United States Environmental Protection Agency

Office of Solid Waste and Emergency Response

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TITLE: GUIDANCE FOR COORDINATING ATSDR HEALTH ASSESSSMENT ACTIVITIES INTO THE SUPERFUND REMEDIAL PROCESS

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OSWER Directive Initiation Request

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2. Originator Information

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3. Title

Guidance for Coordinating ATSDR Health Assessment Activities with Superfund Remedial Process

4. Summary of Directive (include brief statement of purpose)

Provides Guidance to support STSDR in meeting health assessment requirements as outlined in Section 110 SARA; summarizes EPA response activities for which consultation with ATSDR may be requested and outlines ATSDR's management process for citizen petitions.

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This Request Meets OSWER Directives System Format Standards.

9. Signature of Lead Office Directives Coordinator	Date
Richard Hyde	3/11/87
10. Name and Title of Approving Official	**Date**
Henry L. Longest II	3/11/87

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GUIDANCE FOR COORDINATING ATSDR HEALTH ASSESSSMENT ACTIVITIES INTO THE SUPERFUND REMEDIAL PROCESS

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INTRODUCTION

The Superfund Amendments and Reauthorization Act (SARA) mandates that the Agency for Toxic Substances and Disease Registry (ATSDR) perform specific public health activities associated with actual or potential exposure to toxic substances identified at hazardous waste sites. Although this mandate covers a wide range of health-related activities, this document focuses on the specific requirement that ATSDR conduct a health assessment for each site on, or proposed for inclusion to, the National Priorities List (NPL) (§110(6)(a)). Health assessments are to be completed by December 10, 1988 for those facilities proposed for inclusion prior to October 17, 1986 and within a year of the date of proposal for those facilities proposed for inclusion after October 17, 1986. Furthermore, SARA directs ATSDR to consider NPL schedules and the needs of EPA pursuant to remedial investigations and feasibility studies (RI/FS) when determining its priorities, and to complete health assessments "promptly" and to the "maximum extent practicable" before completion of the RI/FS.

Purpose of Document

The purpose of this document is to (1) provide guidance to support ATSDR in meeting its health assessment requirements as outlined in Section 110 under SARA, (2) summarize the various EPA response activities for which consultation with ATSDR may be requested and (3) outline ATSDR's management process for citizen petitions. The new health assessment requirements will necessitate the exchange of information and data on sites between ATSDR and EPA and will require continual coordination to address priorities and to clarify schedules for performing health assessments. The procedures outlined in this document are intended to facilitate the completion of health assessments in a timely fashion and to minimize potential delays in the remedial process (see Appendix 1.0 for a summary of this process). This document is intended for use by EPA Remedial Project Managers (RPMs), ATSDR Regional Representatives (RRs) and other parties participating in the health assessment process.

Outline of Document

The first two sections of this document briefly describe EPA risk assessments and ATSDR health assessments. Section 3.0 outlines the procedures for coordinating EPA's remedial activities with ATSDR's health assessment activities and clarifies the roles and responsibilities of each agency. Section 4.0 summarizes those additional support activities provided by ATSDR upon request from EPA. The last section outlines ATSDR's management process for citizen petitions.

1.0 EPA RISK ASSESSMENTS

EPA is responsible for conducting quantitative risk assessments (i.e., the public health evaluation and endangerment assessment) which characterize the nature and magnitude of potential risks to human health and the environment from exposure to hazardous substances, pollutants or contaminants released from specific sites. This process is initiated during the RI and consists of an evaluation of the nature and extent of contamination, the potential pathways of human exposure, and a comparison of expected human exposure levels with recommended exposure levels. The results of the public health evaluation are reported in the feasibility study and the analysis of remedial alternatives. EPA risk assessments are prepared by scientists from a variety of fields (e.g., toxicology, hydrology, chemistry); the complexity of an assessment depends upon site-specific factors such as the number and type of chemicals present; the number and complexity of exposure pathways; and the availability of appropriate standards and/or toxicity information.

