitoring should occur onsite and offsite:

1. Continuous air monitoring for radionuclides and hazardous materials, including heavy metal analysis.
2. Sampling of biota (aquatic plants and animals, dairy products, food crops).
3. Sampling of river sediments along the Hanford Reach for the presence of radioactive and hazardous materials.

STATUS OF IAG:

Figure 4. Prototype ATSDR Summary Page for the Hanford 100 Area

determining the potential for adverse effects, they are not designed to be used as cut-off or trigger levels.^(a)

Three categories of major environmental pathways were reported: groundwater, air and surface water. Additional pathways may include surface soil, subsurface soil, food chain, or sediment.

The summary page also identifies and links the human exposure pathways (inhalation, dermal absorption, ingestion) to the environmental pathways. The public health implications of the site on the local community and the conclusions and final recommendations in the health assessment are noted.

The final sections of the summary page contain the actions that ATSDR recommends be taken by local, state or federal agencies. The last entry on the summary page is a statement of the status of the IAG between DOE and ATSDR that defines the specific responsibilities of each agency regarding health-related activities at the specific DOE site. Figure 5 is a conceptual design of the information contained in the summary page.

RELATIONSHIP OF ATSDR HEALTH ASSESSMENT TO OTHER STUDIES

An increasing number of health-related studies are being undertaken at DOE facilities. A knowledge and understanding of the site-specific health studies would assist OEC in its oversight role. Information contained in the studies would enable OEC to identify and assess inconsistencies among studies for the same site. In addition to site-specific studies, contaminant-specific information may also be useful to OEC staff. Some studies and other information that may be of value to OEC are listed below.

(a) Agency for Toxic Substances and Disease Registry. Undated draft. "Health Assessment Format, Guidelines and Methodology."

- *Endangerment Assessment* - This is the initial assessment conducted to determine whether there is an imminent and substantial endangerment to public health from activity associated with a site. Information contained in the endangerment assessment serves as baseline information for the EPA risk assessment completed during the RI/FS process (i.e., identification of hazardous wastes, exposure assessment, toxicity assessment, characterization of human risks and/or environment) (EPA 1989).
- *EPA Risk Assessment* - EPA risk assessments are quantitative studies that use statistical and biological models to determine the health risks associated with a compound. Risk assessments are used in the selection of an appropriate site remediation strategy.
- *Health Consultation* - A health consultation is an ATSDR response to facility-specific or substance-specific inquiry. A consultation is a more limited response by ATSDR than that provided in a health assessment (ATSDR 1989).
- *Other ATSDR Studies* - Other studies conducted by ATSDR may include health effects studies, epidemiological studies, and health surveillance studies.
- *Toxicological Profiles* - ATSDR is required to prepare toxicological profiles for 275 of the most hazardous substances found at Superfund sites. ATSDR has finalized the first 25 profiles and issued an additional 25 draft profiles (Siegel 1990).
- *Other Studies* - The National Institute of Health and other federal and state agencies support various types of health-related research.
- *TOXNET* - TOXNET is a database of potentially hazardous chemicals. The National Library of Medicine (NLM) operates the database. Some of the on-line databases accessed through TOXNET are

