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Guidance Manual for the Preparation of Demonstration and Quality Assurance Project Plans for the Verification of Field Characterization and Monitoring Technologies

RESEARCH AND DEVELOPMENT

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Guidance Manual for the Preparation of Demonstration and Quality Assurance Project Plans for the Verification of Field Characterization and Monitoring Technologies

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Notice

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Foreword

This work represents the technical and editorial contributions of a large number of U.S. Environmental Protection Agency (EPA) employees and others familiar with or interested in the demonstration and evaluation of innovative site characterization and monitoring technologies. In the mid-1990s, the EPA National Exposure Research Laboratory, Environmental Sciences Division - Las Vegas first convened a body of experts – the Consortium Action Team – to define the elements of a guidance document. Subsequent discussions and meetings were held to revise and expand the contents. EPA staff from each of the 10 Regions, the Office of Solid Waste and Emergency Response, and the Office of Research and Development participated in this process. This interdisciplinary, inter-programmatic team was convened to ensure that the demonstration procedures articulated were acceptable across the Agency. This collaboration resulted in the development of a 1996 interim guidance document for developing demonstration plans to gain the acceptance of innovative technologies for use in characterizing and monitoring the environment. In 2008, the interim guidance document was revised and updated to create this document which now represents the current approach to development of demonstration/quality assurance project plans for independent performance testing of site characterization and monitoring technologies. For the most part, it relies on the experiences and the evolution of thinking gained over the last 12 years of conducting demonstrations under the Superfund Innovative Technology Evaluation (SITE) Monitoring and Measurement Technology (MMT) and other technology evaluation programs.

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Abbreviations and Acronyms

CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act (a.k.a. Superfund)
CSCT	Consortium for Site Characterization Technology
DER	Data Evaluation Report
DoD	U.S. Department of Defense
DOE	U.S. Department of Energy
D/QAPP	Demonstration/Quality Assurance Project Plans
EPA	U.S. Environmental Protection Agency
ESTCP	Environmental Security Technology Certification Program
ETV	Environmental Technology Verification Program
HASP	Health and Safety Plan
ITO	Independent Testing Organization
ITVR	Innovative Technology Verification Report
MDL	Method Detection Limit
MMT	Monitoring and Measurement Technology
NERL	National Exposure Research Laboratory
ORD	Office of Research and Development
OSWER	Office of Solid Waste and Emergency Response
PE	Performance Evaluation
QA	Quality Assurance
QAPP	Quality Assurance Project Plan
QC	Quality Control
RPD	Relative Percent Difference
RSD	Relative Standard Deviation
SARA	Superfund Amendments and Reauthorization Act
SITE	Superfund Innovative Technology Evaluation
SOP	Standard Operating Procedure
SW-846	Test Methods for Evaluating Solid Waste, EPA Publication SW-846
TSA	Technical Systems Audit
TTEP	Technology Testing and Evaluation Program

Acknowledgements

The 1996 interim guidance document was prepared by Stephen Billets, Eric Koglin, and Gary Robertson of the U.S. EPA National Exposure Research Laboratory (NERL). The interim guidance document served as the basis of this revised and final guidance on the preparation of demonstration/quality assurance project plans. The current document was prepared from the interim guidance document by Battelle under the guidance and leadership of Dr. Billets. EPA NERL thanks Eric Koglin, EPA, and Roger Jenkins, private consultant, for their peer review of this document. EPA NERL also acknowledges the many developers who participated in the Superfund Innovative Technology Evaluation Program who helped to make it a more effective and efficient process, leading to the approaches which are described in this document.

Chapter 1
Introduction

1.1 Purpose and Content of This Guidance Manual

The purpose of this manual is to provide guidance to testing organizations and technology vendors for preparing a demonstration plan for the performance testing of field characterization and monitoring technologies. A carefully developed demonstration plan assures that testing will be performed in a manner that generates the high quality data necessary to verify the performance of the technology. Furthermore, the demonstration plan assures that all appropriate health, safety, regulatory, quality assurance (QA), and environmental concerns related to the demonstration are addressed. This manual provides general guidance on the various aspects of the performance verification process, and specifically how to develop such a plan. Where appropriate, specific examples of how the guidance can or has been implemented by the EPA Superfund Innovative Technology Evaluation (SITE) Monitoring and Measurement Technology (MMT) Program are provided for reference.

Potential users of innovative approaches must be confident that new technologies perform as anticipated. This is particularly important when environmental data are being collected to support important decisions (for example, protection of human health and the environment, remedy selection, risk assessment, regulatory enforcement, or litigation). Typically, most information about the performance of innovative technologies comes from the vendor or developer. However, a user's confidence and willingness to apply an innovative technology is more likely following independent verification by a credible third-party organization. Ideally, the test protocol should be recognized and accepted by EPA. The user community looks to the EPA, because of its regulatory mission, to evaluate innovations that will improve the way the Nation manages its environmental problems. Potential users may find new technologies appealing, but without government acceptance of such technologies, users will often continue to rely on accepted, conventional approaches, whether or not they are the most appropriate or cost-effective.

This guidance document is divided into four chapters. Chapter 1 (this chapter) provides an overview of the purpose of the SITE MMT Program and predecessor and successor programs that were the basis of this guidance. A general description of the technology demonstration process is also provided. Chapter 2 contains a description of how to use this guidance manual, and an introduction to Chapter 3. Chapter 3 provides an example of how to prepare a demonstration and quality assurance project plan (D/QAPP) under the SITE MMT Program. The

guidance is in the form of an annotated outline. Each section of the D/QAPP is identified as a subsection of the chapter. Each subsection contains a short description of the information that should be included in the D/QAPP. The use of this standard structure will facilitate document preparation and may reduce the amount of review time required for plan approval. This approach will also help, if there is an EPA point of contact or a technical expert involved, to provide timely assistance to the plan authors. References are provided in Chapter 4.

A note regarding the types of technologies applicable to this guidance is warranted here. Site characterization and monitoring instruments can include a diverse assortment of technologies. These can range from test kits (e.g., enzyme linked immunosorbent assays) to field portable instrumentation (e.g., x-ray fluorescence spectrometers). Most, if not all, of the demonstration plan elements described in Chapter 3 will be applicable to all types of technologies. However, there are often special conditions and concerns that are unique to a particular type of technology. These should be addressed on a case-by-case basis following the framework presented in Chapter 3.

1.2 Evolution of the SITE MMT Program

A historical account of the evolution of the SITE MMT Program has been documented.[1] The U.S. Congress enacted the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), commonly known as Superfund, in 1980.[2] The creation of this law provided broad federal authority to respond directly to releases or threatened releases of hazardous substances that might endanger public health or the environment. The 1986 Superfund Amendments and Reauthorization Act (SARA) amendments to CERCLA provided legislation which mandated EPA, through its Office of Solid Waste and Emergency Response (OSWER) and Office of Research and Development (ORD), to create the SITE Program. Prior to enactment, the draft legislative language focused only on remediation, but the pressing need to test field analytical measurement technologies prompted EPA to recommend the expansion of this legislation to include monitoring. This led to the formation of the MMT arm of the SITE Program.[3]

Technical staff in EPA's ORD National Exposure Research Laboratory, at the Environmental Sciences Division facility in Las Vegas, Nevada, managed the MMT Program since its inception. The early years of the program (1986-1992) focused solely on EPA ORD-sponsored projects, by evaluating the performance of field monitoring technologies that were developed as part of ORD contracts or cooperative agreements. These demonstrations were viewed as an extension of the research which provided an opportunity for additional testing of the monitoring device. In 1995, on the 25th anniversary of the first Earth Day, the president announced a new environmental technology strategy, *Bridge to a Sustainable Future.* This government-wide strategy recognized that industry is the primary creator of new technology and the main engine of sustained economic growth. It assigned to government a catalytic role in promoting the development of new technologies across a range of environmental sectors. It became clear that the objectives of the MMT Program were shared by the U.S. Department of Defense (DoD) and the U.S.

Department of Energy (DOE). On this basis, EPA integrated the MMT Program into the Consortium for Site Characterization Technology (CSCT). The CSCT brought federal agencies with a common need for faster, cheaper, and better monitoring technologies together with end-users of these technologies to facilitate unbiased, third-party performance verification testing.[4] In 1995, the CSCT and a newly formed EPA program called the Environmental Technology Verification (ETV) Program[5] collaborated jointly on technology verifications. The CSCT was one of 12 pilot programs under ETV. Some of the other ETV pilot programs included air pollution control, drinking water systems, and greenhouse gas emission technologies. During this period, the SITE MMT Program, through the CSCT and the ETV Program, was leveraging resources to verify monitoring and site characterization technologies. The collaboration ended in 1999 with the SITE MMT Program focusing on soil and sediment technologies that could be applied to Superfund sites (more closely related to the original mission), while the ETV Program focused primarily on monitoring technologies for air and water.

The SITE MMT Program was not the only pathway for developers and users of new and emerging monitoring, measurement, and site characterization technologies trying to gain acceptance or commercialize a technology. However, the Program attempted to fill many technical and institutional needs. These included:

- Providing a sound scientific basis for demonstrating and evaluating technology performance;
- Facilitating acceptance of innovative technologies by state, local, and federal regulators;
- Supporting the implementation and use of verified technologies;
- Identifying and meeting changing user needs;
- Increasing the number and commercial availability of innovative technologies;
- Accelerating the routine use of innovative technologies being developed by DoD, DOE, and other public and private entities into routine use at a faster rate;
- Providing an incentive for developers to push the state of the technology beyond present capabilities;
- Leveraging resources and expertise among federal agencies, the private sector, and academia; and
- Identifying the technology and data gaps that impede cost-effective and efficient environmental problem-solving and communicating them to the developer community.

An important product of the CSCT partnership was the development of the interim guidance manual that captured the process by which technologies were to be demonstrated and evaluated.[6] The interim guidance manual was used for 12 years and was the basis of this document, which is an update to the original guidance. The current document represents the approach to development of demonstration/quality assurance project plans (D/QAPPs) for independent performance testing of site characterization and monitoring technologies. For the most part, it relies on the experiences and the evolution of thinking gained over the last 12 years of conducting demonstrations under the SITE MMT and other technology evaluation programs.[3, 5, 7, 8]

1.3 Overview of the Technology Demonstration Process

This guidance provides developers and independent testing organizations (ITO) with a proven and clearly defined technology demonstration pathway, from planning through testing, reporting, and finally information dissemination (Figure 1-1). The technology demonstration process is intended to serve as a template for conducting technology demonstrations that will generate high-quality data needed by EPA and others to verify technology performance. The verification process is a model process that can help in moving innovative site characterization and monitoring technologies into routine use more quickly. An ITO can be funded by a technology developer, EPA, or some other source. Following this guidance document will allow the ITO to conduct an unbiased performance test of a technology or group of technologies. Activities performed by the ITO include: assisting in designing the performance tests; assisting with identification, selection, and/or access of the field test site(s); overseeing or conducting the actual testing of technologies; conducting quality assurance/quality control (QA/QC) oversight activities; and submitting reports on technology performance. These activities can be performed in whole or in part by the technology developer, but the independence of the testing organization brings credibility to the demonstration process. It is important that the results of the demonstration be publicly available through posting on Web sites, technical presentations, press releases, and newsletters. If EPA is involved in the demonstration process, then the relevant information from the demonstration will be posted on the program's Web sites. However, much of the responsibility for information dissemination rests with the developer, which must put the information in the hands of those who need the performance information in order to gain interest and/or acceptance of their technology.

