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Technical Document for Ecological Risk Assessment: Planning for Data Collection

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14. ABSTRACT

This paper presents a condensed version of the Technical Project Planning (TPP) process, focusing on its application to Environmental RIsk Assessments (ERAs) conducted in accordance with EPA Superfund Guidance (USEPA 1997). The TPP Process should be applied any time that data collection is required (for both screening-level and baseline ERAs), and will assist the ecological risk assessor in insuring that the most appropriate data is collected. The TTP process highlights where in EPA's 8-step process TPP can be beneficial, through analysis of existing data to the evaluation of what new data needs to be collected. By emphasizing the planning process, it is expected that the ERA will be useful as a site decision-making tool.

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TPP-Technical Project Planning; Ecological Risk Assessment (ERA); the Army Biological Technical Assistance Group (BTAG); planning for data collection

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INTRODUCTION. Planning and problem identification are critical to the success of an ERA and its usefulness with respect to decision-making. The interface among risk assessors, risk managers, and stakeholders at the beginning of the process, and the communication of risk at the end of the ERA, is critical to ensure that the results of the assessment can be used to support a management decision (USEPA 1998). The characteristics of an ERA are determined by agreements reached by risk assessors and risk managers during the planning process. These agreements include: (1) clearly established and articulated management goals, (2) characterization of decisions to be made within the context of the management goals, and (3) agreement on the scope, complexity, and focus of the ERA, including the expected output and the technical and financial support available to complete it (USEPA 1998).

An interdisciplinary team including, but not limited to biologists, chemists, ecologists, soil scientists, and environmental toxicologists is needed to design and implement a successful ERA and to evaluate the weight of evidence obtained to reach conclusions about ecological risks. The ERA process should be coordinated with the overall site investigation process to the extent possible. Overall site-assessment costs are minimized when the needs of the ecological and human health risk assessments are incorporated into the chemical sampling program (USEPA 1997).

The Technical Project Planning (TPP) Process (USACE 1998) delineated in Engineer Manual (EM) 200-1-2 was developed to focus on data needs and to design quality data collection options. The TPP Process also encourages early refinements of potential data collection options as a means of identifying the most cost-effective options for selection. TPP is a four-phased process, culminating in generation of detailed data quality objectives (DQOs), a detailed cost estimate or Independent Government Estimate (IGE), and a scope/statement of work (SOW) or work plans. Appendix F of EM 200-1-2 (USACE 1998) contains worksheets that can be used for documentation of the process, although use of these worksheets is not mandatory. The important aspect is that the planning process be documented for future use or reference.

The complete document, EM 200-1-2, is available electronically at the following URL:
http://www.usace.army.mil/inet/usace-docs/eng-manuals/em200-1-2/toc.htm
Additionally, a four-page brochure explaining the TPP Process and its benefits can be downloaded at:
http://hq.environmental.usace.army.mil/tools/tpp/tpp.html

This paper presents a condensed version of the process, focusing on its application to ERAs conducted in accord with EPA Superfund guidance (USEPA 1997). The TPP Process should be applied any time that data collection is required (for both screening-level and baseline ERAs), and will assist the ecological risk assessor in insuring that the most appropriate data is collected. Figure 1 shows the four-phase TPP Process and highlights where in EPA's 8-Step process that TPP can be beneficial, through analysis of existing data to the evaluation of what new data needs to be collected. By emphasizing the planning process, it is expected that the ERA will be useful as a site decision-making tool.