2.0 ATSDR HEALTH ASSESSMENTS

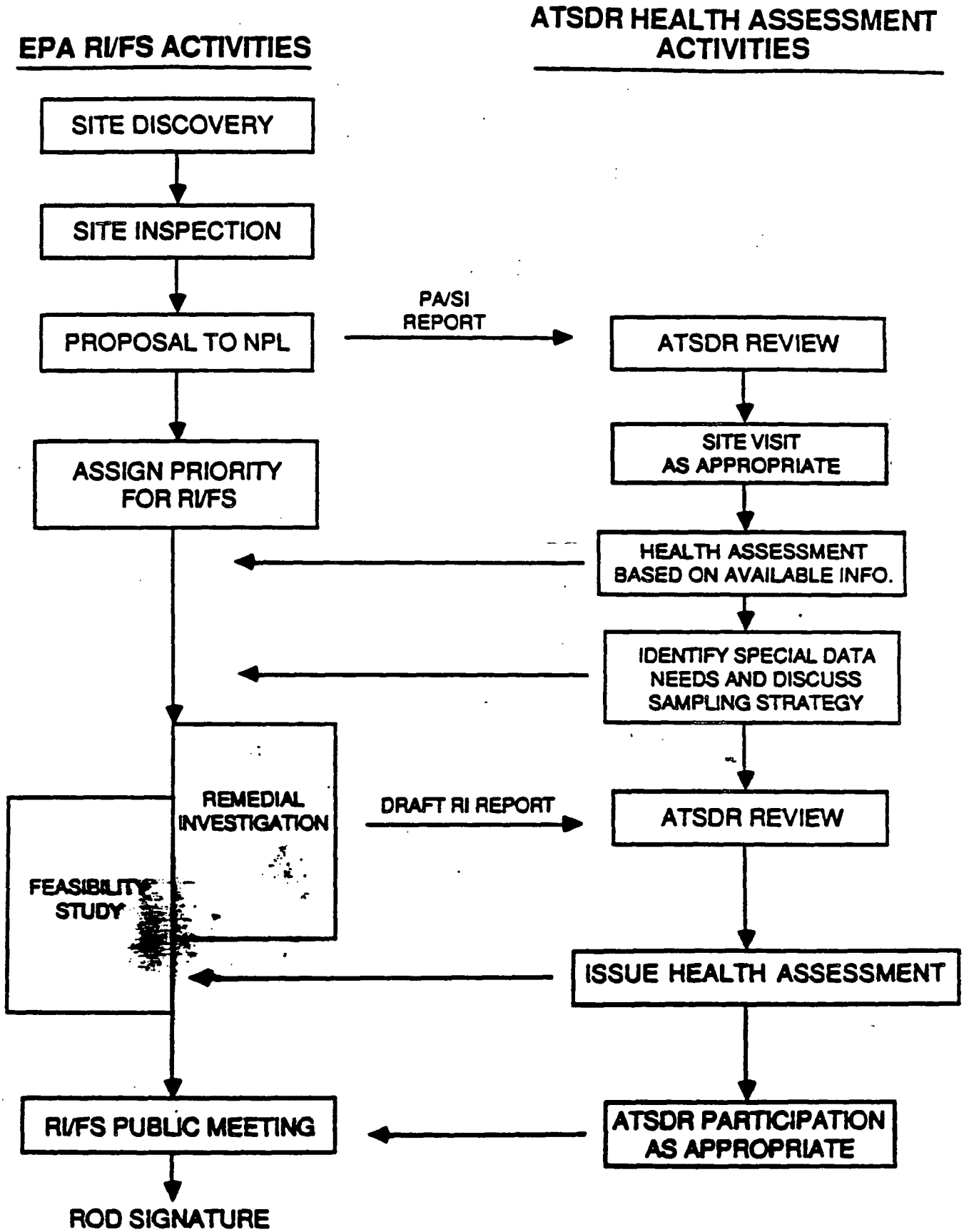
ATSDR health assessments are qualitative assessments of the potential risks to human health posed by individual sites. The ATSDR health assessment is performed by a multi-disciplinary team (e.g., physicians, toxicologists, public health specialists, etc.) and consists of reviewing environmental sampling data and other site-related information (e.g., remedial investigation reports, risk assessments) available from EPA. These data are evaluated to (1) assess whether any current or potential health threat exists; (2) to develop health advisories as necessary; and (3) to identify studies needed to evaluate human health effects. The ATSDR assessment will serve to assist EPA in determining whether immediate actions (e.g., provision of alternate water supply, relocation of individuals) are necessary to reduce human exposure. The format for ATSDR health assessments is provided in Appendix 2.0.