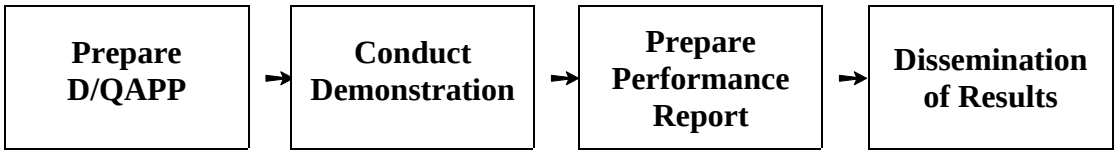

Figure 1-1. Overview of Technology Demonstration Process

Chapter 2
How to Use This Guidance Manual

2.1 Demonstration/Quality Assurance Project Plan Overview

As an expansion of Figure 1-1, Figure 2-1 depicts the major activities associated with each step in a technology demonstration.[1] This guidance manual focuses on key elements of a demonstration plan. The activities associated with the planning, demonstration, and data evaluation steps are described as part of the plan's development.

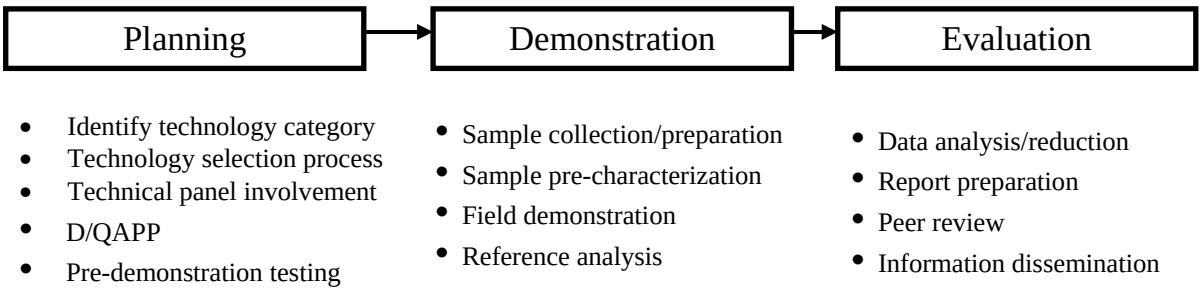

Figure 2-1. Elements of a Technology Demonstration

Typically, D/QAPPs are 50-100 pages in length, plus appendices where procedures, checklists, and other documents related to the execution of the demonstration, as appropriate, are housed. The D/QAPP serves a number of purposes. First, it provides a "roadmap" for the demonstration. It contains detailed guidance for those executing the demonstration on how data need to be generated and collected to support an objective performance evaluation (PE) of the technology. Second, it is an important reference for those who choose to review the steps used by the developer or ITO in executing the demonstration to assess the validity of the process. Finally, it can serve as a useful reference for other organizations in building future demonstration plans involving related technologies.

2.2 Building a D/QAPP

Figure 2-2 is a typical Table of Contents for a D/QAPP. It is derived from the section headings in Chapter 3. The section order and content specified in Chapter 3 of this manual should be used as guidance. The user of Chapter 3 is advised of the font appearance conventions used to distinguish text that is intended to provide guidance from text that can be directly included in the plan. The portions of Chapter 3 with the font having a normal appearance are intended to be included directly into the demonstration plan, assuming the narrative is appropriate to the demonstration. In places where there is a **name**, **date, single word**, or **phrase** to be inserted, it appears in bold. Finally, the text in *italics* is intended to serve as guidance to the user in how to prepare the specific section. The developer should provide the technology-specific information, while the D/QAPP author, who may not be the technology developer, can provide the remaining

portions identified in Chapter 3. Variations in the content of a technology-specific demonstration plan are expected, since different technologies have different characteristics and needs. For example, some field analytical technologies will have a directly corresponding laboratory method for reference analysis, while others, such as down-hole geophysical measurements, may require other methods of confirming performance. In addition, the preparer of the D/QAPP may choose not to include all technical elements that are suggested in Chapter 3. It is expected that content of a D/QAPP will be modified to meet the needs of a particular technology category while still meeting the general guidelines and data quality expectations set forth in Chapter 3.

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9.3 Audits, Corrective Actions, and QA Reports
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9.3.3 QA Reports
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APPENDICES (procedures; checklists; lists, etc., as required by the plan)

Figure 2-2. Table of Contents from a Typical Technology Demonstration Plan

Chapter 3
Elements of a Demonstration/Quality Assurance Project Plan

Title Page

The title page should include the name of the technology category (or the technology itself if only one technology is being demonstrated) and the authors responsible for development of the D/QAPP.

Concurrence Signatures

This is the page where approval signatures are documented. It is important to note that the completed D/QAPP must be approved by the appropriate people prior to implementation and use. Who approves the D/QAPP will be dependent upon the circumstances surrounding the demonstration, but written approval by the technology developer should always be required. Other possible signatory approvals include EPA, ITO technical lead, QA staff, Health and Safety staff, reference laboratory personnel, and other key site personnel, as appropriate.

Notice

Notices (e.g., disclaimers) are part of all EPA publications. This may not be required if the D/QAPP is not being prepared/reviewed in conjunction with EPA.

Abstract

The abstract should be less than a one-page description of the demonstration. Include a summary description of the primary and secondary objectives which will be verified during the demonstration, the demonstration sites, schedule, and a list of participants.

Table of Contents

An example Table of Contents is provided as Figure 2-2. The Table of Contents should include the headings provided in this manual although they may be modified as appropriate for a particular technology demonstration.

Abbreviations and Acronyms

A list of the abbreviations and acronyms used in D/QAPP should be provided.

Acknowledgements

This section should recognize those people who are not authors of the D/QAPP but who contributed to its development. Examples of people to include in the Acknowledgements are technical support personnel, sample collection personnel, test site hosts, and reference laboratory staff.

1.0 INTRODUCTION

This chapter describes the program under which the demonstration is being conducted, the scope of the demonstration, and pertinent information on the purpose of the demonstration. The following is an example as if the demonstration was being conducted under the SITE MMT Program.

The U.S. Environmental Protection Agency (EPA), Office of Research and Development (ORD), National Exposure Research Laboratory (NERL) has contracted with **ITO** to conduct a demonstration of monitoring and measurement technologies for **contaminants of interest** in **environmental matrix to be tested**. The demonstration is being conducted as part of the EPA Superfund Innovative Technology Evaluation (SITE) Monitoring and Measurement Technology (MMT) Program from **date** to **date**, in **City, State**. The purpose of this demonstration is to obtain reliable performance and cost data on the participating technologies in order to provide (1) potential users with a better understanding of the technologies' performance and operating costs under well-defined field conditions and (2) the technology developers with documented results that will help promote the acceptance and use of their technologies.

This demonstration plan describes the procedures that will be used to verify the performance of each measurement technology. The plan also incorporates a site health and safety plan and the quality assurance and quality control (QA/QC) elements needed to ensure that data of sufficient quality is generated to document each technology's performance. This plan has been prepared using, "A Guidance Manual for the Preparation of Site Characterization and Monitoring Technology Demonstration Plans."

This demonstration plan describes the **name of testing program**, the scope of the demonstration, and *other pertinent information on the purpose of the demonstration, such as descriptions or definitions of the problem being addressed by the technology(ies)* (Chapter 1); the demonstration organization and responsibilities of the participants (Chapter 2); the **number of** technologies that will be demonstrated (Chapter 3); sample collection, sample handling procedures, and *other sample preparation procedures that might be unique to this demonstration, such as sample homogenization* (Chapter 4); the demonstration site and the sampling locations (Chapter 5); the demonstration approach, including the objectives, experimental design, data analysis procedures, and the demonstration schedule (Chapter 6); the confirmatory process, including the reference

methods and the reference laboratory that will be used during the demonstration (Chapter 7); the data management procedures (Chapter 8); the QA/QC procedures (Chapter 9); the health and safety plan (Chapter 10); and references (Chapter 11).

1.1 Description of Testing Program

The following is an example as if the demonstration was being conducted under the SITE MMT Program.

Performance verification of innovative environmental technologies is an integral part of the regulatory and research mission of EPA. The SITE Program was established by the EPA Office of Solid Waste and Emergency Response and ORD under the Superfund Amendments and Reauthorization Act of 1986. The overall goal of the Program is to conduct performance verification studies and to promote the acceptance by the user and regulatory community of innovative technologies that may be used to achieve long-term protection of human health and the environment. The Program is designed to meet three primary objectives: (1) identify and remove obstacles to the development and commercial use of innovative technologies, (2) demonstrate promising innovative technologies and gather reliable performance and cost information to support site characterization and cleanup activities, and (3) develop procedures and policies that encourage use of innovative technologies at Superfund sites as well as at other waste sites or commercial facilities.

The demonstration of monitoring and measurement technologies for **compound(s) of interest** is being conducted as part of the MMT Program, which provides developers of innovative sampling, monitoring, and measurement technologies with an opportunity to demonstrate their technology's performance under actual field conditions (where appropriate). These technologies may be used to sample, detect, monitor, or measure hazardous and toxic substances in water, soil, soil gas, and sediment. The technologies include chemical sensors for *in situ* measurements, groundwater, soil, and sediment samplers, field portable analytical equipment, and other systems that support field sampling and analysis.

The MMT Program promotes acceptance of technologies that can be used to (1) accurately assess the degree of contamination at a site, (2) provide data to evaluate potential effects on human health and the environment, (3) apply data to assist in selecting the most appropriate cleanup action, and (4) monitor the effectiveness of a remediation or mitigation process. The Program places a high priority on innovative technologies that provide more cost-effective, faster, or safer methods for producing real-time or near-real-time data than conventional, laboratory-based technologies. These innovative technologies are demonstrated under field conditions, and the results are compiled, evaluated, published, and disseminated by the ORD.

The MMT Program's technology verification process is designed to conduct demonstrations that will generate high-quality data so that potential users have reliable information regarding the technology performance and cost. Four steps are inherent in the process: (1) needs identification and technology selection, (2) demonstration planning and implementation, (3) report preparation,

and (4) information distribution. The first step of the technology verification process begins with identifying technology needs of the EPA and regulated community. The EPA Regional offices, the U.S. Department of Energy, the U.S. Department of Defense, industry, and state environmental regulatory agencies are asked to identify technology needs for sampling, measurement, and monitoring of environmental media. Once a need is identified, a search is conducted to identify suitable technologies that will address the need. The technology search and identification process consists of examining industry and trade publications, attending related conferences, exploring leads from technology developers and industry experts, and reviewing responses to announcements of the demonstration.