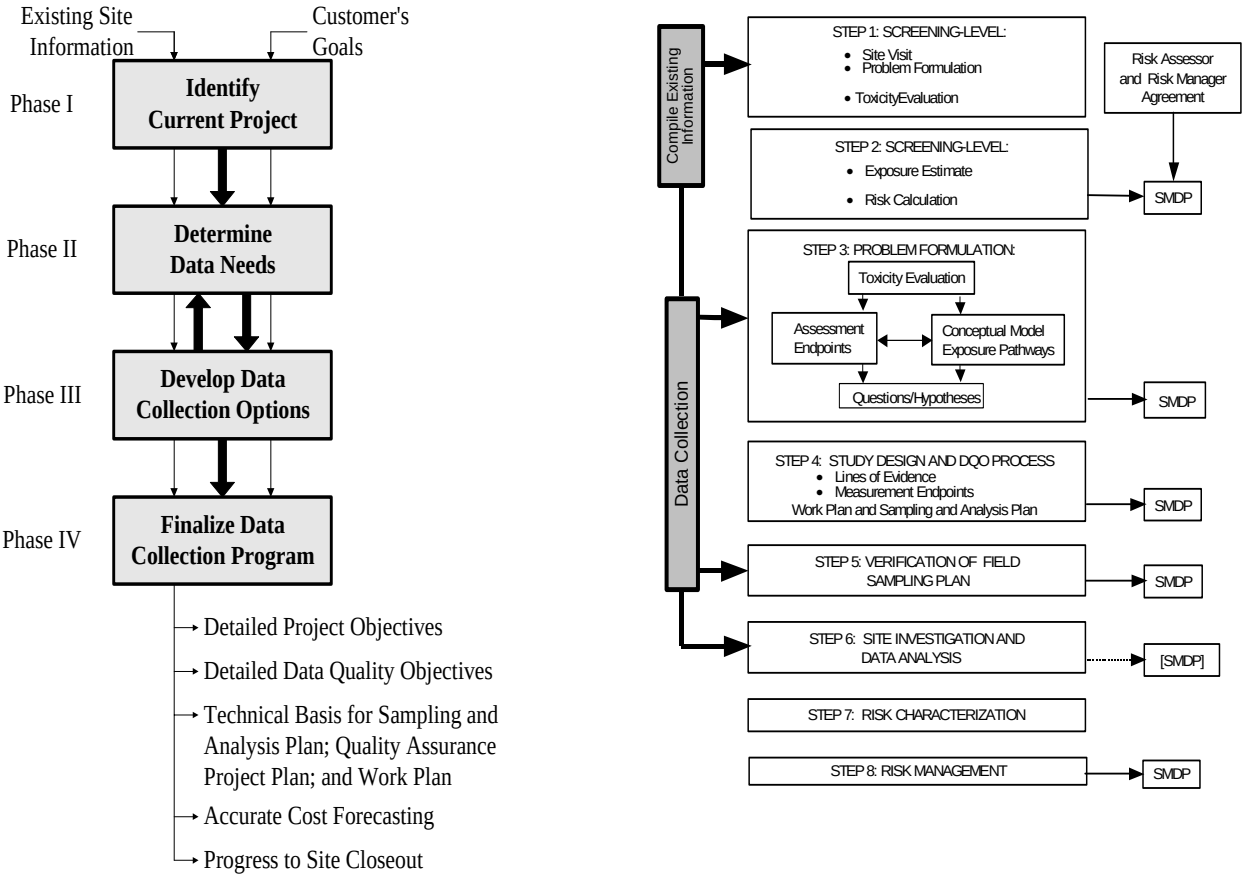

FIGURE 1. THE FOUR-PHASE TPP PROCESS and EPA's 8-STEP PROCESS.

1.0 PHASE I – IDENTIFY CURRENT PROJECT. Phase I activities bring together decision-makers and technical personnel to identify the current project and to document both short- and long-term project objectives through completion of all work at a site. Although Phase I activities are designed to "front-load" conflicts and decision making, the resultant project efficiency more than compensates for the early commitment to proactive planning and communication. The ecological risk assessor is crucial to the development of appropriate site strategy and will identify data needs and the associated quality requirements to support risk management decisions.

1.1 Prepare Team Information Package. A team information package is an informal collection of all existing site information that is compiled for reference by the entire team. Common components of a team information package include these items:

- List of individuals who constitute the multi-disciplinary TPP team for the site;
- The Customer's concept of site closeout;
- The Customer's schedule and budget requirements;
- All correspondence to and from regulators, including an index of the project file or administrative record, if available; and,
- Existing site data, reports, illustrations, or drawings.

1.1.1 Identify TPP Team Members. Progress to site closeout requires collaborative involvement of many technical disciplines and the risk manager(s); the nature and complexity of the project will dictate

the skills, disciplines, and other personnel needed. The remedial project manager (RPM) is responsible for ensuring that all the TPP perspectives are represented within the team. In general, several disciplines of technical personnel will collaborate to represent each of the ***data user*** and ***data implementor*** perspectives for a site.

1.1.1.1 Decision-Makers. Many perspectives of decision-makers are typically associated with a site. The Customer, RPM[1], regulators, and other stakeholders each have specific interests in the outcome of site-related activities. Decision-maker input should be included during all TPP activities and their concerns need to be introduced as early as possible. The most important responsibility of the decision-makers is to participate in the team's efforts to identify and document project objectives during Phase I, including establishing the management goals for the valued ecological resources to be protected.

1.1.1.2 Data Users. Data users are technical and other personnel responsible for engineering, scientific, and legal evaluations that are the basis for site decisions. Data users participate throughout the TPP Process. The four data user perspectives are as follows:

- **Risk Perspective.** Prepares ecological conceptual site model [ECSM]; defines the scope and level of effort for the ERA, based upon Customer needs, limitations, and the management goals identified by the decision-makers; establishes assessment and measurement endpoints; identifies media to be sampled; identifies number and location of samples (both abiotic and biotic); identifies requirements for analytical quantitation limits;
- **Compliance Perspective.** Evaluates, monitors, and ensures legal and regulatory compliance;
- **Remedy Perspective.** Identifies, designs, constructs, operates, and maintains site remediation systems; and
- **Responsibility Perspective.** Focuses on the Customer's liability and apportionment of responsibility with other potentially responsible parties (PRPs); less critical for Installation Restoration Program [IRP] work as other PRPs are normally not involved.