3.0 EPA/ATSDR COORDINATION IN THE REMEDIAL PROCESS

The purpose of this section is to outline the health assessment process and discuss the procedures by which ATSDR will obtain the necessary information to complete health assessments for NPL sites. Under these procedures, ATSDR is to review information and participate in technical project briefings at specified points in the RI/FS process (Figure 1). ATSDR has assigned personnel to each of the ten EPA Regional Offices to facilitate interaction with EPA. (See Appendix 3.0 for a listing of the current assignees and telephone numbers.)

FIGURE 1

ATSDR/EPA INTERFACE



3.1 Overview of the Health Assessment Process

In determining the priority in which to conduct health assessments, SARA directs ATSDR, in consultation with EPA, to give priority to those facilities at which there is documented evidence of the release of hazardous substances and where the potential risk to human health appears highest. Furthermore, Congress has directed ATSDR to complete health assessments promptly, and to the maximum extent practicable, before completion of the RI/FS, and to consider NPL schedules and EPA needs pursuant to RI/FS schedules.

Because of the need to consider the congressionally mandated schedules for completing health assessments and EPA remediation schedules, the first task in the process will be to establish priorities among sites. This prioritization process consists of two concurrent acivities: (1) an ATSDR review of all NPL sites to identify those that have no prior ATSDR review/recommendation; and (2) EPA orderly submission of sites to ATSDR based on EPA remediation schedules (discussed in the following section). EPA and ATSDR will work together to establish priorities for all sites. Sites posing an imminent health threat (i.e., evidence of significant acute or chronic exposure presently occurring) will receive the highest priority. Sites not posing an imminent health threat will be prioritized according to EPA remediation schedules.

Due to the scheduling requirements for completing health assessments (refer to Table 1.0) and the number of sites in the various stages of the remedial process, there will be varying amounts of data available for specific sites on which to base the health assessment. For sites where only preliminary assessment (PA) and site inspection (SI) data are available, a subsequent assessment may be performed once the remedial investigation report is completed. Therefore, coordination between the RR and RPM will be needed to assure that data and information are provided at appropriate times and arrangements made to procure and transmit new information when necessary.

Due to the large number of sites presently on the NPL and the short time frame allotted to complete health assessments, the status of health assessments will be tracked and updated through CERCLIS, a national database that contains information on all potential hazardous waste sites including information on Superfund removal, remedial, and enforcement activities. These updates are intended to serve both a managerial and tracking function and to assure that health assessments are completed in a timely fashion while avoiding unnecessary delays in the remedial process. Updates to CERCLIS should indicate specifically whether a health assessment has been completed or whether additional data/information is needed. The RPM and RR will coordinate and track the status of ATSDR data requests.

Table 1

INITIAL ATSDR HEALTH ASSESSMENT DEADLINES

NPL PROPOSAL DATE	ATSDR HEALTH ASSESSMENT DEADLINE
Update 6 - January 1987	January 1988
Update 7 - September 1987 (planned)	September 1988
NPL Sites Proposed prior to October 17, 1986	December 1988

3.2 Prioritization of Sites

The prioritization approach presented below reflects EPA's desire to have health assessments completed at sites prior to the signing of RODs and to assure that all health concerns are adequately addressed prior to initiating last operable unit response actions. Although this approach should be followed to the extent practicable, sites posing an imminent health threat (i.e., evidence of significant acute or chronic exposure presently occurring), regardless of their stage in the remedial process, constitute the highest priority and therefore, would require a more expeditious response. The priorities are as follows:

First Priority — Ongoing Projects -- includes those projects which have an approved workplan and the RI/FS is currently underway or has been completed:

(a) ROD or FS expected within 3-6 months

(b) RD/RA stage (only if last operable unit)

(c) On-going RI/FS

(d) RD/RA stage (other than last operable unit).

Second Priority — New Start Projects -- includes those projects which have not yet begun and/or do not have a finalized workplan:

(a) New RI/FS

(b) No RI/FS (i.e., may not be initiated within the time frame requirement for health assessment).