The second step of the technology verification process is to plan and implement a demonstration that will generate representative, high-quality data to assist potential users in selecting a technology. Demonstration planning activities include a pre-demonstration sampling and analysis investigation that assesses existing conditions at the proposed demonstration site or sites. The objectives of the pre-demonstration investigation are to (1) provide an initial assessment to the technology developer as to the potential performance of the technology without going to the expense of a full-blown verification test; (2) confirm available information on applicable physical, chemical, and biological characteristics of contaminated media at the sites to justify selection of site areas for the demonstration; (3) provide the technology developers with an opportunity to evaluate the areas, analyze representative samples, and identify logistical requirements; (4) assess the overall logistical requirements for conducting the demonstration; and (5) select and provide the reference laboratory involved with an opportunity to identify any matrix-specific analytical problems associated with the contaminated media and to propose appropriate solutions. Information generated through the pre-demonstration investigation is used to develop the final demonstration design and to confirm the nature and source of samples that will be used in the demonstration.

Demonstration planning activities also include preparation of a demonstration plan that describes the procedures to verify the performance and cost of each technology. The demonstration plan incorporates information generated during the pre-demonstration investigation as well as input from technology developers, demonstration site representatives, and technical peer reviewers. The demonstration plan also incorporates the QA/QC elements needed to produce data of sufficient quality to document the performance and cost of each technology.

During the demonstration, each technology is evaluated independently and, when possible and appropriate, is compared to a reference technology. The performance and cost of one technology are not compared to those of another technology evaluated in the demonstration. Rather, demonstration data are used to evaluate the performance, cost, advantages, limitations, and field applicability of each technology.

As part of the third step of the technology verification process, EPA publishes a detailed evaluation in an innovative technology verification report (ITVR) for each participating technology. The participating technologies are not directly compared to each other, only where possible to a reference method’s results, since each technology is typically targeted for different

needs. In addition, it was not the purpose of the SITE Program to choose a winner or endorse a particular technology, but to provide information on each technology leading to an informed decision. To ensure its quality, the ITVR is published only after comments from the technology developer and external peer reviewers are satisfactorily addressed.

All demonstration data used to evaluate each technology are summarized in a data evaluation report (DER) that constitutes a complete record of the demonstration. The DER documents the underlying quality of the demonstration and contains much more detailed information than the ITVR, including items such as certificates of analysis, completed chains-of custody forms, and raw data results, which are not appropriate to include in the ITVR. The DER is not published as an EPA document, but an unpublished copy may be obtained from the EPA project manager.

The fourth step of the verification process is to distribute demonstration information. To benefit technology developers and potential technology users, EPA distributes fact sheets, newsletters, brochures, bulletins and ITVRs through direct mailings, at conferences, and on the Internet. Information on the SITE Program, including the publication of all D/QAPPs and ITVRs, is available on the EPA ORD Web site (http://www.epa.gov/ORD/SITE). Additionally, a Visitor's Day is held in conjunction with the demonstration so that potential users can have a first-hand look at the technologies in operation.

1.2 Purpose and Scope of Demonstration

Describe the intent of the demonstration. Note how many technologies will participate in the demonstration, and where and when the demonstration will take place. Any other pertinent information to the scope of the demonstration can also be noted in this section.

1.3 Background of the Problem

Provide a brief background of the problem that the technology(ies) being tested are designed to address. For example, if the demonstration is designed to evaluate a technology's ability to detect an organic contaminant in soil, then provide background information on the contaminant, the different names and categorization strategies for these compounds, and other relevant information that will be needed by the reader to fully understand why this demonstration should be conducted. This description should include relevancy to EPA and/or state methods and regulations, as appropriate.

1.4 Sources of Contaminant(s) of Interest

This section should briefly describe the sources of target analytes or contaminants being analyzed in the demonstration. The description might include how the test sites became contaminated.

1.5 Traditional Measurement Methods

Describe the traditional measurement methods used to analyze the compounds of interest in this demonstration. If there are multiple traditional methods being used, provide details on each method in individual subsections (i.e., 1.5.1, 1.5.2, etc.). Provide information on specifics such as the calibration range of the technique, general sample sizes, and final sample volume, as applicable. Also, in the case of multiple methods, note which traditional method was chosen as the reference method for the demonstration and the rationale for the decision.

2.0 DEMONSTRATION RESPONSIBILITIES AND COMMUNICATION

This chapter identifies key project personnel and summarizes their responsibilities in planning and executing the demonstration. Figure 2-**X** is an organization chart that shows key project personnel and the lines of communication among them. Table 2-**X** presents the key demonstration participants. During the demonstration, the participants will be asked to follow the health and safety procedures outlined in Chapter 10. However, each organization is directly and fully responsible for the health and safety of its own employees.

*Provide an organizational chart (Figure 2-**X**) on the next full page that identifies all participating parties, the key personnel, and their connections. See Appendix A, Figure A-1 for an example organization chart from a SITE MMT demonstration. On the following page, provide a table (Table 2-**X**) that provides the name of each organization involved in the demonstration, the point of contact for that organization, and the contact information for the point of contact. Each category (organization, point of contact, and contact information) should be a separate column. The contact information should include an address, telephone number, fax number, and e-mail address. Multiple points of contact may be listed in the table, but contact information should only be provided for the lead individual. See Appendix A, Table A-1 for an example of a Demonstration Participant's table from a SITE MMT demonstration.*

2.1 Developer Personnel

The responsibilities of the developer will vary depending on the type of demonstration. The following example assumes that an ITO will be involved.

The developers of the **number** technologies (*or* **developer**) are responsible for providing, mobilizing, operating, and demobilizing their respective technologies at the demonstration site. The developer responsibilities include the following:

- Provide **ITO** with information on the technology.
- Review and concur with the D/QAPP.
- Notify **ITO** in writing of technology-specific requirements, such as the type of power supply and the amount of work space needed, so that proper arrangements can be made for field demonstration of the technologies.

- Provide the personnel and all supplies needed for demonstration of the technologies unless otherwise arranged in advance with **ITO**.
- Analyze the samples specified in the D/QAPP.
- Analyze developer-specified QC samples (for example, blanks or standards) in accordance with the technology specifications.
- Provide technology-specific demonstration results to **ITO** at the end of the demonstration.
- Review and comment on the technology-specific ITVRs.
- Conduct all activities in accordance with the schedule to ensure timely completion of the final report.

2.2 EPA Project Personnel *(if applicable)*

The EPA program manager, **name of EPA project manager**, has overall responsibility for the project. **Name of EPA project manager** will review and concur with the project deliverables, including the demonstration plan, ITVRs, and DER. The EPA QA officer at the EPA NERL, **name of EPA QA officer**, is responsible for reviewing and concurring with the D/QAPP. The roles for EPA in this demonstration include:

- Review and approve the D/QAPP.
- Review and approve the DER and ITVRs.
- Be present at the demonstration.
- Participate in Visitor's Day.
- Coordinate activities with the **ITO** project manager.

2.3 Independent Testing Organization Personnel *(if applicable)*

The **ITO** project manager, **name of ITO project manager**, is responsible for conducting day-to-day management of **ITO** project personnel, maintaining direct communication with the developers (*and EPA, where appropriate)*, and ensuring that all **ITO** personnel involved in the demonstration understand and comply with the D/QAPP. **Name of ITO project manager** is also responsible for distributing the draft and final D/QAPPs to all key project personnel and for reviewing measurement and analytical data obtained during the demonstration. **ITO** project personnel will assist **name of ITO project manager** in preparing project deliverables and in performing day-to-day project activities. **ITO** project personnel are responsible for the following elements of the demonstration:

- Developing and implementing all elements of this D/QAPP.
- Scheduling and coordinating the activities of all demonstration participants.
- Coordinating the collection of samples; performing sample homogenization; performing characterization analyses for **compounds of interest**; and sample aliquoting.
- Coordinating activities with suppliers of certified samples.
- Developing and maintaining sample control process and distributing samples during the demonstration.

- Auditing the reference laboratory (**name of reference laboratory**) to verify that the operations are properly performed.
- Overseeing the operation of the developer technologies and documenting the operation of each technology during the demonstration.
- Summarizing, evaluating, interpreting, and documenting demonstration data for inclusion in the ITVRs and DER.
- Evaluating and reporting on the performance and cost of each technology.
- Preparing draft and final versions of ITVRs (one for each technology).
- Preparing draft and final versions of the DER, consistent with the format and content of historical documents.
- Coordinating meetings among demonstration participants.
- Providing required planning, scheduling, cost control, documentation, and data management for field activities.
- Managing demobilization activities, including proper waste disposal.
- Immediately communicating any deviation from the demonstration plan during field activities to the **EPA program manager** and discussing appropriate resolutions of the deviation.
- Interfacing with the demonstration site representatives and making logistical preparations for the demonstration.

Tasks for specific **ITO** staff will include:
Provide bulleted paragraphs for each of the key personnel from the ITO stating their specific responsibilities for the demonstration.

2.4 Demonstration Site Representatives

Name the representatives for the demonstration site and their affiliation. Identify the responsibilities of each site representative.

2.5 Reference Laboratory Personnel

Identify the reference laboratory that will be performing the reference analyses. Provide the names of key laboratory personnel that will participate in the reference analyses. Also, briefly describe the responsibilities of the key staff.

2.6 Suppliers of Performance Evaluation Samples

Provide any relevant information on the PE samples in this section by adding to the provided language.

The performance evaluation (PE) samples will be supplied from various sources (see Section 6.2.**X**). This will include purchasing standard reference materials and preparation of spiked

samples. All activities, including purchasing standard reference materials and spiked sample preparation, will be conducted under the direct supervision of the **ITO** project manager.

3.0 DEVELOPER TECHNOLOGY DESCRIPTION(S)

This chapter contains technology descriptions for each of the **number** technologies that are participating in the demonstration. *This information was provided by the developer(s) with only editorial changes made by **ITO** to ensure consistency and the needs of this document.* The technology description, operating procedure, and advantages and limitations presented below are based on information provided by the developer(s).

3.1 Technology Name

Provide technology descriptions, supplied by the developer, for each technology that participates in the demonstration. There should be a separate section (i.e., 3.1, 3.2, etc for each technology. Provide a subsection for a technology description (i.e., 3.1.1 Technology Description), one for the technology operation (i.e., 3.1.2 Operating Procedure), and one to discuss the advantages and limitations of the technology (3.1.3 Advantages and Limitations).

3.1.1 Technology Description

The technology description should include:

- *A brief introduction and discussion of the scientific principles on which the technology is based before the Technology Description section.*
- *A brief description of the physical construction/components of the technology. Include general environmental requirements and limitations, size, weight, transportability, ruggedness, power, and other consumables needed, etc.*
- *Identify the parameters or analytes the technology is designed to measure.*
- *Identify the matrices for which the technology is applicable, e.g., soil, water, sludge, etc.*
- *Cost of the technology (purchase or lease and typical operational costs).*
- *Typical operator training requirements and sample handling or preparation requirements.*
- *Define the performance range of the technology and verification requirements of the demonstration.*

- *Identify any special licensing requirements associated with the operation of the technology (for example, a technology that contains a radioactive source).*

- *Provide a picture of each technology and its associated components.*

3.1.2 Operating Procedure

Provide detailed steps to perform an analysis using the technology.