1.1.1.3 Data Implementors. Data implementors are the technical personnel responsible for identifying sampling and analysis methods to satisfy the data users' data needs. Data implementors participate throughout the TPP Process. Several technical disciplines may work together to adequately represent these data implementor perspectives during the TPP Process:

- **Sampling Data Implementor.** Identifies appropriate sampling protocols; and
- **Analysis Data Impelementor.** Identifies appropriate analytical protocols.

1.1.2 Identify Customer Goals. Identifying Customer goals is a critical and deliberate activity within the TPP Process to ensure that the Customer's expectations are understood from the start of the planning efforts. Overall, the Customer's goals are defined by the projected future land use at the site, regulatory compliance, schedule requirements, site budget, stakeholder input, political considerations, and how the ERA will be used to assist in making site decisions.

1.1.3 Gather Existing Site Information. All available existing site information should be compiled and included within the team information package. The following may be included, dependant upon the stage of site activities and the team's experience at the site:

- **Conduct Preliminary Site Visit.** Preliminary site visits should be used to obtain site maps or drawings that depict critical site features (e.g., paved areas, buildings, topography, surface water bodies, critical habitats, etc.)
- **Gather Site Data and Reports.** So that redundant data are not collected, determine and gather all existing site data and reports for reference and use by the team.

[1] Note that in cases where an installation is contracting their own investigations, the Customer and RPM may be the same.

- **Obtain Operations Records.** Obtain historical operations records about the facility or site to understand possible sources and migration paths of contamination.
- **Collect Background Literature.** Collect background literature and obtain other general information (e.g., facility habitat and species information, regional geology and hydrogeology, upstream and downstream NPDES information, local newspaper accounts) for use by the team as necessary. Investigations on nearby sites can often be a source of relevant data.

1.2 Identify Site Approach. Efforts to identify a site approach involve development of an overall strategy for managing a site from its current condition to the desired site closeout condition.

1.2.1 Evaluate Site Information and Data. Individual team members should be tasked to review all of the existing site information and data for the site. Of particular interest to the risk assessor during this review should be the site's physical characteristics; the physical, chemical, and ecotoxicological characteristics of the potential contaminants of interest; the likely transport pathways, and potential receptors.

1.2.2 Prepare Preliminary Ecological Conceptual Site Model. The preliminary review efforts must be sufficient for the ecological risk assessor to develop a preliminary ecological conceptual site model (ECSM). Once drafted, even a preliminary ECSM will help the entire team begin to visually organize all potential current and future exposure pathways at a site, and to identify whether or not they are complete. Those exposure pathways known, or suspected, to be complete need to be represented for the team to efficiently proceed with Phase I of the TPP activities.

1.2.3 Identify and Document Project Objectives. Project objectives are the short- and long-term site issues to be addressed and resolved at a site. Project objectives must be documented to focus the team's thinking toward a specific set of concerns that can be addressed through the planning and completion of an executable stage at a site. Effective planning can only be accomplished when the regulatory requirements are known and understood by the team. Any legally binding agreements (e.g., Federal Facility Agreements [FFAs], Interagency Agreements [IAGs], site compliance orders, permits); applicable or relevant and appropriate requirements (ARARs); and mandatory schedule compliance dates should be identified and reviewed to establish the direction of proposed site activities.

1.2.4 Identify Regulator and Stakeholder Perspectives. The Customer, with support of the RPM and the technical or legal personnel in some cases, needs to solicit and monitor the perspectives of the regulators and other stakeholders during the TPP Process to ensure their needs and concerns are understood. The regulators and stakeholders may have insight relative to requirements for management goals and assessment endpoints, can help establish the significance of risk characterization, and ultimately assist in making risk management decisions.

1.2.5 Identify Executable Stages to Site Closeout. All possible executable stages to site closeout should be identified by the team. The executable stages should be designated from the administrative requirements of the applicable regulatory program (e.g., remedial investigation (RI) under CERCLA).

1.3 Identify Current Project. After developing the overall approach for managing a site from its current condition to the desired site closeout condition, a team can work to identify the current project for a site.

1.3.1 Recognize Site Constraints and Dependencies. Existing site information should be reviewed in the context of the overall site approach to identify constraints and dependencies that may affect project planning and execution.