Third Priority — Completed Projects -- includes those projects where all response actions have been completed other than a long-term response (e.g., 20-year ground water pumping and treatment) and those sites eligible for deletion:

(a) Completed sites eligible for deletion

(b) Long-term response actions (LTRAs)

(c) Deleted sites.

NPL sites should be prioritized in each upcoming quarter by the appropriate RPMs, their Branch Chiefs, and the RR. The RR will then transmit the priority list to ATSDR's Office of Health Assessment for a comparison of priorities among all

Regional submissions. Once sites posing an imminent health threat have been identified, the remaining sites will be ranked according to EPA remediation schedules. Because actual exposure situations are rarely documented upfront, most health assessment priorities will likely be established by remediation schedules.

3.3 Procedures for EPA/ATSDR Coordination (Federal/PRP-lead)

Mechanisms by which ATSDR may interface with the process may vary depending on which organization (EPA, State, PRP, or COE) has lead responsibility for the RI/FS. The primary participants in the coordination process are the ATSDR RR and the EPA RPM. The RPM is the prime coordinator for projects and is responsible for arranging the transfer of information and identifying appropriate contacts in other agencies. The RRs serve as liaisons between ATSDR and EPA and are the principal contact on all ATSDR-related matters.

Because the procedures for addressing a new-start Federal-lead RI/FS offer the most complete scenario and serve as a model applicable to most other situations, they will be discussed first.

New Start Projects -- The appropriate EPA Regional Branch Chief will supply the ATSDR RR with copies of the integrated Superfund Comprehensive Accomplishments Plan (SCAP) on a quarterly basis consistent with the Regional quarterly update. RRs will be responsible for contacting the appropriate EPA RPMs to obtain information on those projects that have been selected for ATSDR action (based upon the prioritization process described in section 3.2).

ATSDR has previously identified the general types of data that will be needed to complete health assessments (see Appendix 4.0). These data should be adequate for the majority of sites investigated, however, both agencies recognize that some sites will require additional data beyond that described in Appendix 4.0. It is important that ATSDR identify such sites and the nature of any additional data required, as early in the process as possible. Therefore the RPM should supply the RR with a copy of the SI report and the Hazard Ranking System information for all sites proposed for inclusion to the NPL. The RR will then be responsible for notifying the RPM of any special data requirements anticipated after reviewing the SI report. This notification should be accomplished by memorandum in a timely manner following receipt of the SI report so the appropriate administrative procedures can be implemented to obtain contract assistance. The memorandum should address the nature of the data required as well as the rationale for justifying the collection of these additional

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data; for potential responsible party lead sites, the additional data would be collected by the PRPs and the RPM would serve as the coordinator between ATSDR and the PRPs.

Through discussions with the RPM, any additional contractor efforts to address these needs should be identified and categorized as a separate task within the RI/FS work assignment. This will allow EPA to identify contract resources expended at the request of ATSDR that are not typically collected in an RI/FS effort. The RPM will manage all contractor efforts and supply the RR with copies of sampling and work plans for informational purposes.

The RPM will issue a copy of the draft RI (when available) to the RR for use in the development of the health assessment. To the extent that they are available at this time, EPA will also provide to ATSDR copies of any site-related risk assessment documents for their use in developing a health assessment. Following review of the RI, a discussion meeting should be held between the RPM and the RR to raise any issues regarding the site.

When feasible and appropriate, the RR will participate in the pre-FS meeting which will cover initial sampling results; proposed remedies to be considered in the FS, and strategies for addressing site remediation. (In the cases where a RI/FS is being conducted by a PRP or Federal agency, the RPM will coordinate meetings.) These discussions will focus on those operable units comprising the final remedy and plans for their implementation. This meeting provides a forum for raising any additional issues or concerns associated with the project and serves as a planning session to update timeframes for future project milestones (including ATSDR schedules for preparing health assessments). Health assessments are to be completed by ATSDR, to the maximum extent practicable, prior to the release of the RI/FS for public comment.