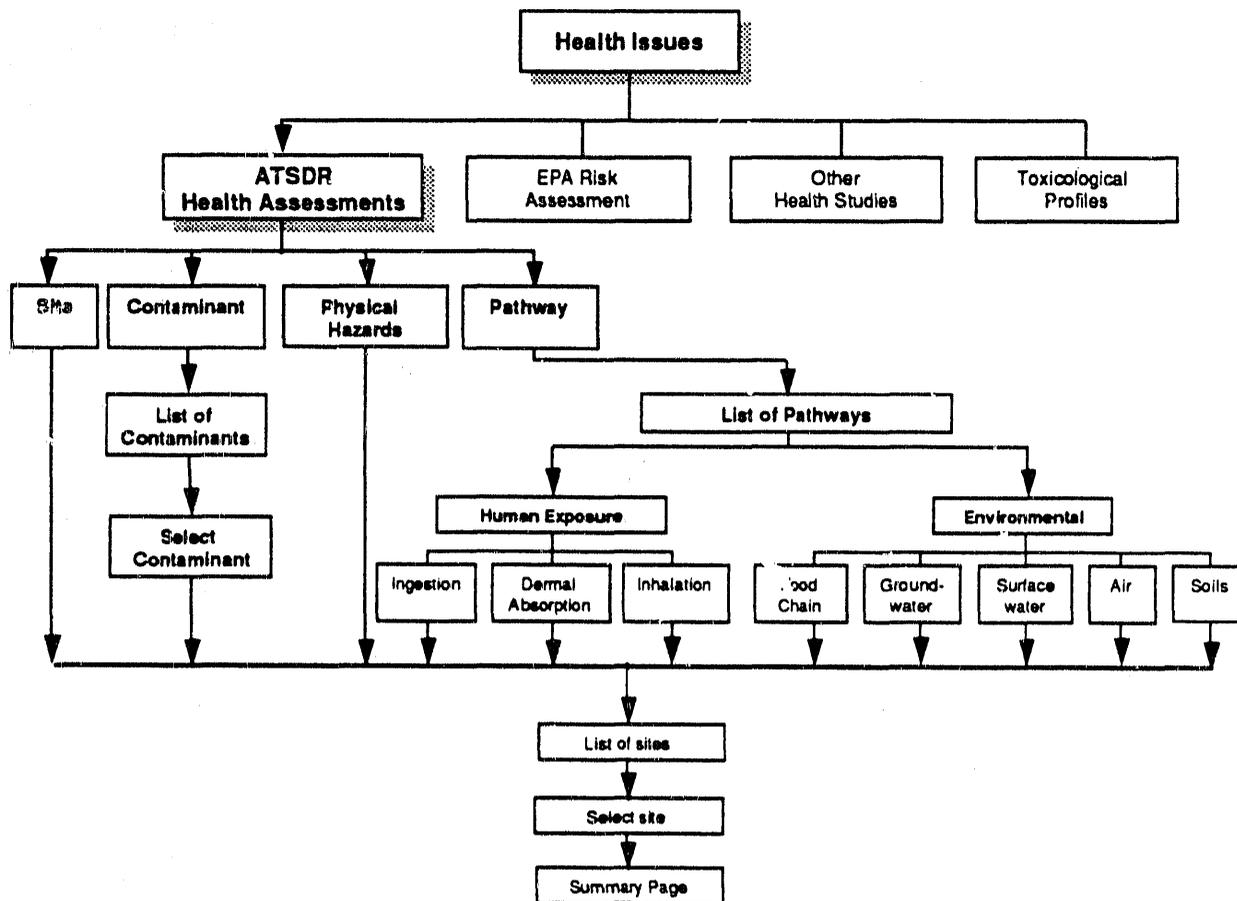


Figure 5. Possible Topics Contained Within the Health Issues Category of the OEC Prototype Summary Page

1. *Registry of Toxic Effects of Chemical Substances (RTECS)* This database includes acute and chronic toxicity data for 91,000 compounds. This database is maintained by the National Institute of Occupational Safety and Health.
2. *Hazardous Substances Data Bank (HSDB)* This data bank includes toxicology data on over 4200 compounds. It includes regulatory requirements and information on environmental fate and human exposure.
3. *Chemical Carcinogenesis Research Information System (CCRIS)* This database includes information from the National Cancer Institute on 1200 chemicals.
4. *Environmental Teratology Information Center Backfile (ETICBACK)* Bibliographic information on teratology and reproductive toxicology is contained in this database.

3.0 REFERENCES

Agency for Toxic Substances and Disease Registry (ATSDR). Undated. "ATSDR Biennial Report to Congress," Vol. 1. Atlanta, Georgia.

Agency for Toxic Substances and Disease Registry. 1989. *Annual Report for FY 1988*. Atlanta, Georgia.

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980. 42 USC 9604 et. seq.

42 CFR Part 90 5136-5141. February 13, 1990. Agency for Toxic Substances and Disease Registry, Public Health Service, Department of Health and Human Services. Final Rule. *Health Assessments and Health Effect Studies of Hazardous Substances and Facilities*.

Geffen, C. A., B. A. Garrett, C. E. Cowan, M. R. Siegel and J. F. Keller. 1989. *Remediation of DOE Hazardous Waste Sites: Planning and Integration Requirements*. PNL-6972, Pacific Northwest Laboratory, Richland, Washington.

Pacific Northwest Laboratory. Undated. "Environmental Restoration Information System." Informational pamphlet from the Vertical Integration of Science, Technology, and Applications (VISTA) project. Richland, Washington.

Siegel, M. R. 1990. "Integrating Public Health Into Superfund: What Has Been the Impact of the Agency for Toxic Substances and Disease Registry." *Environmental Law Reporter*, p. 10013-10020.

U.S. Environmental Protection Agency (EPA). October 1986. "Superfund Public Health Evaluation Manual." OSWER Directive 9285.4-1, Office of Emergency and Remedial Response, U.S. Environmental Protection Agency, Washington, D.C.

U.S. Environmental Protection Agency (EPA). March 11, 1987. "Guidance for Coordinating ATSDR Health Assessment Activities with the Superfund Remedial Process." OSWER Directive 9285.4-02, Office of Solid Waste and Emergency Response, U.S. Environmental Protection Agency, Washington, D.C.

U.S. Environmental Protection Agency, Office of Emergency and Remedial Response. December 1989. "Risk Assessment Guide for Superfund, Vol. 1, Human Health Evaluation Manual (Part A)." Interim Final. Washington, D.C.

END

**DATE
FILMED**

6/18/92