3.1.3 Advantages and Limitations

Describe the applications of the technology and what advantages it provides over existing technology. Provide comparisons in such areas as: initial cost, cost per analysis, speed of analysis, precision and accuracy of the data, usable or linear operating range, field versus laboratory operation, solvent use, durability, potential for waste minimization, etc.

Discuss the known limitations of the technology. Include such items as detection limits in various matrices (as appropriate), interferences, environmental limits (temperature, vibration, light, dust, power requirements, water needs, etc.), upper concentration limits, linear range, operator training, and experience requirements, etc.

4.0 DESCRIPTIONS OF DEMONSTRATION SITE AND SAMPLING LOCATIONS

This chapter describes the demonstration site and the sampling locations and why each was selected.

The technology(ies) should be tested under different geologic, climatologic, and waste environments. The technology(ies) can be demonstrated at more than one site, if resources are available to support multiple demonstration sites. An alternative would be to conduct the demonstration at only one site and bring in samples from various other sites.[1] Information on the site history and site characteristics should be available through the ITO or EPA contact unless the developer is making its own arrangements for the demonstration sites.

4.1 Demonstration Site Description

This section describes the site selected for hosting the demonstration, along with the selection rationale and criteria. The candidate sites were required to meet certain selection criteria, including necessary approvals, support, and access to the demonstration site; enough space and power to host the technology developers, **ITO**, and other participants; and various levels of **analyte of interest**-contaminated soil and/or sediment that could be analyzed as part of the demonstration. Historically, these demonstrations are conducted at sites known to be contaminated with the analytes of interest. The visibility afforded the sites is a valuable way of keeping the local community informed of new technologies.

Provide the demonstration site name(s) and location(s); where appropriate, area and location maps should be included. Be sure to include information on the site history. Include history of ownership and uses, especially information relating to the contamination found at the site. Provide summarized reasons as to why the site was selected. This description should include a geological description of the site, including soil types, etc. Provide a list of the known contaminants at the site, including the distribution and estimated concentrations.

4.2 Description of Sampling Locations

This section provides an overview of the **number** sampling sites and methods of selection. Table 4-**X** summarizes each of the locations, what type of sample was provided, and the number of samples from each location. *Describe why and how the number of sampling locations were selected.* It should be noted that it is not an objective of the demonstration to characterize the concentration of **analytes of interest** in material from a specific sampling location at a particular contaminated site. Because the samples are homogenized, they may not be representative of actual site conditions. It is, however, necessary to ensure comparability between technology results and the reference laboratory results, which is why the samples are homogenized. *State how the samples will be homogenized. An example of homogenization procedures can be found in SITE D/QAPPs.*[9]

Provide a subsection for each sampling location (e.g., 4.2.1, 4.2.2, etc.). Provide descriptions of the sampling site as provided by the site owners/sample providers. As appropriate, note that information was provided by the site owners/sample providers, and only editorial changes were made. The descriptions should include the sampling locations and how specific sampling locations within the site were selected. Considerations would include such things as source of contamination, analytes, concentration, matrix type, sampling depth, etc.

5.0 DEMONSTRATION APPROACH

This chapter presents the objectives, design, data analysis procedures, and schedule for this technology demonstration. *Guidance for demonstration plans is also available from other government programs, such as the DoD's Environmental Security Technology Certification Program (ESTCP).*[8] *In addition, published test plans for assessing the performance of environmental monitoring technologies generated under EPA technology evaluation programs, such as the SITE MMT Program,*[3] *Technology Testing and Evaluation Program (TTEP),*[7] *and the Environmental Technology Verification (ETV) Program*[5] *are valuable resources when planning a demonstration.*

5.1 Demonstration Objectives

The primary goal of the SITE MMT Program is to develop reliable performance and cost data on innovative, commercial-ready technologies. A SITE demonstration must provide detailed and reliable performance and cost data so that technology users have adequate information to make sound judgments regarding comparability to conventional methods. The demonstration has both

primary and secondary objectives. Primary objectives are critical to the technology evaluation and require the use of quantitative results to draw conclusions regarding a technology's performance. Secondary objectives pertain to information that is useful but will not necessarily require the use of quantitative results to draw conclusions regarding a technology's performance. Each report will summarize the findings of these objectives and provide sufficient documentation for a user to choose an alternative to conventional technology.

The primary objectives for the demonstration of the participating technologies are as follows:

P1. Determine the accuracy.
P2. Determine the precision.
P3. Determine the comparability of the technology to EPA standard methods.
P4. Determine the method detection limit (MDL).
P5. Evaluate the impact of matrix effects on technology performance.
P6. Estimate costs associated with the operation of the technology.

The primary objectives should at least include the six listed above, provided that they are appropriate for the technology(ies) being tested. Other primary objectives can be added, such as false positives/false negatives, depending on the technology data and output.

The secondary objectives for the demonstration of the participating technologies are as follows:

S1. Document the skills and training required to properly operate the technology.
S2. Document health and safety aspects associated with the technology.
S3. Document the portability of the technology.
S4. Evaluate sample throughput.

The secondary objectives should include those listed above, provided that they are appropriate for the technology(ies) being tested. Others could be added if necessary.

The objectives for the demonstration were developed based on input from the **analyte of interest** SITE Demonstration Panel members *(if appropriate)*, general user expectations of field measurement technologies, the time available to complete the demonstration, technology capabilities that the developers participating in the demonstration intend to highlight, and the historical experimental components of former SITE Program demonstrations to maintain consistency.

5.2 Overview of Demonstration Samples

The goal of the demonstration is to perform a detailed evaluation of the overall performance of the technology for use in contaminated site evaluation. The demonstration objectives will be centered on providing performance data that support action levels for contaminated sites. *Describe the action levels prescribed for the contaminant(s) of interest. Describe the different sample types that will be used as part of this demonstration. Provide information on what test*

parameters will be determined with each set of test samples. Provide a table that gives the performance objective, the type of sample that will be evaluated for that objective, and the range of concentrations (or the contaminant(s) of interest) that will be tested for that objective.

Provide a detailed description of each sample type that will be used in the demonstration in a separate subsection. For example, provide information on PE samples in one section (6.2.1), environmental samples in another (6.2.2), and extracts in another (6.2.3). For each sample type, discuss details about each sample as appropriate, such as from where the samples will be obtained (e.g., NIST or demonstration site locations), the organization responsible for handling and/or analyzing the samples, brief descriptions of the analysis methodology, and, in the case of PE samples, analysis guidelines.

5.3 Pre-Demonstration Study

The best way to predict and prevent problems from occurring during the demonstration is to perform a "dry run" exercise. This was accomplished through a pre-demonstration study. The pre-demonstration study served as a final readiness check for the developer so that modifications could be made to their procedure if warranted by site-specific conditions. It was also a test of the demonstration plan to ensure a well-established process of sampling, compositing, homogenizing, splitting, extract preparation and aliquoting, and shipping of samples to the developers and the reference laboratory. The pre-demonstration study consisted of **number** samples, including **list the samples used in the pre-demonstration study**. A distribution of the sample concentrations, as determined by the characterization analyses (see Section 4.3), is presented in Figure 5-**X**. The samples selected for the pre-demonstration study covered a wide range of concentrations and included a representative of each environmental site that will be analyzed during the demonstration.

Briefly describe the overall design of the pre-demonstration study. The reference laboratory should analyze all pre-demonstration samples blindly, and this should be noted in this section. Describe how the data was collected and distributed by the ITO. Note that if an ITO is not involved, it is still appropriate for the developer to perform a pre-demonstration study to confirm that the technology is fully ready for verification testing.

5.4 Demonstration Schedule

Describe where the developer will analyze the demonstration samples. Discuss in detail the schedule for the demonstration study. Indicate day-by-day what will happen. Because the demonstration study is meant to simulate the use of the technology of interest in the field, developers should analyze the samples at the site. Indicate how many and what type of samples the developers are required to analyze in the field. Discuss what will happen if a developer is unable to complete all analyses in the field. Provide a figure detailing the events and schedule. Example demonstration schedules[9] are provided in Appendix A in Table A-2 and Figure A-2.

5.5 Demonstration Design

Tables 6-**X** through 6-**X** include a generic summary of the samples to be included in the demonstration.

Describe how the samples will be identified for analysis, what samples will be tested (including the use of any QC samples), how samples will be randomized and labeled, and how chain-of-custody will be used to ensure the proper delivery of the samples. Include a brief explanation of why the concentrations to be used are distributed as they are (for example, including more samples around key regulatory decision levels). Also detail what (if any) sample information will be provided with the samples (e.g., samples believed to be above a certain concentration should be marked to alert the recipient of potential safety concerns). Discuss any sample identification requests that the developers have made.

Understanding the operational aspects of a technology is important for any end-user. To accomplish this in a demonstration study, it is recommended that independent technical observers (for example, from the ITO) be on location at the demonstration site to watch the developers use each technology. Checklists can be provided to each observer to guide their observations. An example checklist is provided in Appendix A, pages A-9 through A-13. Any such checklist used in the demonstration should be provided in a separate appendix in the report. Describe the use of independent technical observers as part of the demonstration study.

Discuss any waste that might be generated and how it will be handled. Describe how long testing will be allowed to continue on each day. If an ITO is involved, reiterate that the developers will be operating their own technologies and state what equipment they are responsible for bringing (e.g., all supplies and equipment necessary for operating their technology, any needed personal protective equipment, etc.).

5.6 Assessment of Primary and Secondary Objectives

The purpose of this section is to discuss how each objective will be assessed. Each objective will be discussed in detail in a separate subsection. Before beginning the first subsection, provide details on the analysis by the reference laboratory. List what the reference laboratory will be analyzing for and how (i.e., methods used). Also, discuss the QA/QC procedures employed by the reference laboratory, including how non-detects and flags will be handled and implemented. If useful, a table listing what the reference laboratory will report versus what each technology will report could be included.

Primary Objectives generally include the following measures: accuracy, precision, comparability, method detection limits, matrix effects, and technology costs. Secondary Objectives generally include skills and training required to properly operate the instrument, health and safety aspects, portability, and sample throughput. Other objectives, such as false positives/false negatives, can be added based on the technology category. These objectives can be presented in any order. Information is provided below for each objective. The text should be

expanded as necessary to discuss the particulars of a given technology category. The general concepts should not change, but the parameters to be evaluated within a category can vary depending upon the specific circumstances. In addition, appropriate consideration should be given to additional or alternative statistical approaches. The text provided below should only serve as an example.