Ongoing Projects -- To ensure that ATSDR is informed of all current RI/FS efforts and projected ROD signatures for that year, EPA Branch Chiefs will provide RRs with a list of all ongoing remedial projects with estimated completion dates (final remedy). Subsequent to receiving this project list, the RR will notify appropriate RPMs (in conjunction with the Branch Chief) to identify and prioritize projects for health assessments. Depending upon the stage of the project, an appropriate schedule for supplying required documents should be arranged between the RPM and the RR. Although health assessments should be completed prior to completion of the RI/FS, in some situations this will not be possible. In such cases EPA and ATSDR should discuss preliminary findings of the health assessment prior to ROD signature. Health assessments are desirable as early as possible and should precede the initial ROD whenever possible. However, the ROD should not

be delayed solely because the health assessment is not complete. RODs for limited site actions (e.g., alternate water supply) may be signed prior to obtaining the health assessment.

If additional data needs are identified by ATSDR, the RPM should issue a work assignment amendment to incorporate the required contractor efforts. This amendment will constitute a separate work task. PRP-lead RI/FSs should be addressed as discussed for newstart projects. In addition, ATSDR will coordinate with the RPM so that qualified persons are hired to supplement ATSDR for oversight of PRP activities.

Completed Projects -- Because ATSDR must complete health assessments for all NPL sites by December 10, 1988, Regional Branch Chiefs are to assemble the appropriate documentation for all completed projects and make it available to the RR in a timely manner. The appropriate Regional staff person to serve as a contact for each respective project should be identified.

3.4 Procedures for EPA/ATSDR Coordination (State-lead)

State-lead projects are administered under different procedures than Federal-Lead projects, however, the same priority approach discussed earlier will be followed. The RPM will serve as the liaison and will arrange for the RR to work with their State agency counterparts. The State will supply all necessary information to the RPM and the ATSDR RR. The RPM will be advised on the progress of health assessments, and notified in the event that additional data are needed. Where contractor support is needed to collect additional data, the State must submit budget and scope amendments to EPA for the cooperative agreement. The RPM and the State will establish procedures for State-lead enforcement sites on a site-by-site basis.

4.0 ATSDR ADDITIONAL SUPPORT/CONSULTATION ACTIVITIES

In addition to the health assessments required by SARA, ATSDR assessments and consultation may be requested for a variety of other remedial-related activities. Other types of consultations that may be requested of ATSDR include, but are not limited to, the following:

- Review and comment on remedial and removal alternatives. This does not include selection of the remedial action (an EPA risk management decision) but can include a review of such action to ensure it adequately addresses public health concerns.

- Review and comment on various documents or papers (e.g., risk assessments, health reports, etc.), prepared by EPA or other involved parties.

- Review and comment on worker health issues. ATSDR, with technical assistance from the National Institute for Occupational Safety and Health (NIOSH), may review site safety plans or address additional concerns such as evaluation criteria.

ATSDR consultation concerning these EPA response-related activities may be requested by Regions in separate memoranda. Because ATSDR responses relevant to selection of response action will become part of the Administrative Record, memoranda should state clearly the type and extent of review that is desired and the time frame in which the response is needed. These requests should be made through the ATSDR RR.

5.0 CITIZEN PETITION FOR HEALTH ASSESSMENTS

SARA permits a private citizen to petition ATSDR to perform a health assessment of a site or an incident. A complete health assessment may not be necessary to address the citizen's concerns, i.e., an ATSDR health consultation may be sufficient to answer the inquiry. It must also be anticipated, however, that sufficient environmental data may not be currently available to provide either a consultation or to perform a health assessment.

The procedures for petitioning ATSDR and the process for responding to petitions will be developed by ATSDR as Federal regulations and promulgated in the Federal Register. This section provides an overview of the process which may be subject to change as the regulations are developed.

5.1 Notification Process

ATSDR's policy is to require petitioners for a health assessment to do so in writing to the Associate Administrator of ATSDR. It is likely that petitioners who are not aware of the formal petitioning procedure may contact the Regional Offices. The ATSDR RRs will inform the petitioner to submit their request for a health assessment in writing to the Associate Administrator of ATSDR.

Citizen inquiries for assistance and/or information may be addressed at the regional level by the ATSDR RR. If such inquiries evolve into a formal petition for a health assessment the petitioner will be advised to submit their petition in writing to the Associate Administrator of ATSDR. Citizens with health concerns who contact the RPMs should be referred to the RR.