- **Site related**
  - Access limitations
  - Adjacent property(ies) characteristics/habitats/investigations
- **Administrative**
  - Availability of technical personnel
  - Funding limitations.
- **Technical**
  - Physical considerations – topography; climatology; buildings; pavements; utilities; streams or ponds.
  - Temporal considerations – frozen conditions; low-flow conditions of streams, seasonal variability of ecological receptors.
  - Spatial considerations – depth to aquifer; potential for UXO.
  - Chemical considerations – radioactivity; chemical agent testing/disposal; breakdown products.
  - Field sampling considerations – cross contamination; height restrictions around a flightline; vehicle access; utility availability; field screening techniques.
  - Analytical considerations – quantitation limit requirements, matrix interferences; sample shipment; turn around time requirements; data evaluation procedures.
- **Legal**
  - Applicable or relevant and appropriate requirements (ARARs)
  - Agreements, permits, orders, or notice of violation.
  - Schedules and compliance dates (established within RCRA permits, FFAs, and other types of compliance agreements).

1.3.2 Define Courses of Action for Achieving Site Closeout. It is important to recognize that several options to achieve site closeout may be combined into a single executable stage. Efforts to define project execution options should consider at least these following typical project execution options.

1.3.2.1 Operable Units/Exposure Areas. Operable units are typically associated with suspected source areas or affected media at a site. Exposure areas are typically areas at or adjacent to a site that include a related group of exposure pathways; involve common receptors, similar habitats, and/or overlapping home ranges; and can be easily identified on the preliminary ECSM.

1.3.2.2 Expedited Removal. Removal actions (time critical or non-time critical) and interim remedial actions, or interim corrective measures, can be taken anytime during the CERCLA or RCRA process. Early activities can include source reduction or isolation of contamination to protect critical habitats.

1.3.2.3 Phasing (Series or Parallel). A common project execution option to be considered by the team is phasing site activities, either concurrently or consecutively. Phasing of site investigations can be very important and useful for ERAs.

1.3.2.4 Field Screening and Field Analytical Methods. Field screening and field analytical methods can be useful tools to characterize site contaminants and exposure pathways while reducing analytical costs. Field methods can provide definitive data when used in conjunction with fixed laboratory confirmation.

1.3.2.5 Expedited Site Characterization. Expedited site characterization (ESC) is an execution option that also merits consideration during the TPP Process. Use of an ESC approach utilizes in-field decision making, dynamic work plans, and real-time data acquisition and interpretation.

1.4 Complete Phase I Activities.

1.4.1 Initiate Scope of Work Sections. The RPM should rely on support from technical personnel to initiate introductory-type scope of work (SOW) sections, or work plan components, as appropriate.

1.4.2 Prepare Phase I Worksheet. To complete Phase I activities, a worksheet should be prepared, documenting the team's findings and decisions during Phase I. The RPM and technical personnel should reference portions of the previously prepared team information package, preliminary ECSM, listed project objectives, management goals, and assessment endpoints. The worksheet should clearly document the current project and associated project objectives within the context of the overall site approach for the current executable stage of site activities.

2.0 PHASE II – DETERMINE DATA NEEDS.

Phase II of the TPP Process is designed to ensure that all data needed to satisfy a site's project objectives are identified.

2.1 Determine Data Needs.

Determining data needs is an iterative thought process. As presented in this paper, many technical personnel must collaborate to define what is required to satisfy the project objectives.

2.1.1 Review Phase I Worksheet. The RPM should distribute the Phase I Worksheet and any project objective worksheets to technical personnel involved in Phase II. Data user's efforts to determine data needs should begin with their review of the Phase I worksheet. Review of Phase I information is particularly critical for those personnel not involved in Phase I efforts and for the entire team when some time has passed since Phase I efforts were completed.

2.1.2 Establish Data User's Roles. Efforts to establish data user's roles will help focus all technical personnel on their responsibilities and what is required to satisfy the site's project objectives. The RPM should reinforce the premise that data users must work to identify "basic" data needs of the current project; "optimum" data needs that are cost-effective and prudent to fulfill during the current project for a future executable phase; and any "excessive" data needs specifically requested by someone besides the data users, but not needed by the data users.

2.1.2.1 Risk Data User Perspective. Technical personnel who collaborate to determine risk-related data needs typically have the following roles at a site:

- Evaluate potential risk-based screening levels to ensure appropriate quantitation limits are established for chemical analyses;
- Perform a preliminary determination of hazard or risk to support the decision as to whether further action is warranted, and if proper information exists to make such a determination;
- Prepare a baseline risk assessment or quantitative evaluation of ecological risk to support a determination of whether remediation is required;
- Develop remedial action objectives (RAOs) and cleanup levels, as well as analyses of risk reduction provided by remedial alternatives;
- Evaluate suitability of site controls for mitigating short-term risks associated with remediation; and
- Evaluate monitoring data to determine if the site no longer poses risk and if long-term monitoring can be discontinued.

2.1.2.2 Compliance Data User Perspective. Compliance data users evaluate and monitor satisfaction of legal and regulatory requirements at a site.

