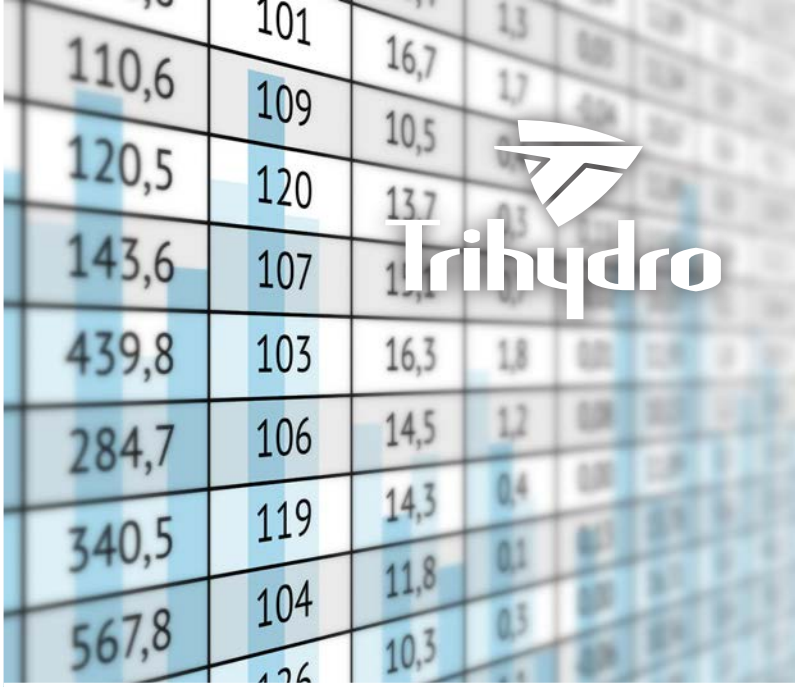

Trihydro

Data Defensibility Guidebook

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1.0 INTRODUCTION

When organizing a project sampling or data collection event, ensuring defensible data may not be the first factor that is considered. However, if the validity of the data comes into question, data defensibility becomes the most important aspect of the project. Data defensibility, like safety, should not be left to chance.

Planning and preparing for a complex project can be daunting on its own. When you add in the fact that some regulatory agencies do not require specific planning documents, it becomes more difficult to ensure defensible data. Moreover, each project, state, and client have different defensible data planning requirements, and budget considerations do not always allow for the development of planning documents, such as: Sampling and Analysis Plans (SAPs), Quality Assurance Project Plans (QAPPs), Data Management Plans (DMPs), Standard Operating Procedures (SOPs), or Field Sampling Plans (FSPs).

Stepping through the process systematically will help to increase your confidence in producing defensible data:

1. **Define:** The first step in planning for legally defensible data is defining what will make your project successful. Understanding the final goal of your project will help you take inventory of the data you will need to produce and evaluate the specific needs associated with your project.
2. **Plan:** Choose project tools that support your success. This includes developing data quality objectives (DQOs) and determining which planning documents you will use (i.e., SAP, QAPP, DMP, SOPs, FSP, etc.) to measure the defensibility of your data. The most important aspect of this stage is to communicate project success requirements to the laboratory, managers, and sample crew.
3. **Preparation:** Preparation of what tools will be used to measure the defensibility are initiated. The most important aspect of planning will be to effectively communicate project success requirements to the laboratory, managers, and sample crew.
4. **Execute:** Ensure samples are collected in accordance with the planning documents. Chain-of-custody should be properly documented and maintained, and the laboratory should analyze the data in accordance with approved methodology.
5. **Review:** The review process confirms you have followed your plans and executed them in accordance with what was approved.
6. **Manage:** Following review, approve or reject data, as necessary. Data must be maintained with data validation and laboratory data qualifiers, as well as associated notes.

Due to the increased awareness of environmental risk factors affecting human and ecological receptors, the quality of the procedures involved in reviewing and managing the data is under greater scrutiny than ever before. This user guide provides guidance on critical steps toward producing defensible data, improving data quality, and assisting users in defending their data.

2.0 DEFINING DATA DEFENSIBILITY

The first step will be to define what constitutes defensible data at the beginning, middle, and end stages of the project. Understanding the final goals at the outset will provide insight on planning and preparations for the project as a whole.

Preparing a Problem Statement:

To define defensible data, you must determine the problem and what questions need to be answered. A problem statement should be detailed and define the problem that requires data collection (i.e. Why are we collecting data?). The more detailed the problem statement, the better chance of producing usable and defensible data. The United States Environmental Protection Agency (USEPA) Intergovernmental Data Quality Task Force (Task Force)'s Workbook for Uniform Federal Policy for Quality Assurance Plan (USEPA 2005) serves as a tool you can use to prepare your problem statement. Refer to the Defining Data Defensibility Checklist for considerations as well as sample answers.

At this stage, you should consider who needs to be involved in making the project decisions. The project manager will want to obtain input from the regulator, client, and other personnel who have dealt with similar issues and review the local and federal regulations. Lastly, the most important question to ask is: What does success for this project look like? If you do not know that answer, you cannot start planning.