5.2. Management of Petitions

Based upon a review of the citizen petition and any accompanying data, as well as current ATSDR priorities and activities, ATSDR will determine whether 1) a health assessment is warranted at the particular site; or 2) the petition can be addressed through some ATSDR activity other than a health assessment; or 3) additional information is required to determine whether a health assessment is warranted. If ATSDR determines that a health assessment is not warranted, it will notify the petitioner of this fact in writing. Should ATSDR determine that additional information is required to decide whether a health assessment is warranted, it will notify in writing the petitioner and seek the additional data from other sources.

If ATSDR decides to conduct a health assessment, it will notify the petitioner and will request data relevant to the site in question from the petitioner, EPA, state or local agencies, or other appropriate parties. In the event that the data necessary to perform a health assessment is not available from other sources, ATSDR may arrange for sampling or additional data gathering at a site for the sole purpose of determining the existence of current or potential health problems at the site. Handling of all additional data requirements will be coordinated by ATSDR's RR (on NPL sites ATSDR's RR will coordinate with the RPM).

If additional environmental sampling is required and/or a full health assessment is warranted, the citizen's petition may not be completely addressed for several months. ATSDR will respond to the citizen in writing, notifying the citizen of what course of action will be followed and when a full response to their request may be anticipated. Other consultation and advice will be provided that could help alleviate their concerns. If ATSDR concludes that a health problem does exist at a site or incident (i.e., actual exposure and/or health effects have been documented), ATSDR will advise the citizen in writing about other public health actions if any are appropriate.

APPENDICES

APPENDIX 1.0

OVERVIEW OF THE REMEDIAL RESPONSE PROCESS

The National Contingency Plan (NCP), the "blueprint" for implementing the Superfund program under CERCLA, defines two specific types of action to respond to releases of hazardous substances.

(1) Removal Action - prompt response to prevent or mitigate harm to human health or the environment. Removals usually must be completed in twelve months or after expenditure of $2 million.

(2) Remedial Response - generally involves a more extensive response than removals with additional outlays of time and money and is intended to achieve a permanent solution to the maximum extent practicable.

Removal actions will, by definition, be accomplished within a short time frame. The remedial response process, however, is more extensive and involves a series of steps. Each of the steps in the process is briefly described below.

Site Identification

Hazardous waste sites are generally identified in one of two ways. Sites come to EPA's attention following the report of a release. These reports may be directed to the National Response Center or the Emergency and Remedial Response Information System which maintains a current listing of those facilities at which hazardous wastes are located. Sites may also be identified as part of ongoing State or Federal hazardous waste site discovery programs.

Site Evaluation

Once a site has been identified, a preliminary assessment is performed to determine the extent of potential release. This preliminary assessment includes the collection and review of all available information regarding the source and nature of the hazardous substances present. A site inspection is then performed which includes sampling, surveying, monitoring and other field activities required to characterize the problem. Data gathered during the site evaluation serves as the basis for the ranking of sites on the NPL.

Initial Planning

The information generated through the site evaluation process is reviewed during the initial planning phase to

determine the scope of prospective remedial activities. The decision as to who will take the lead (PRP, State or EPA) for the remedial investigation and feasibility study (RI/FS) is made at this stage.

Remedial Investigation (RI)

The purpose of the RI is to collect and analyze those data necessary to define the nature and extent of threats to human health and the environment, and to support development and evaluation of alternatives in the feasibility study. During this phase of the process, the initial scope may be revised as additional information is gathered. Typical RI activities include: waste analysis and development of profiles, hydrogeologic investigations, surface/ground water analyses and air monitoring.

EPA's public health assessment and risk assessment are usually initiated during the RI stage. These quantitative evaluations of the potential health threats posed by specific sites are utilized by decision-makers in the final selection of an alternative and to guide them in making risk-management decisions.

Feasibility Study (FS)

The purpose of the FS is to identify and assess those remedial alternatives that would be appropriate for application at a site. Typically an FS involves several steps: development of alternatives, initial screening of alternatives (based on health/environmental, technical feasibility, and cost impacts), detailed analyses of remaining alternatives, recommendation of an alternative and development of a preliminary conceptual design.