2.1.2.3 Remedy Data User Perspective. Remedy data users identify possible alternatives for response actions and design all response action components.

2.1.2.4 Responsibility Data User Perspective. Responsibility data users attempt to define what federal or non-federal entity has responsibility for the site's conditions in the event that any response actions are required. Responsibility-related data needs are typically related to determining federal liability at a site, developing a legally defensible position, creating a cost allocation strategy, defining settlement terms with other potentially responsible parties, or presenting or defending in legal proceedings related to responsibility.

2.1.3 Evaluate Use of Existing Data. Before defining new data needs for a project, data users and data implementors should evaluate the usability of existing data to determine whether additional data are required. Experience has shown that some, if not most existing data may be suitable for qualitative or quantitative uses. The question of whether and how existing data can be used (e.g., in a risk assessment calculation) will require specific evaluations of their usability for each intended use.

2.1.4 Define Data Needs. Efforts to define data needs must focus on establishing data need requirements for each media type, including sampling areas and depths; chemical concentrations of interest; and the number of samples necessary to satisfy the project objectives. While defining data needs, data users should:

- Consider the consequences of unacceptable decisions or decision errors throughout completion of the work at the site;
- Consider how much data is required;
- Consider data collection approaches, including expedited site characterization and field screening approaches;
- Consider the cost of additional data collection in dollars and time; and then,
- Decide how data needs can be balanced within project cost and schedule constraints.

2.1.4.1 Probabilistic/Non-Probabilistic Decisions. As data users define data needs and the number of samples required, they must recognize that both probabilistic and non-probabilistic data needs should be identified, as appropriate, based on intended data uses and the project objectives. If a probabilistic-type data need is identified during this TPP activity, the data user should use Steps 5 and 6 of the USEPA's 7-Step DQO Process (USEPA 2000a, 2000b). Appendix E of the TPP manual (USACE 1998) provides a detailed "crosswalk" to the EPA's 7-Step DQO Process from the TPP Process.

Although a powerful tool, obtaining concurrence among decision-makers regarding probabilistic decisions can be difficult. Application of probabilistic methods can only be accomplished when these three conditions exist:

- A precise study question is defined;
- The Customer and lead regulator are willing to and successful in establishing tolerable limits on decision errors; and
- The support of a qualified environmental statistician is available to work on the project.

When probabilistic methods are either inappropriate or cannot be employed for a data need because the three conditions are not met, data collection planning can be judgmentally based on the expertise of the technical personnel representing the applicable data user perspective.

2.1.4.2 Number of Samples. Each data user is responsible for identifying the number of samples, or the decision logic, required for each data need based on the intended data use(s) and the project objectives. In some cases, the number of samples needed to satisfy an objective (e.g., determining if a contaminant is present) may be based on professional judgment of the technical personnel representing the data user

perspectives for each specific site. In others, data needs should be fulfilled using probabilistic or random sampling. It is important that data users recognize that use of statistical techniques as the basis for designing environmental sampling plans can reduce the number of unnecessary samples taken in the field, and improve the sampling representativeness by quantifying the statistical uncertainty of the sampling design. Inappropriate application of statistics for probabilistic data needs can also result in either the collection of too many or too few samples.

When necessary, in accordance with recommendations within EPA's ***Guidance for Data Useability in Risk Assessment*** (USEPA 1992), risk assessment personnel should indicate the number of samples in terms of classical statistics. Decisions to use classical statistics methods or geostatistical methods must also be based on the intended data use(s) and known or anticipated variability of the data in the environment. USACE has published guidance (USACE 1997) on to the use of geostatistics for environmental applications that may be consulted for additional information.

2.1.4.3 Risk Data Needs. The first step in determining risk data needs is identification of site-specific management objectives for protecting valued ecological resources. In general, valuable ecological resources include those without which ecosystem function would be significantly impaired, those providing critical resources (e.g. habitat, fisheries), and those perceived as valuable by humans (e.g., endangered species and other issues addressed by legislation) (USEPA 1997). No single set of ecological values to be protected can generally be applied. Rather, these values are selected from a number of possibilities based on both scientific and policy considerations. U.S. Army BTAG guidance on the development of site-specific management objectives is being developed.

Based on the above, the risk assessor must establish the appropriate assessment and measurement endpoints for the ERA. Additionally, the risk assessor must determine the level of effort required for the ERA (i.e., how many lines of evidence are required to provide an adequate level of certainty). In assessing risks to environmental receptors, one needs to be able to show a relationship between potentially exposed populations and the chemicals detected onsite. Using the preliminary ECSM, the risk assessor should conceptualize and identify the data needed to address each of the pathways identified as complete and significant for the ERA. It is important to gain regulator and stakeholder input for the selection of assessment and measurement endpoints, as well as how risk characterization will be applied to making risk management decisions.