2.1 Defining Data Defensibility Checklist Example

✓ **What is the problem to be addressed by the project:**
A train accident resulted in release of 100 gallons of gasoline fuel. Impacts are expected in the surface (0-0.5 feet) and subsurface soils (0.5-6 feet). The area of investigation is 200 square feet on the surface. The spill site is approximately 20 feet from a river, carrying water to crops, environmental receptors, and industrial properties.

✓ **What are the environmental questions being asked:**
How far has the spill migrated? Does it have the possibility of affecting human and environmental health? What steps will be needed to clean up the site to previous conditions? What were previous conditions? Was the spill stopped before reaching water provided to crops? Were crops affected? What environmental and human health receptors might be affected? Did diesel from the train also spill?

✓ **What were the observations from the site reconnaissance reports:**
Gasoline was noticed in a 200 square foot area and visually looks to be 2 to 3 feet below-ground surface (ft-bgs). The train company has stopped the leak and has placed berms next to the river to prevent migration.

✓ **Can the data user synopsis any secondary data or information from site reports:**
Previous reports from the train company indicate geological conditions and current conditions of the site based on data from 2 years prior.

✓ **What are the possible classes of contaminants and the affected matrices:**
The primary concerns are related to the gasoline spill. Therefore, volatile organic compounds (VOCs) and possible semi-volatile organic compounds (SVOCs) will be assessed. Diesel did not appear to be leaking from the train.

✓ **What is the rationale for inclusion of chemical and nonchemical analyses:**
The list of chemicals related to this project will be based on state and federal requirements and methodology. In addition, soil and groundwater parameters may be collected based on state and federal requirements and to assess migration to groundwater potential.

✓ **What information is available concerning various environmental indicators:**
Pre-existing condition reports or other information will be used to assess changes to the river and surrounding soils and groundwater.

- **What project decision conditions ("if..., then..." Statements) can be defined:**
  If the spill migrated to groundwater, then we will assess fate and transport. If the spill migrated to the river, then we will sample the crops and soils surrounding the crops.
- **Who are the decision makers:**
  Train company, federal/state local regulators (EPA, USFWS, DEQ/DNP/PHE), local municipality, affected land owners and farmers.
- **What federal, state, and local regulatory requirements apply to this site:**
  EPA Regulations, State Regulations, Ecological Regulations
- **What does success look like:**
  Success is cleaning up the site to ecological standards for goundwater, soil, and surface water.

3.0 PLANNING

Often, data users rush to begin collecting samples. However, taking the time to thoroughly plan increases your ability to produce defensible data. To plan correctly, develop an organizational chart with the appropriate laboratory and field personnel.

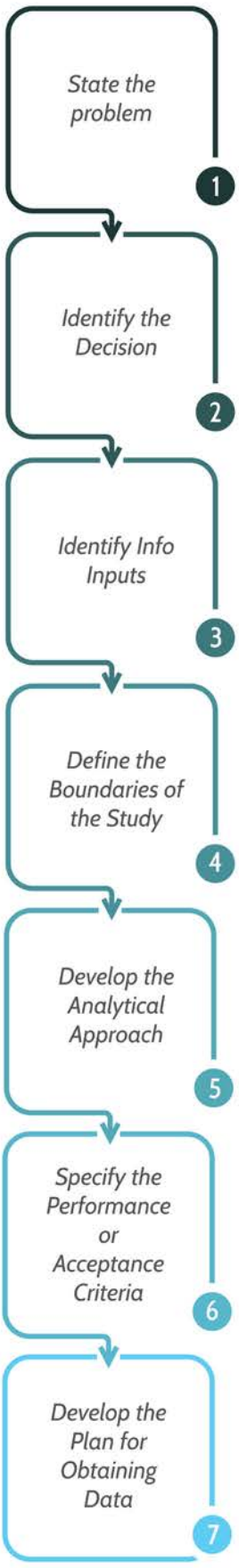
3.1 Develop Data Quality Objectives

Use your problem statement to define data quality objectives (DQOs) by considering how the data will be used both now and in the future. See Figure 3-1 for DQO steps. DQOs help establish what types of data should be collected, how much data should be collected, how data should be collected, laboratory analyses methods, and screening levels. The Task Force (USEPA 2005) also provides a list of questions to help determine the best data quality objectives:

- Who will use the data?
- What will the data be used for?
- What data type is needed (target analytes, analytical groups, field screening, on-site analytical or off-site laboratory techniques, sampling techniques)?
- How "good" do the data need to be to support the environmental decision?
- How much data are needed? (number of samples for each analytical group, matrix, and concentration)
- Where, when, and how should the data be collected/generated?
- Who will collect and generate the data?