5.6.1 Primary Objective P1: Accuracy

The determination of accuracy for each technology's measurements will be based on the extent to which they agree with the certified or spiked levels of PE samples. For each technology, PE samples containing concentrations from across the analytical range of interest will be analyzed. The technology measurements from the **number** PE samples will be evaluated to determine whether there is a statistically significant difference between the technology measurements and the certified value or spiked level. Percent recovery values relative to the certified or spiked concentrations will also be calculated. **ITO** *(if appropriate)* will evaluate whether a statistically significant difference exists between a given technology's results and the reference values by performing a two-tailed, paired, Student's t-test. The null hypothesis will be that the mean difference between the technology results and the certified or spiked value is zero. The PE samples will also be analyzed by the laboratory reference method for confirmation of certified and spiked values.

To evaluate accuracy, the average of replicate results from the field technology measurement will be compared to the certified or spiked value of the PE samples to calculate percent recovery. The equation to be used will be:

$$R = \overline{C} / C_R \times 100$$

where $\overline{C}$ is the average concentration value calculated from the technology replicate measurements and C_R is the certified value. For the spiked samples, if the reference laboratory's average measured value is within 10% of the spiked concentration value, the spiked concentration value will be used as the certified value. If the average measured value by the reference laboratory is > 10% different, the reference laboratory's average measured value will be the certified value.

Acceptable R values are between 75% and 125%.

It is possible that PE samples will not be commercially available for the contaminants of interest. If such is the case, PE materials could be prepared by a reputable source. Alternatively, accuracy could be measured relative to reference laboratory measurements rather than to certified concentrations if such samples are not available and/or appropriate for the technology being tested.

5.6.2 Primary Objective P2: Precision

A technology's precision refers to its reproducibility. Higher precision leads to less uncertainty in the results. To evaluate each technology's precision, all samples, both environmental and PE, will be analyzed in at least triplicate, with quadruplicate preferred. Replication is necessary because precision will be evaluated at both low and high concentration levels, and across different matrices. The statistic used to evaluate precision is relative standard deviation (RSD). The equation used to calculate standard deviation (SD) between replicate measurements will be:

$$SD = \left[\frac{1}{n-1} \sum_{k=1}^{n} \left(C_k - \overline{C} \right)^2 \right]^{1/2}$$

where SD is the standard deviation and C is the average measurement.

The equation used to calculate RSD between replicate measurements will be:

$$RSD = \left| \frac{SD}{\overline{C}} \right| \times 100 .$$

Low RSD values (< 20%) indicate high precision. For a given set of replicate samples, the RSD of a given technology's results will be compared with that of the laboratory reference method's results to determine whether the reference method is more precise than the technology or vice versa for a particular sample set.

Homogeneity of the sample concentrations provided to the developers is an important factor to consider with regards to evaluating a technology's precision.

5.6.3 Primary Objective P3: Comparability

A third primary performance objective is comparability, i.e., the degree of agreement between each technology and reference laboratory results. For comparability, **ITO** will evaluate whether a statistically significant difference exists between the measurements provided by a given technology and the laboratory reference method by performing a two-tailed, paired, Student's t-test. If the data are found to be non-normally distributed, a nonparametric Wilcoxon signed-rank test will be performed to determine if the two sets of results are statistically the same or different.

Technology results will also be compared to the corresponding reference laboratory by calculating a relative percent difference (RPD) for the average of each paired and replicate measurement. The equation for RPD is as follows:

$$RPD = \frac{\left(M_R - M_D \right)}{average\left(M_R, M_D \right)}$$

where M_R is the reference laboratory measurement and M_D is the developer measurement. RPD values between ± 25% will indicate good agreement between the two measurements. Because the absolute value will not be taken, negative RPD values would indicate that the technology measurements were less than the reference laboratory measurements. As such, the median RPD

value will be calculated (rather than the average RPD where the negative and positive values would be neutralized) to provide a summary calculation of comparability between each technology's results and reference laboratory measurements.

The types of comparability assessments to be performed should be appropriate for the technology demonstration, although the approach described should be applicable to most site characterization and monitoring technologies. Other methodology such as linear correlation can also be used. In addition, it may be appropriate to evaluate the comparability of the technologies to the reference method on a semi-quantitative basis (such as using performance intervals) if it is anticipated that the technology being tested and the reference method do not generate results that are directly comparable.[10]

5.6.4 Primary Objective P4: Method Detection Limit

A fourth primary performance objective is to determine the MDL for each technology. To determine the MDLs, the developer will analyze seven aliquots of a *low-level PE or environmental sample*. The concentration of the samples will be dependent on the detection capability of each technology, but will ideally be three-to-five times the reporting limit for each technology. **ITO** will use these data to calculate an MDL for each technology.

The MDL calculation procedure[11] involves use of the Student's t-value and standard deviation to calculate the MDL for each technology in soil and sediment as shown in the following equation:

$$MDL = t_{(n-1,1-\infty=0.99)}(SD)$$

where t(n-1,1-4=0.99) = Student's t-value appropriate for a 99 percent confidence level and a standard deviation estimate with n-1 degrees of freedom.

If data is not obtained from all seven replicates, an "estimated" MDL can be calculated with the data that is available.

5.6.5 Primary Objective P5: Matrix Effects

The likelihood of matrix-dependent effects on performance will be investigated by evaluating the data sets in multiple ways. This will include evaluation of: samples from the **number** different environmental sampling locations individually and as a group to determine if performance was different for environmental samples versus PE samples; grouping the data by matrix; assessing the performance with samples containing high levels of contaminants other than **analyte(s) of interest**; and evaluation of in-field versus laboratory conducted measurements (where appropriate).

Discuss any further sample analysis or comparison that may occur to determine potential matrix effects. These analyses will vary by technology category.

5.6.6 Primary Objective P6: Technology Costs

Since conventional laboratory-based analytical methods for measuring **analyte(s) of interest** are relatively costly, the cost of each field technology is an important evaluation factor. With input from each technology developer, **ITO** will document the full cost of each technology and compare those costs to typical and actual costs for **analyte(s) of interest** analytical methods. At a minimum, cost inputs will include equipment, consumable materials, mobilization and demobilization, and labor.

5.6.7 Secondary Objective S1: Skills and Training Requirements

The operator should be trained to safely set up and operate the technology. The amount of training required depends on the complexity of the technology. Most developers have established standard training programs. The time required to complete the developer's training program will be estimated.

If an observer from an ITO will be included in the demonstration, then language such as below should be included:

ITO observers will be assigned to each of the technologies. *An example is on Page A-9.* These notes and observations will help to assess the skill level required of the operator. The observers will also determine the type of background and training required to properly operate the technology. The evaluation of this secondary objective will also include how user-friendly the technologies are. The developers will have the opportunity to review and comment on the observer's notes before the observations are incorporated into the report to ensure accuracy.

5.6.8 Secondary Objective S2: Health and Safety

It is important to understand the health and safety aspects associated with each technology. This will include health and safety issues when operating the technology as well as the amount and type of hazardous and nonhazardous waste generated by the technology. Not included in the evaluation are potential risks from exposure to site-specific hazardous materials or physical safety hazards.

5.6.9 Secondary Objective S3: Technology Portability

This evaluation will document if the technology can be readily transported to the field and how easy the technology was to operate in the field. The size of the technology, including physical dimensions and weight, will be recorded. The number of components, power requirements, support structures, and reagent requirements will also be reported.

The durability and availability of the technology could also be included as a secondary objective either with portability or as separate secondary objectives, if it is deemed appropriate for the technology category.

5.6.10 Secondary Objective S4: Sample Throughput

Sample throughput is a calculation of the total number of samples that can be evaluated in a specified time (i.e., generally a typical 8-hour work day, *although a field demonstration work day may exceed 8 hours*). The primary factors that affect sample throughput include the time required to prepare a sample for analysis, to conduct the analytical procedure for each sample, and to process and tabulate the resulting data.

The start and end of sample throughput recording will depend on the operation of the technology. State when sample throughput times will be collected and how often they will be evaluated. If a technical observer is used in the demonstration, their notes could be used to determine sample throughput.

6.0 SAMPLE COLLECTION AND CHARACTERIZATION

This chapter discusses the sample collection, sample preparation, and sample characterization procedures used in the demonstration.

6.1 Sample Collection

This section describes the environmental sample collection activities performed at various sites across the country.

Provide a brief introductory paragraph that provides an overview of the samples that will be collected for the demonstration. Include information on who will collect the samples, where they will be shipped or if analyses will be performed on-site immediately following sample collection, pre-analytical holding time considerations (if applicable), sample preservation procedures (if required), and estimated concentration ranges.

6.1.1 Procedure

This section describes the method that will be used to collect the samples by each of the site personnel.

Describe the detailed sample collection procedures. Sufficient detail must be provided to direct the step-by-step sample collection process. A summary can be provided in this section with further details given in an appendix. Identify the specific collection tools, devices or containers, and procedures; contamination prevention; and decontamination procedures.

6.1.2 Sample Shipping

Describe how the samples will be received (if they are being collected prior to testing) and how they will be stored.

6.2 Sample Preparation

Describe the procedures that will be used to preserve or homogenize the sample. Provide details on the equipment and containers to be used in the sample preparation process. Cite differences between field analysis and requirements for reference laboratory analysis, if applicable. Justify any differences between the standard method and the field sample preparation requirements. If applicable, provide a separate subsection (e.g., 6.2.1) on the criteria employed to determine that the samples were adequately prepared (i.e., preserved or homogenized).

6.3 Characterization of Environmental Samples

If applicable, provide a brief introductory paragraph describing the number of environmental samples that will be characterized. Include a reference to the Sample Preparation section (6.2), what the samples will be characterized for, what methods will be used for characterization, and who will perform the analyses. Also, note the purpose of the characterization and criteria for its success. Characterization may not be necessary or possible if analyses are being conducted on-site as samples are being collected. However, if possible, it is advisable to collect soil and sediment samples ahead of time so that homogenization and characterization of the samples can be performed prior to use in the demonstration.

6.4 Sample Handling, Sample Tracking, and Sample Management

Describe the procedures used for sample handling, tracking, and management. This includes detailing any chain of custody procedures, how samples are distributed for shipping, how the samples are randomized, how the samples are distributed, how the samples will be stored an archived, and how any sample by-products will be handled. If an ITO is involved, that organization is responsible for sample distribution.

7.0 REFERENCE LABORATORY AND METHOD(S)

This chapter describes the process for the selection of the reference method and laboratory. *Note if the reference laboratory provided any method performance information presented in the chapter.*

7.1 Reference Method Selection

The reference analytical method should be chosen from standard methods approved by EPA or another recognized body, such as ASTM International or AOAC International. The method selected should generate data similar in quality and type expected to be derived from the technology being demonstrated. A justification for selecting a specific method must be provided. Typically, SW-846 methods were used as reference methods for SITE MMT demonstrations since these methods were closest in approach to innovative technologies that were being tested.