Remedy Selection

In selecting remedial alternatives, EPA must consider which remedies are protective of human health and the environment, cost effective, and utilize permanent solutions and alternative technologies to the maximum extent practicable. Remedies must also meet applicable or relevant and appropriate Federal and State standards. Once all requirements are satisfied, a Record of Decision (ROD) is signed to formalize the remedy selection process.

Remedial Design/Remedial Action

The last step in the process is to clearly define the selected remedy and outline the necessary plans and specifications in a bid package (remedial design). After the award of a contract, construction activities necessary to implement the selected remedy begin (remedial action).

Completion/Deletion

Once all of the required response actions as described in the ROD are completed, a site may be classified as a completion (i.e., receives a "C" cleanup status on the NPL). Completed sites undergo a technical evaluation to assure they satisfy the necessary deletion criteria as delineated in the NCP and related guidance before they are deleted from the NPL.

APPENDIX 2.0

ATSDR HEALTH ASSESSMENT FORMAT

Depending on the individual sites, and the extensiveness of the material being reviewed, and the report prepared, the actual health assessment may or may not contain the formal sections presented below, but will usually cover material which would be appropriate in each section.

I. Executive Summary: A one paragraph summary of the report should be provided if the report exceeds several pages.

II. Statement of the Problem
- A. Questions asked by EPA.
- B. Background and history of the project.

III. List of Documents Reviewed

IV. List of Principal Contaminants

V. Environmental Pathways

VI. Human Exposure Pathways

VII. Health Evaluation (Include information on human complaints.)

VIII. Health Effects (Toxicological information on the principal contaminants. Include this if it is a specific question. Otherwise, put it in the discussion.)

IX. Discussion of the Presence of a Health Hazard
- A. Imminent
- B. Chronic
- C. Potential

X. Conclusions

XI. [redacted]endations (In numbered, "bullet" format.)
- [redacted] for immediate action
- [redacted] for long-term action
- [redacted]onal data needs

XII. References

XIII. Attachments (Optional)

XIV. Signature Block
- A. Office Director
- B. Copy to G. Buynoski and H. Longest

APPENDIX 3.0

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Relationship to Nearby Community

- Activities on the site (estimated number of people involved in each activity)
- Records of environmental and health complaints by public about sites
- Estimated frequency of activities on-site (e.g., dirt biking, camping, hunting, fishing, etc.)
- Log of actions taken by State/county health unit at/near site regarding health issues, concerns, complaints, etc.

Data on Environmental Pathways

- Ground water
  - Geologic Profile
  - Map of water table contours and monitoring wells, if any
  - Map showing locations and uses of wells within 2 miles of site
  - Map showing locations and uses of wells within 2 miles of site (within +/- 60 degrees of ground water direction if flow direction is constant)
  - Approximate number of users as source of potable water
  - Average net rainfall and evaporation rate
  - Hydraulic conductivity of saturated zone (estimated or measured)
  - Sampling data and description of sampling survey with summary table
    - Locations of contaminated monitoring wells
    - Contaminant concentrations over time
- Surface Water
  - Indication on site map of 100 year flood plain
  - Stream classifications and water uses downstream from site
  - Sampling data and description of sampling strategy with summary table
- Soil and Sediment
  - Sampling data and description of sampling strategy with summary table
- Air
  - [redacted]nd rose (if available)
  - [redacted]pling data and description of sampling strategy with summary table
  - Subsurface gas migration sampling data
  - Biological sampling data (fish, animals, plants)

Summary of current and historical sampling data for all pathways

Site History

Dates of operation and significant events
Description of prior release and actions taken by EPA to remedy
Description of physical barriers to prevent pollutant transport (i.e:, liners, slurry, walls, fences, dikes)
Current CERCLA/RCRA status of site

Information on quality control/quality assurance

Data Review Summary prepared by EPA Regional staff. This documents the validation of sample holding times, instrument, performance, calibration, blanks, surrogate recovery, matrix spike recovery, and compound identification. It includes documentation of actions taken to resolve data quality problems and an overall case assessment.

For non-CLP data, equivalent information should be provided (see Guidelines for Providing Laboratory Data and Quality Control Information, CEH, CDC)