Taken from USEPA (1998), the following questions should be addressed by the risk assessor to assist in determining the data needs for an ERA:

- What is the scale of the risk assessment?
- What are the critical ecological endpoints and ecosystem and receptor characteristics?
- How likely is recovery, and how long will it take?
- What is the nature of the problem: Past, present and future?
- What is our state of knowledge of the problem?
- What data and data analyses are available and appropriate?
- What are the potential constraints (e.g., limits on expertise, time, availability of methods and data)?
- What are the desired risk characterization methods?

Throughout the planning discussions, the risk assessor should strive to point out potential setbacks, problems, or difficulties that may be encountered in a "real world" situation. Biological sampling programs often entail scheduling constraints (e.g., surveys for endangered species should be conducted in the appropriate season). When special circumstances preclude a full assessment, such circumstances should be explained and their impact on the risk assessment discussed. The risk assessor should also explain the minimum data quality considered to be acceptable, how non-detected concentrations will be

treated, and how medium-specific data will be evaluated or compiled to derive or model the exposure point concentration used in the risk assessment.

Additionally, the risk assessor should identify data that may be required in the future ("optimum" data needs). For an ERA, the risk assessor should consider potential data needed to allow evaluation of additional lines of evidence. It is also very important that the data needed for evaluation of potential risks to human health be identified as well as that required for the ERA. Careful coordination between the two risk assessment data needs will insure that all required data is collected, and that overlapping or redundant data needs are identified (see Section 3.1.2.1).

2.1.4.4 Compliance Data Needs. Compliance data users should compare site conditions or activities with legal and regulatory requirements and standards to determine what is required for site compliance. Potentially applicable regulatory standards are defined by the primary regulatory program and may specify chemical analysis requirements and point(s) of compliance (location and type of samples) used to assess compliance.

2.1.4.5 Remedy Data Needs. Remedy data users define data needed to identify, screen, and analyze possible response action alternatives at a site.

2.1.4.6 Responsibility Data Needs. The technical and legal counsel personnel responsible for defining responsibility data needs will not only be concerned with determining the legal basis for a response action, but also with defining responsibility at a site. Responsibility data users must rely on legal counsel to identify the phase of execution and specific position and negotiation strategies that will affect the identification of responsibility data needs.

2.2 Document Data Needs. Personnel representing data user perspectives are responsible for communicating their data needs so the needs can be incorporated within data collection options developed during Phase III activities.

The critical aspects of documenting data needs can be reduced to the following:

- What data are needed (e.g., contaminant of interest, and media)?
- Who needs the data?
- What is the intended data use(s), including whether the number of samples is fixed, somehow contingent upon field screening results, or is the minimum anticipated by the dynamic decision logic approach defined by the data user?
- What is the reference concentration of interest or other performance criteria (e.g., action level, compliance standard, decision level, design tolerance)?
- Where is the area of interest or desired sampling location(s) and depth(s)?
- What are the desired risk characterization methods?

2.3 Complete Phase II Activities. The technical personnel should review the data needs to ensure that each project objective has been considered and related data need considerations have been made by each applicable data user perspective.

3.0 PHASE III – DEVELOP DATA COLLECTION OPTIONS. Phase III of the TPP Process is designed for planning sampling and analysis approaches that will satisfy the data needs identified during Phase II.

3.1 Plan Sampling and Analysis Approach. Planning the most appropriate sampling and analysis approaches for a site is an iterative thought process, requiring technical personnel to collaborate to determine suitable sampling and analysis methods and develop data collection options for a site.

3.1.1 Review Phase I and Phase II Information. Efforts to plan sampling and analysis approaches should begin with review of the earlier TPP information. Review of Phase I and Phase II information is particularly critical for those personnel not involved in those efforts, and for the entire team when some time has passed since Phase I and Phase II efforts were completed.

3.1.1.1 Review Phase I Worksheet. Review of the Phase I worksheet will refresh technical personnel of the site approach, project objectives, current project focus, and any site constraints and dependencies.

3.1.1.2 Review Phase II Data Needs. Data implementors should review the range of data needs identified during Phase II by the data users. Documentation prepared at the end of Phase II should communicate the intended data uses, the required number of samples, the contaminant concentrations of interest, and the necessary sampling areas or locations and depths. The Phase II documentation should also designate each of the data needs as "basic," "optimum," or "excessive," as well as any opportunities for use of field screening or field analytical methods and ESC approaches.

3.1.2 Plan Sampling and Analysis Approaches. The sampling data implementor should generally lead efforts to first sort and then combine the data needs prior to developing and documenting sampling strategies.