The selection process may identify a nonstandard method as providing the best data match. Since many field technologies offer qualitative data (e.g., immunoassay techniques), rigorous quantitative laboratory methods may make direct comparisons unreasonable. Some modification of existing methods may be required to ensure that an appropriate method is used for comparison. Alternatively, different approaches to data analyses may be implemented which do not focus on direct comparison of the tested technologies and the conventional method. For example, in the SITE MMT Dioxin Demonstration, in addition to a direct quantitative comparison of the data, the assessment also involved whether the technology data and the reference data fell into the same data interval, which were based on decision action levels.[10]

7.2 Reference Laboratory Selection

Describe how the laboratory was chosen. This decision should be based on the experience of prospective laboratories with QA procedures, reporting requirements, and data quality parameters consistent with the goals of the program.

The laboratory must demonstrate past proficiency with the method selected and could be asked to participate in a review of the experimental design. Laboratory management should be briefed on the nature and purpose of the demonstration and may suggest enhancements to the proposed procedure.

7.3 Reference Laboratory Sample Preparation and Analytical Methods

The purpose of this section is to describe the reference methods that will be used in the demonstration sample analyses. This section briefly describes the procedures for instrument setup and calibration for the selected methods. In addition, sample management procedures are also discussed.

Discuss the reference method(s) that the laboratory will use for this demonstration. Describe in detail, including modifications from a standard method that the reference laboratory might have used. The information can be presented either by analyte of interest or by method used. Each discussion (whether analyte or method) should be a separate subsection (e.g., 7.3.1, 7.3.2, etc.).

8.0 DATA MANAGEMENT

To ensure that the demonstration data are scientifically valid and defensible, appropriate procedures will be used to perform data management. This chapter describes (1) data reduction, (2) data review, (3) data reporting, and (4) data storage procedures for the demonstration.

8.1 Data Reduction

Each analytical method participating in the demonstration and each developer technology's instruction manual contain detailed instructions and equations for generation of results. *If an ITO*

*is involved, the developer will be responsible for reducing its own data and providing final results to **ITO** in an agreed upon form.* The reference laboratory will generate concentration data for the analyte(s) of interest using reference method(s). The reference laboratory will generate the data, and **ITO** will review those results using standard data validation procedures. Comparisons between the developer and reference laboratory data will be dependent on how the developer is reporting its data and if the results are intended to be directly comparable.

8.2 Data Review

A review of technology and laboratory analytical data will be conducted by each developer and the reference laboratory, respectively. *If appropriate, **ITO** will also conduct a review of all field and laboratory data.* The review processes that will be used for developer and laboratory analytical data are described below.

8.2.1 Data Review by Developers

Each developer will review all results generated by its technology. The developer will review all demonstration sample data as well as QC results for their technology. The developer will report results to **ITO**. *Provide information on any details that the developer will follow in presenting data to the ITO, as appropriate. Also, describe any procedures that the ITO might use to transcribe the developer's reviewed data, if appropriate.*

8.2.2 Data Review by Reference Laboratory

Include information on the data review process for the reference laboratory. If this is a complex process, this information can be provided in an appendix.

8.2.3 Data Review by **ITO** *(if applicable)*

In addition to the review process that will be used by the developers and reference laboratory, the **ITO** project manager or designee will review all laboratory and developer results, based on demonstration objectives. The **ITO** project manager or designee (such as the QA manager) will also conduct a complete data validation for 100 percent of the data as an independent check of the reference laboratory results. If this validation reveals no oversights or problems, **ITO** will consider all data to be acceptable. If oversights or problems are identified, the reference laboratory project manager will be consulted. If appropriate, the reference laboratory data will be compared to the data generated by **ITO** during the sample characterization analyses. This will be a key comparison which will confirm the overall quality of the data set. *A checklist for performing the data validations can be included in an appendix, with a reference to that here. Or, brief details on the data validation procedures by the ITO can be provided here.*

During its data review, **ITO** will identify project outlier data using statistical testing and will report these data to the EPA program manager. Project outlier data are defined as sample data outside specified acceptance limits that are established during the demonstration planning

process. For example, for data known or assumed to be normally distributed, the specified acceptance limits could be the 95 percent confidence limits defined by the Student's two-tailed t-test. Consistent procedures will be used to identify outliers for both reference laboratory and developer data. No data will be rejected simply because they are statistical outliers, but data may be reported with and without the statistical outliers as appropriate. **ITO** will conduct a thorough check to identify the reasons for the outliers and will provide an explanation of why some data appear to be outliers.

8.3 Data Reporting

Each developer and the reference laboratory will prepare and submit data packages reporting their results. Both the reference laboratory and the developer should be required to produce both hard copy and electronic data reports to avoid transcription errors. Described below are the data reporting requirements for (1) developer data packages, (2) reference laboratory data packages, (3) ITVRs, and (4) the DER.

8.3.1 Developer Data Package

The developers will compile their results on standard forms provided by **ITO**. *An example form should be provided as an appendix.* The forms will contain sample identification numbers and spaces for a developer to enter their results as appropriate (i.e., each form will be unique to each developer). These forms can double as chain-of-custody forms to document sample transfer. The developers will only be required to report their sample results for evaluation. Developer-supplied QC sample results will be requested for the DER. Raw data, copies of logbook pages, standards preparation logs, etc., that are included in a typical laboratory data package will not be required from the developers. If the developers are completing the analysis of the demonstration samples on-site, each developer will be expected to submit their complete results for the demonstration samples before they leave the demonstration site to assure the integrity of the developers' data.

8.3.2 Reference Laboratory Data Package

The reference laboratory will provide the data package to **ITO** in standard analytical data forms and in electronic format. *A specified procedure can be provided in an appendix.*

8.3.3 Innovative Technology Verification Reports

In accordance with the demonstration plan, **ITO** will evaluate the performance and cost data collected for each technology demonstrated and prepare an ITVR for the technology. Each ITVR will be a focused report of about 100 pages and will include the following:

- An introduction
- A description of the technology
- Site descriptions and the demonstration design
- Deviations from the demonstration plan

- A description of the reference method and its performance
- A description of the technology's performance
- A sample cost analysis
- A summary of demonstration results.

The reports will be written in such a way that a reader with a basic science background can understand their contents and make an informed decision regarding the performance of the technologies. The ITVRs will undergo a rigorous review process that will include reviews by external peer reviewers, project collaborators, and stakeholders. *If the ITVR will be written by **ITO** for EPA, the format will follow EPA guidance for reports (e.g., "Visual and Product Standards Graphics Manual," EPA 600/R-07/054, July 2007) and project-specific guidance from the EPA program manager.*

8.4 Data Evaluation Report

The DER contains all of the detailed demonstration records that are not provided in the ITVR. **ITO** will prepare a DER containing tabular summaries of investigative and QA/QC data from the demonstration as well as results of technical systems and performance audits. The DER will include raw data files, including reference laboratory data, chains-of-custody, certificates of analysis, completed log sheets, etc. These data are important to documenting the quality of the demonstration but are not necessary to be included in the summary of performance that is described in the ITVR. The DER will be made available after completion of all demonstration activities (including final ITVRs).

8.5 Data Storage

The reference laboratory analysts responsible for performing measurements will enter raw data into logbooks or on data sheets. In accordance with standard document control procedures, the laboratory will maintain on file the original logbooks or data sheets, which will be signed and dated by the laboratory analysts responsible for them. Similar procedures will be used for all data entered directly into the laboratory information management system. Separate instrument logs will also be maintained by the laboratory to allow reconstruction of the run sequences for individual instruments. The reference laboratory will maintain all raw data, including raw instrument output on tape or diskette, on file for 5 years after the submission of the data packages to **ITO**. The data will be disposed of upon receipt of instructions to do so or after 5 years, whichever is sooner. A central project file for the demonstration will be established at **ITO**. This file will be a repository for all relevant field and laboratory project documentation. *If ITO is under contract to EPA, the project files will be maintained in accordance with the terms of the contract.*

9.0 QA/QC PROCEDURES

This chapter describes the QA/QC procedures that will be implemented in this demonstration to ensure that the data generated are of high quality.

9.1 QA/QC Objectives

The overall QA objective for the demonstration is to produce well-documented data of known quality. Where appropriate, data quality will be measured in terms of precision, accuracy, representativeness, completeness, and comparability. Table 9-1 contains the objectives for the data quality indicators, which applies to both the developer and reference laboratory data. If analytical data from the reference laboratory fail to meet the QA objectives described in this section (except for comparability, which does not apply), the source of the errors will be investigated and corrective actions will be taken if necessary and possible. (Corrective actions associated with the reference method are discussed in detail in Section 9.2.) If analytical data from the field technologies did not meet the QA objectives, the discrepancies will be described in the ITVRs, as well as the usefulness and limitations of the data generated.

Table 9-X. Data Quality Indicator Objectives for Reference Laboratory and Developer Data

Data Quality Indicator	Calculation	Objective
Precision	Relative standard deviation (RSD) of replicate samples	Average of all RSDs < 20 percent
Accuracy	Percent recovery of certified or spiked sample values	75 percent to 125 percent
Representativeness	Valid samples from each matrix type	At least one valid sample result generated from each sampling location
Comparability of reference method*	Average absolute median RPD	Within ± 25 percent
Completeness	Percent of total samples analyzed and valid results provided	98 percent

*Applies only to developer data

9.2 Internal QC Checks

9.2.1 Reference Method QC Checks

Tables 9-**X**, through 9-**X** summarize the QC checks that will be performed by the reference laboratory as described in **reference method or reference laboratory standard operating procedure (SOP) names**.

Provide a table or tables of the information described above. Further details on the QC procedures for each method(s) (calibration, blanks, spikes, duplicates, etc.) can also be provided in subsections (i.e., 9.2.1.2, 9.2.1.3, etc.).

9.2.2 Developer Technology QC Checks

Quality control checks to be performed by the developers will be at each developer's discretion, although it is highly recommended that quality controls such as blanks, spikes, and duplicates, be systematically analyzed throughout the demonstration. Developer QC data will be reported to I**TO** for inclusion in the DER.

9.3 Audits, Corrective Action, and QA Reports

The assessment stage involves procedures to verify that demonstration efforts are in compliance with the quality system and that upon conclusion of the data gathering stage of the demonstration, the collected data meet the performance and acceptance criteria (e.g., data quality objectives) specified in the planning stage. The QA manager or designee conducts audits at planned, scheduled intervals; implements provisions for timely responses and implementation of corrective actions if needed; and completes the evaluation process with written reports to technical and management staff. The **ITO** project manager will ensure that this individual has sufficient authority, access to project staff, access to documents and records, and organizational freedom to conduct the assessment.

QA audits are independent assessments of measurement systems and associated data and are more rigorous than routine assessments. QA audits may be internal or external and most commonly incorporate technical system reviews and analysis of blind or double-blind performance audit samples. System audits, performance audits, and associated corrective action procedures are described below.

9.3.1 Technical Systems Audits

Technical systems audits (TSA) include thorough evaluations of field and laboratory sampling and measurement systems. The QA manager or designee will conduct a TSA during the time when the reference laboratory is analyzing the demonstration samples. *Provide information on how the TSAs will be performed and what activities and documents will be reviewed as part of*

the TSA. These activities and documents should be provided either as a list or in a table. If possible, a separate TSA will be performed by **ITO** at the demonstration site to ensure that the demonstration plan is being implemented properly.

If the demonstration is being conducted with EPA involvement, the EPA quality manager has the authority to conduct an independent TSA at any time during the demonstration.

9.3.2 Corrective Action Procedures

Corrective action procedures are an important component to ensuring a quality demonstration. Each demonstration plan must incorporate a corrective action plan. This plan must include the predetermined acceptance limits, the corrective action to be initiated whenever such acceptance criteria are not met, and the names of the individuals responsible for implementation. These procedures may vary depending on the type and severity of the finding.

Describe how ITO will respond to noted deficiencies in any of the audits that will be performed. Briefly note the procedures that will be followed, including the chain of command for notification of a problem.

9.3.3 QA Reports

The outcome of each assessment will be fully documented. The **ITO** project manager will archive all audit documentation collected during the project and include it in the DER. The QA manager or designee will report the findings of each audit to **ITO** or **Reference Laboratory** project manager, as appropriate, who will then address the audit findings and provide an appropriate response. QA reports require a written response by the person performing the inspected activity and acknowledgment of the audit by the **ITO** project manager.

Authority to report all TSA results is designated to the **ITO** QA manager or designee. These reports should:

- Identify and document problems that affect quality and the achievement of objectives required by the demonstration and quality assurance project plan and any associated SOPs.
- Identify and cite noteworthy practices that may be shared with others to improve the quality of their operations and products.
- Propose recommendations (if requested) for resolving problems that affect quality.
- Independently confirm implementation and effectiveness of solutions.
- Provide documented assurance (if requested) that, when problems are identified, further work performed is monitored carefully until the problems are suitably resolved.

Responses to adverse findings are addressed immediately during a debriefing after the assessment is completed and preferably at the site of the assessment. Responses to each adverse

finding will be documented in a letter or memo to **ITO** project manager. The letter or memo will indicate for each adverse finding the corrective action(s) taken or planned.

The **ITO** QA manager or designee will review the responses to each adverse finding and will follow up with the **ITO**, developer, or reference laboratory representative on any findings that were not adequately addressed. Once all corrective actions associated with the QA report have been verified, the QA manager or designee will approve the QA report. The QA report and responses to adverse findings will be sent to the **ITO** project manager for review and approval. The QA report and responses will be maintained in the QA project files and will be included in the DER.

10.0 HEALTH AND SAFETY PLAN

This chapter contains the site health and safety plan for demonstration activities. This plan will be reviewed and signed by all demonstration participants before work begins. *The Health and Safety Plan (HASP) is a very important part of the demonstration plan. It should be an adaptation or appendix to the existing site HASP with any additions that are specific to the demonstration. A copy of the site HASP should be available from the site manager or through the ITO. Figure 3-1 contains a representative list of topics that should be addressed in the HASP. The HASP may have different components, particularly if the demonstration is only being conducted in a laboratory setting.*

Health and Safety Plan - XYZ, Inc. Site

- Introduction
- Purpose and Policy
- Health and Safety Plan Enforcement for the XYZ, Inc. Site
  - Project Manager and Field Site Supervisor
  - Health and Safety Director
  - Site Health and Safety Officer
- Requirements for Visitors
- Site Background
- Demonstration-Specific Hazard Evaluation
- Exposure Pathways
  - Inhalation
  - Dermal Contact
  - Ingestion
- Health Effects
- Physical Hazards
  - Fire
  - Heat/Cold Stress
  - Mechanical
  - Unstable/Uneven Terrain
  - Insect and Other Animal Stings, Bites, and Encounters
  - Plant/Vegetation Hazards
  - Noise
  - Electrical
  - Inclement Weather
- Training Requirements
- Personal Protection
  - Levels of Protection
  - Protective Equipment and Clothing
  - Limitations of Protective Clothing
  - Duration of Work Tasks
  - Respirator Selection, Use, and Maintenance
- Medical Surveillance
  - Health Monitoring Requirements
  - Documentation and Recordkeeping Requirements
  - Medical Support and Followup Requirements
- Environmental Surveillance
  - Initial Air Monitoring
  - Periodic Air Monitoring
  - Monitoring Parameters
- Use and Maintenance of Survey Equipment
- Site Control
  - Site Control Zones
  - Safe Work Practices
  - Health and Safety Plan Enforcement
  - Complaints
- Decontamination
  - Personnel Decontamination
  - Equipment Decontamination
- Emergency Contingency Planning
  - Injury in the Exclusion or Contamination Reduction Zones
  - Injury in the Support Zone
  - Fire or Explosion
  - Protective Equipment Failure
  - Emergency Information Telephone Numbers
  - Directions to Hospital (or On-Site Clinic)

Figure 3-1. Typical Table of Contents from a Health and Safety Plan

Chapter 4
References

(1) Billets, S. and Dindal, A. "History and Accomplishments of the U.S. Environmental Protection Agency's Superfund Innovative Technology Evaluation (SITE) Monitoring and Measurement Technology (MMT) Program." *Journal of Testing and Evaluation.* 35(5), 486-495, September 2007.

(2) U.S. Code, 2004, Title 42, Chapter 103. Comprehensive Environmental Response, Compensation, and Liability Act. http://www.access.gpo.gov/uscode/title42/chapter103_.html

(3) U.S. EPA. Superfund Innovative Technology Evaluation Program, Publications. http://www.epa.gov/ORD/SITE/reports.html.

(4) Billets, S. and Koglin, E. "Overview of the EPA's Verification Program for Site Characterization Technologies," *EEMI Environmental News*, Summer 1997.

(5) U.S. EPA. Environmental Technology Verification Program, Test and Quality Assurance Plans. http://www.epa.gov/nrmrl/std/etv/tqap.html.

(6) U.S. EPA, 1996. *A Guidance Manual for the Preparation of Site Characterization and Monitoring Technology Demonstration Plans,* interim final report, version 5.0, October.

(7) U.S. EPA. Technology Testing and Evaluation Program. http://www.epa.gov/nhsrc/ttep.html.

(8) U.S. Department of Defense. Environmental Security Technology Certification Program, Demonstration Plan Guidance. http://www.estcp.org/pi_resources/index.cfm, Accessed November 3, 2008.

(9) U.S. EPA, 2004. Demonstration and Quality Assurance Project Plan: Technologies for the Monitoring and Measurement of Dioxin and Dioxin-like Compounds in Soil and Sediment. EPA/600/R-04/036.

(10) U.S. EPA, 2005. *Innovative Technology Verification Report Technologies for Monitoring and Measurement of Dioxin and Dioxin-like Compounds in Soil and Sediment Xenobiotic Detection Systems, Inc. CALUX® by XDS* Section 7.1.3, pp 42-44. http://www.epa.gov/ORD/SITE/reports/540r05001/540r05001r072005.pdf

(11) Electronic Code of Federal Regulations. Definition and Procedure for the Determination of the Method Detection Limit – Revision 1.11. 40 CFR Part 136, Appendix B.

APPENDIX

Examples from Previous SITE MMT D/QAPPs

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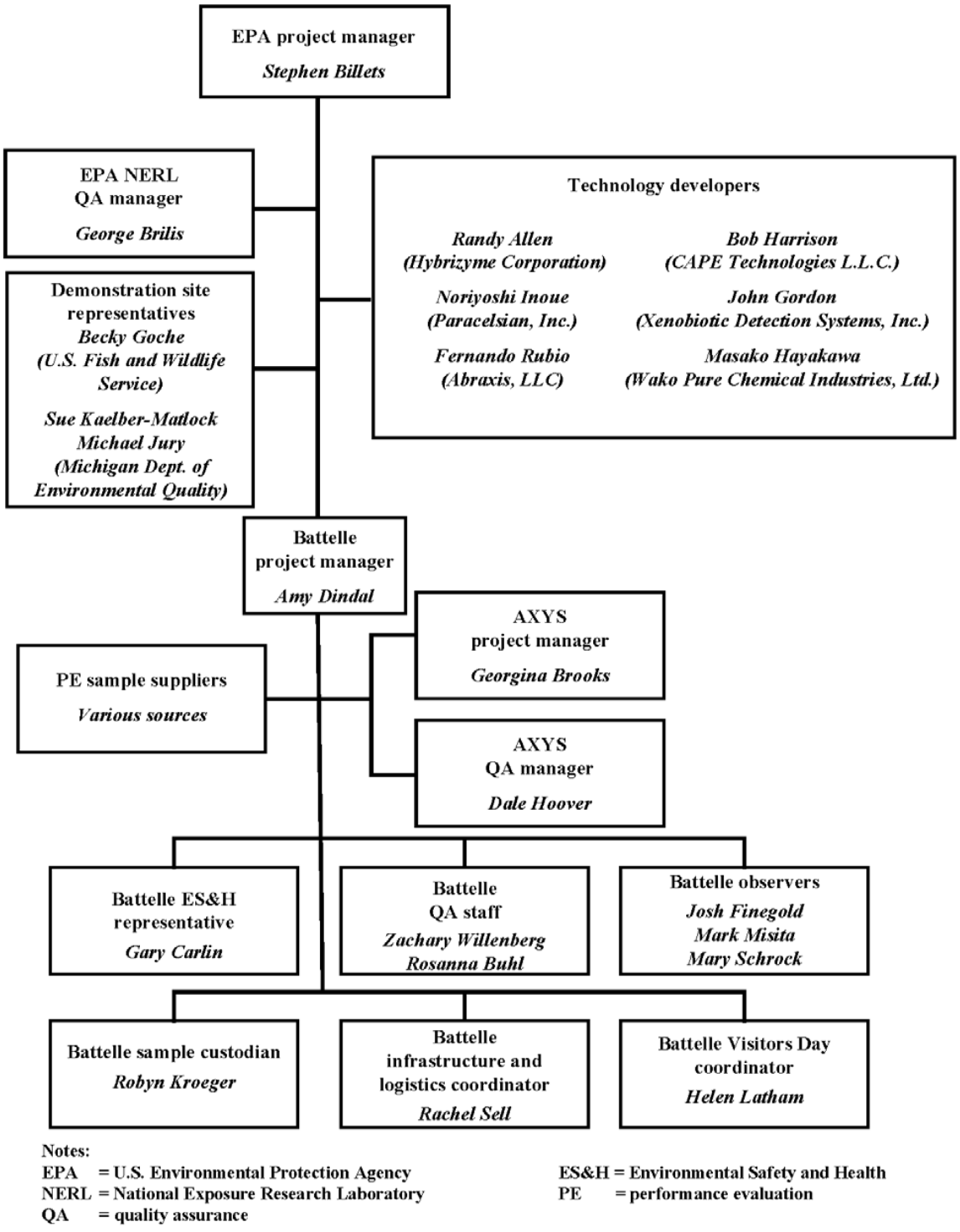

Figure A-1. Example organizational chart to be used in Chapter 2 of the D/QAPP.

Table A-1. Example Demonstration Participant's Table to be used in Chapter 2 of the D/QAPP.