3.1.2.1 Sort and Combine Data Needs. Data implementors should first sort and then combine data needs by media and location. It is important to identify overlapping data needs at a particular location and unique data needs from common locations at a site. When sorting and combining data needs, it is intended that some of the efforts include the following:

- **Balancing Sensitivity Requirements.** When combining similar data needs, data implementors are cautioned to only apply the most stringent or lowest concentrations of interest requirements to those locations designated by the data users based on the intended data use. When balancing sensitivity requirements, data implementors must be sure to effectively communicate and involve the appropriate laboratory personnel to prevent misunderstandings during sample analysis.
- **Meeting Sampling Depth Requirements.** In the instances where some data needs directly overlap each other in location and depths, data implementors should be sure to meet the discrete sampling depth requirements of any data users with unique sampling depth needs.
- **Evaluating Data Need Trade-Offs.** Data need trade-off situations may be discovered where an alternate adjacent sampling location may be acceptable and representative for several data user needs, instead of merely collecting data from several individual but adjacent sampling locations. After consultation with the data users who requested the data, they may agree to reduce the number of samples or increase their concentrations of interest on some data needs to help meet project cost or schedule constraints.

3.1.2.2 Develop and Document Sampling Strategies. Developing the sampling strategy requires a thorough understanding of a site, and all the information generated during TPP Phases I and II. The sampling data implementor should work to ensure that the entire field sampling activity can be conducted within the time allotted on the project schedule and within the project's budget constraints.

3.1.2.3 Develop and Document Analysis Strategies. The analysis data implementor should evaluate the testing requirements, media to be sampled, and chemical and physical characteristics of the contaminants to select the analytical strategy. The analysis data implementor must incorporate a

comprehensive and multifaceted approach to quality assurance/quality control (QA/QC) in order to achieve and document that data quality requirements have been attained for the intended data usage.

3.1.2.4 Refine Plans Within Project Constraints. Data implementors should generate order-of-magnitude cost estimates to determine if the proposed sampling and analysis scheme can be executed within the budget constraints. Data implementors should also evaluate effects of schedule and any temporal constraints that apply to site activities.

3.2 Develop Data Collection Options. After planning sampling and analysis activities, data implementors should work with data users to group the data needs into data collection options for consideration during Phase IV activities.

3.2.1 Basic Data Collection Option. The "basic" data collection option is the data set needed to satisfy the current project objectives. The data collection efforts would produce data that generally meets all the data quality requirements of the data users for ***only*** the current project. The RPM should be advised if planning compromises have been incorporated by the data implementors when existing sampling or analysis methods cannot achieve action levels or concentrations of interest required by the data users, a typical problem when evaluating chemical exposure to ecological receptors. If all the basic data needs for the current project cannot be obtained within budget or schedule constraints, the technical personnel should prioritize the data needs within this basic group of data needs, but not eliminate any data needs at this step in the TPP Process.

3.2.2 Optimum Data Collection Option. The "optimum" data collection option highlights opportunities to collect data needed to satisfy ***future*** project objectives or allow evaluation of additional lines of evidence during the current project. The optimum data collection option includes only those future data needs that the data users believe are good current investments toward potential future work at a site.

3.2.3 Excessive Data Collection Option. This unique group of data needs is those data needs that the data users believe are excessive for the purposes of satisfying both current and future project objectives. The data needs classified as "excessive" will be those specifically requested, imposed, or mandated by others and ***not required*** by the data users.

3.3 Document Data Collection Options. Data implementors' efforts to document project-specific requirements for the basic, optimum, and excessive data collection options are critical for the success of TPP activities and continued progress to site closeout. Critical aspects of documenting the appropriate sampling and analysis methods and data collection options are as follows:

- What data needs are being met;
- What project objectives will be satisfied;
- How many samples need to be collected;
- What sample collection methods need to be used (e.g., discrete or composite samples; sampling equipment and technique; QA/QC samples);
- What sample analysis methods need to be used (e.g., sample preparation; laboratory analysis; method detection limit and quantitation limit; laboratory QA/QC); and
- What technical limitations, cost benefits, and imposed requirements are associated with each applicable data collection option.

4.0 PHASE IV – FINALIZE DATA COLLECTION PROGRAM. During Phase IV, the Customer, RPM and appropriate technical personnel discuss data collection options and finalize a data collection program that best meets the Customer's short- and long-term goals for a site. Communication

and interaction with both the Customer and the regulators are strongly encouraged during Phase IV efforts.

4.1 Finalize Data Collection Program. Finalization of the data collection program will be based on the Customer's preferred combination of meeting the current project objectives ("basic" data needs), obtaining data cost-effectively for future executable stages ("optimum" data needs), and including any "excessive" data needs the Customer chooses to retain.

4.1.1 Prepare Customer Communications. If the Customer was not directly involved in determining the data needs (Phase II) and developing the data collection options (Phase III), then summary information should be provided.

4.1.2 Encourage Customer Participation. The Customer should always be invited and encouraged to participate in design of the data collection program for their site. Regardless of a Customer's level of technical expertise related to the site work, the Customer's participation at this time will facilitate a design that provides maximum Customer satisfaction within the schedule, budget, technical, and regulatory constraints associated with a site.

The RPM or an assigned technical team member should lead the team through this sequence of activities to obtain the Customer's input and to support the Customer's considerations.

- The RPM and technical personnel should recommend to the Customer the basic data collection option and present all elements of the optimum data collection option.
- The uncertainty, costs, and benefits associated with the basic and optimum data collection options should be explained and discussed. Primary considerations should include schedule, budget, technical constraints, regulatory perspective, and site precedents.
- The ecological risk assessor should also identify for the Customer how the ERA will be used to assist in making site decisions:
    - How the data to be collected (the measurement endpoints) relate to the assessment endpoints;
    - How the assessment endpoints relate to the management goals; and
    - How risks will be characterized.
- The RPM and technical personnel should present and explain all elements of the excessive data collection option.
- The TPP team should finalize design of the data collection program by combining the Customer-preferred components of the basic, optimum, and excessive data collection options, as appropriate.

4.1.3 Suggest Regulator Participation. Regulator participation in the TPP activities can reduce the number of technical comments received from the regulators, reduce the time expended to plan and execute work, and increase opportunities for the entire team to be flexible and creative in resolving site problems. In order to achieve regulator acceptance of the data collection program, their input and concerns should be considered.

4.1.4 Consider Participation of Others. In many cases, stakeholder interests and concerns can have a significant effect on decisions made by both the Customer and regulator at a site. If stakeholders are actively interested in site activities, some level of their participation is likely appropriate during this phase of TPP.

4.2 Document Data Collection Program. Documentation of the final data collection program involves preparation of detailed DQOs, finishing the SOW or work plan, and preparing the detailed cost estimate or IGE.

4.2.1 Prepare Data Quality Objective Statements. The DQOs become the formal documentation of the project's data quality requirements. A DQO statement should be prepared for each data need, should be comprehensive, and include each of the following data quality requirements:

- **Intended Data Use(s):**
  (1) Project objective(s) satisfied.
- **Data Need Requirements:**
  (2) Data user perspective(s) (i.e., risk, compliance, remedy, or responsibility) satisfied;
  (3) Contaminant or characteristic of interest identified;
  (4) Media of interest identified;
  (5) Required sampling areas or locations and depths identified;
  (6) Number of samples required (e.g., fixed number or dynamic estimate; probabilistic or non-probabilistic basis); and,
  (7) Reference concentration of interest of other performance criteria (e.g., action level, compliance standard, decision level, design tolerance) identified.
- **Appropriate Sampling and Analysis Methods:**
  (8) Sampling method (e.g., discrete or composite sample; sampling equipment and technique; QA/AC samples) identified; and,
  (9) Analytical method (e.g., sample preparation, laboratory analysis method detection limit and quantitation limit, laboratory QA/QC) identified.

4.2.2 Prepare Final Scope of Work or Work Plan. The team should prepare and finalize the SOW or work plan for the project.

4.2.3 Prepare Detailed Cost Estimate. The RPM should coordinate the efforts of various technical personnel to prepare detailed cost estimates (or an Independent Government Estimate [IGE] for contracted services) for all components of the data collection program.

4.3 Complete Phase IV Activities. The RPM should distribute copies of all data collection program components (e.g., Phase I worksheet; project objective worksheets; data need worksheets; sampling and analysis planning worksheets; summary tables of data collection options; DQOs; final SOW or work plan; and detailed cost estimates) to the Customer and technical personnel, as appropriate.

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The Army Biological Assistance Group (BTAG) is a technical work group that provides the Department of the Army (DA) environmental restoration program managers with technical information, guidance, and recommendations pertaining to ecological risk assessment (ERA) issues at Army environmental sites. The Army BTAG is sponsored and coordinated by the U.S. Army Environmental Center (USAEC), in its role as the Army's Installation Restoration Program Manager, and staffed with experts in the biological sciences, ecological risk assessment, natural resources, and toxicology with proficiency in field sampling, site evaluation and risk analysis techniques. Four Army organizations currently comprise the BTAG – USAEC, the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM), the U.S. Army Corps of Engineers (USACE) Hazardous, Toxic and Radioactive Waste Center of Expertise (HTRW CX), USACE Engineer Research and Development Center (ERDC), and the U.S. Army Edgewood Chemical Biological Center (USAECBC). Technical Chairperson of the BTAG is Dr. Mark Johnson, USACHPPM. The author of this document is Mr. Terry L. Walker, USACE HTRW CX. Technical reviewers are Mr. Matt McAtee, USACHPPM, Ms. Laurie Haines, USAEC, and Mr. Mike White, USACHPPM. This Technical Document for Ecological Risk Assessment is a product of the U.S. Army Biological Technical Assistance Group (BTAG).