Organization	Point of Contact	Contact Information
U.S. Environmental Protection Agency	Stephen Billets George Brilis	National Exposure Research Laboratory 944 East Harmon Avenue Las Vegas, Nevada 89119 Telephone: (702) 798-2232 Fax: (702) 798-2261 E-mail: billets.stephen@epa.gov
Battelle	Amy Dindal	505 King Avenue Columbus, Ohio 43201-2693 Telephone: (561) 422-0113 Fax: (561) 258-0777 E-mail: DindalA@battelle.org
Michigan Department of Environmental Quality	Sue Kaelber-Matlock Michael Jury	Remediation and Redevelopment Division 503 N. Euclid Avenue Bay City, Michigan 48706 Telephone: (989) 686-8025, X 8303 Fax: (989) 684-9799 E-mail: matlocks@michigan.gov
U.S. Fish and Wildlife Service	Becky Goche	Green Point Environmental Learning Center 3010 Maple Street Saginaw, Michigan 48602 Telephone: (989) 759-1669 E-mail: becky_goche@fws.gov
Abraxis LLC	Fernando Rubio	54 Steamwhistle Drive Warminster, Pennsylvania 18974 Telephone: (215) 357-3911 E-mail: frubio@abraxiskits.com
CAPE Technologies L.L.C.	Bob Harrison	3 Adams Street South Portland, Maine 04106-1604 Telephone: (207) 741-2995 E-mail: cape-tech@ceemaine.org
Hybrizyme Corporation	Randy Allen	Suite G-70 2801 Blue Ridge Road Raleigh, North Carolina 27607 Telephone: (919) 783-9595 E-mail: rallen@hybrizyme.com

Xenobiotic Detection Systems, Inc.	John Gordon	1601 E. Geer Street, Suite S Durham, North Carolina 27704 Telephone: (919) 688-4804 E-mail: johngordon@dioxins.com
Wako Pure Chemical Industries, Ltd.	Masako Hayakawa	1600 Bellwood Road Richmond, Virginia 23237-1326 Telephone: (877) 714-1920 E-mail: hayakawa.masako@wako-chem.co.jp
Paracelsian, Inc.	Noriyoshi Inoue	72 Hampton Road Scarsdale, New York 10583 Telephone: (914) 472-5152 E-mail: inomak@earthlink.net
AXYS Analytical Services	Laurie Phillips	2045 Mills Road Sidney, British Columbia, Canada V8L358 Phone: (250) 655-5800 E-mail: lphillips@axys.com

Table A-2. Example demonstration schedule for inclusion in Chapter 5 of the D/QAPP.

Event	Original Schedule for Completion	Revised Schedule for Completion	Actual Completion Date
Prepare and distribute developer survey	July 18, 2003	n/a	July 18, 2003
First Conference Call	**July 28, 2003**	**n/a**	**July 29, 2003**
Distribute summary notes from the conference call	August 5, 2003	n/a	July 31, 2003
Develop preliminary strategy for sample homogenization	August 12, 2003	n/a	August 12, 2003
Prepare one-page demonstration flyer for Dioxin 2003 Conference	August 22, 2003	n/a	August 22, 2003
Obtain dioxin-contaminated soil from one site and test homogenization procedure	September 30, 2003	n/a	October 7, 2003
Draft homogenization procedure	October 3, 2003	n/a	October 1, 2003
Second Conference Call	**October 8, 2003**	**n/a**	**October 8, 2003**
Identify, obtain, and homogenize samples from additional sites	November 28, 2003	n/a	November 13, 2003
Third Conference Call	**December 4, 2003**	**n/a**	**December 4, 2003**
First draft demonstration plan to EPA, developers, peer reviewers, and 1 or 2 technical advisors	December 12, 2003	n/a	December 12, 2003
Final receipt of environmental samples	December 19, 2003	n/a	December 24, 2003
PE samples sent to dioxin laboratories and audits scheduled	January 9, 2004	n/a	January 12, 2004
Comments due to Battelle on first draft demonstration plan	January 15, 2004	n/a	January 15, 2004
Fourth Conference Call	**February 5, 2004**	**n/a**	**February 5, 2004**
Reference laboratory selected	February 3, 2004	n/a	February 20, 2004
Pre-demonstration samples distributed	February 10, 2004	n/a	Phase 1: February 12, 2004 Phase 2: March 16, 2004
Developer and reference laboratory pre-demonstration results due to Battelle	March 31, 2004	n/a	April 16, 2004
Distribute second draft demonstration plan to EPA, developers, and entire Dioxin SITE Demonstration Panel (includes peer reviewers, technical advisors, and observers) for final review	March 31, 2004	n/a	April 2, 2004

Pre-demonstration results distributed to developers	April 9, 2004	n/a	April 16, 2004
Fifth Conference Call	**April 8, 2004**	**n/a**	**April 8, 2004**
Comments due to Battelle on third draft demonstration plan	April 12, 2004	n/a	April 12, 2004
Demonstration plan finalized	April 16, 2004	n/a	April 20, 2004
Field demonstration (Saginaw, Michigan)	April 26 through May 5, 2004 Visitor's Day on April 28	n/a	April 26 - May 5, 2004; Visitors Day on April 28
Audit of reference laboratory	May 24, 2004	n/a	May 26, 2004
First draft report template to EPA	August 2, 2004	n/a	August 3, 2004
Five draft report templates to EPA and developers	September 6, 2004	n/a	September 10, 2004
Final pre-demonstration results to developers and selected technical panel members	new milestone	October 4, 2004	October 4, 2004
Data tables to developers after receipt of developer review comments on report template	new milestone	October 15, 2004	December 6, 2004
Reference laboratory data set completed	November 30, 2004	December 17, 2004	December 20, 2004
Reports to developers for review	October 1, 2004	n/a	n/a – combined this review step with peer review
First full draft reports to EPA project mgt., EPA QA, EPA technical editor, developers, and peer reviewers	January 7, 2005	January 21, 2005	January 28, 2005
EPA administrative report and comment reconciliation review. Draft final copy (with comments incorporated) to developers and peer reviewers	February 4, 2005	February 25, 2005	March 8, 2005
EPA report publication	new milestone	March 30, 2005	
Sixth Conference Call	**January 27, 2005**	**May 10, 2005**	
Data Evaluation Record (DER) to EPA in hard copy and electronic formats	new milestone	April 30, 2005	April 27, 2005

Participant	April											May						Number of samples to be analyzed on-site
	19	20	21	22	23	24	25	26	27	28	29	30	1	2	3	4	5	6	
Abraxis																			116
CAPE Technologies																			116
Hybrizyme																			110
Paracelsian																			0
Wako																			209
Xenobiotic Detection Systems																			43
AXYS Analytical Services																			0

Figure A-2. Example demonstration schedule to be included in Chapter 5 of the D/QAPP.

EXAMPLE
Procedural Observations and Questionnaire
ABRAXIS LLC Coplanar PCB ELISA Kit

Procedure witnessed by: Date witnessed:

Time/Date procedure started: Time/Date procedure ended:

Name of Kit Used: Individuals witnessed:

Lot Number of Kit:

Expiration Date of Kit:

Answer the following questions:

Could this kit be performed in the field without a mobile lab/trailer?

Would it take long to set up in the field before first samples could be processed?
How long?

How many samples could be prepared and analyzed in one day in the field once setup is complete?

By an experienced kit user?
By the novice kit user?

Would sample throughput be faster in the lab than in the field?
If so by how much?

Are the instructions supplied with the kit the same as the operating procedure listed in the demo plan?
If not, why?
If not, use the kit instructions for evaluation.

Was testing carried out at kit-recommended temperature of 20 °C to 25 °C?

How was temperature measured?

Was measuring device calibrated?

Are the following equipment and reagents supplied with the kit? (Note if item not used at all; also note grade and supplier of solvents)

thermometer
soil collector bottle (containing dispersion device)
digital balance
30-mL high-density polyethylene (HDPE) bottle
steel mixing ball
anhydrous sodium sulfate
acetone
hexane
shaker/rotator
filter
centrifuge
extraction tube
concentrated sulfuric acid
nitrogen evaporator
methanol
water
1:10 in 50% methanol/water
anti-coplanar PCB antibody solution
controls
standards
Parafilm
strip holder
pipettor
enzyme conjugate solution
waste container
1X wash solution
paper towels
color solution
stop solution
microplate reader
graph paper
commercial ELISA program

Were any supplies or equipment used that were not listed in the instructions?
If so, please list.

What are recommended hold times and storage conditions for:
Samples?
Extracts?
Reagents?
Standards?

Would you know based on the instructions provided (if not how did you decide):

How much sample to extract?

How many samples to extract in a “batch”?

How much sodium sulfate to mix with sample?

Which solvent and how much to extract with?

How long to extract?

How many controls and standards to prepare with “batch”?

How long to agitate during oxidation cleanup (acid wash) before letting phases separate and removing top layer?

Maximum number of oxidation (acid wash steps) that can be complete before results are affected?

After acid wash, is sample evaporated to complete dryness during nitrogen evaporation step?

Is additional cleanup ever necessary?

How do you know and what additional cleanup options are there?

Are all samples diluted? If not, how do you know which ones to dilute?

How long do you mix the wells by moving in a circular motion? (If measured, what did you measure with?)

How long to incubate? (If measured, what did you measure with?)

What temperature to incubate? (If measured, what did you measure with? Is it calibrated?) How critical is this temperature?

How long do you mix the wells with the enzyme conjugate solution?

How long to incubate? (If measured, what did you measure with?)

What temperature to incubate? (If measured, what did you measure with? Is it calibrated?) How critical is this temperature?

How dry do the wells have to be after the 1X wash step?

Do you have to mix in the color solution? How long does color solution incubate? Is its incubation temperature critical? If so, what temperature is recommended?

How critical is it that the plate be read within 15 minutes of adding the stop solution?

How to use/measure with the microplate reader? Is it calibrated, if so, how?

How much sample solution needs to be used with the microplate reader?

How do you calculate PCDD/PCDF amounts from the data generated? Is it clear how to account for dilutions? For the cross-reactivity factor?

Must all procedures be completed in the same day?

If not, when can procedure be stopped and how must samples be stored?
Is that in the instructions?

Were any procedural steps performed differently than you interpreted from the instructions?
Were any of the instructions confusing?
If so please comment:

What QC samples are required with this approach and at what frequency?

What are recommended QC acceptance criteria?
Did QC samples meet acceptance criteria?
If not, is it clear what corrective action to take?

What QC samples would vendor recommend, but not require and at what frequency?

Do you recommend that some of the data be verified by conventional methods?
What method?
What frequency?
How accurate do weights and volumes used with this technique have to be?

Were all balances, pipettes, and thermometers calibrated?

Following the procedure you just observed, including QC requirements, how many samples do you, the observer, think you could process in a day?

In a week?

Does the vendor provide training in kit use? Is this extra charge?

Video?
Classes?
Phone support?
What education/experience would vendor recommend kit users have?

What do you think would be required education/experience for successful operation of this technology?

Additional Comments:

United States
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