The USEPA also provides Guidance on Systematic Planning Using the Data Quality Objectives Process (USEPA 2006), the Region V Quality Assurance Plan (USEPA 2002), and other state and federal guidelines. Again, when understanding who will use the data, the DQO's should consider any potential future uses for that data. For another example, if the data are being collected as part of an initial site investigation but may eventually be used in a risk assessment, then the final data use has changed. The reporting limits required for a risk assessment may need to be lower than they are for the site investigation. You should consider any potential final use of the data and plan for the worse-case scenario. This approach can help avoid costly recollection of samples.

Figure 3-1



3.2 Choosing the Laboratory

When choosing a laboratory, it is important to review the laboratory accreditation requirements for anyone who will use the data, including state agencies, regulatory programs, and regulatory agencies. Most regulatory bodies or states require that specific methodology is certified or accredited to approve the submitted data. In fact, many states and regulatory bodies require that laboratories be certified by organizations such as the National Environmental Laboratory Accreditation Program (NELAP), International Organization for Standardization (ISO)/ International Electrotechnical Commission (IET) 17025 Laboratory Accreditation Bureau through the American National Standards Institute/American Society for Quality (ANSI/ASQ) ACLASS, or the American Association for Laboratory Accreditation (A2LA). Laboratories performing work for federal agencies may also require Department of Defense (DOD) or Department of Energy (DOE) environmental laboratory accreditation. It is critical that the project laboratory have adequate accreditation to ensure data will be accurate, precise, reproducible, and complete. Using an accredited laboratory is one of the easiest ways to plan for defensible data, as the accreditation process verifies that the laboratory maintains necessary regulatory requirements.

Second, select a laboratory that can meet your project goals. This includes meeting required hold times and rush turnaround times, when requested. Ensuring that the laboratory has the capacity to analyze samples and still meet method and regulatory analyses requirements is important to prevent resampling or unusable data. For a project requiring a quick turnaround (e.g. one day) and/or collecting a significant amount of data, the laboratory may not have the capacity to meet the project requirements. Therefore, the laboratory should be able to provide capacity numbers and a back-up plan before committing to a project. At times, the laboratory back-up plan will include use of a subcontracted laboratory. Similarly, you should approve any subcontracted laboratory in the same manner as the primary laboratory.

Third, the laboratory selected should be able to meet defined project objectives. The project objectives may include the specific methods and reporting limits, regulatory standards or clean-up levels, and/or dilution requirements as required by the governing regulatory agency, regulatory program, or state program. Good project planning ensures that these objectives be communicated to the laboratory before the bottle order completion. Otherwise, reporting limits may be left to laboratory discretion, which could result in limits that do not meet the project objectives. Understanding the different limits offered and the data usability at those different limits (i.e., what limits are required by the project) is another essential part of defining your project objectives. For example, a practical quantitation limit (PQL) is defined as having a 100% certainty level and a method detection limit (MDL) is defined as having a 99.9% certainty level. Therefore, data between those two values would be qualified as estimated by the lab (J flagged). You may need to report to the MDL to meet the required regulatory standards or clean-up levels. Proactive communication with the laboratory will help ensure that project goals are met.

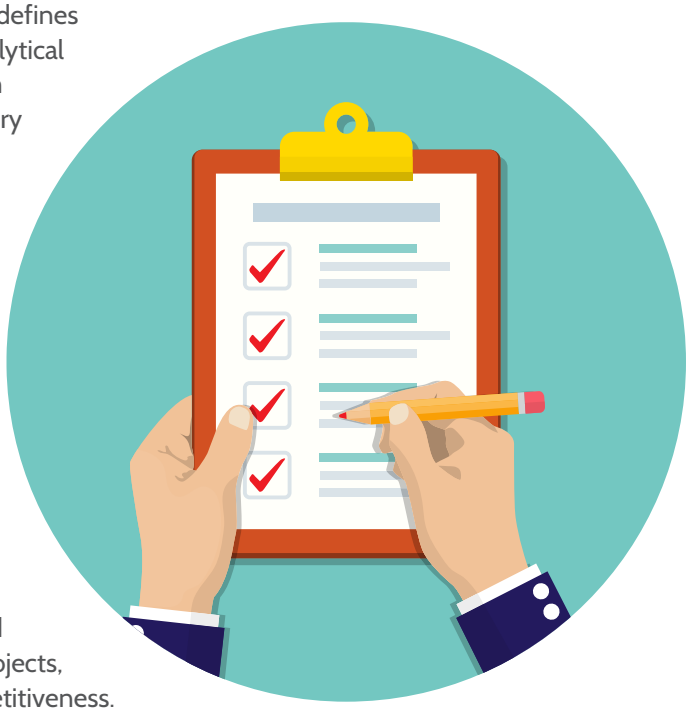
3.3 Choosing Field Personnel

Field personnel play an important role in data defensibility. Incorrect data collection can quickly result in failure to meet project objectives. Field personnel trained in the specific collection methods as defined by project objectives are essential to ensuring samples are collected and submitted in a defensible manner. Field personnel can find tools for collecting defensible data in the Contract Laboratory Program Guidance for Field Samplers.

3.4 Developing Planning Documents

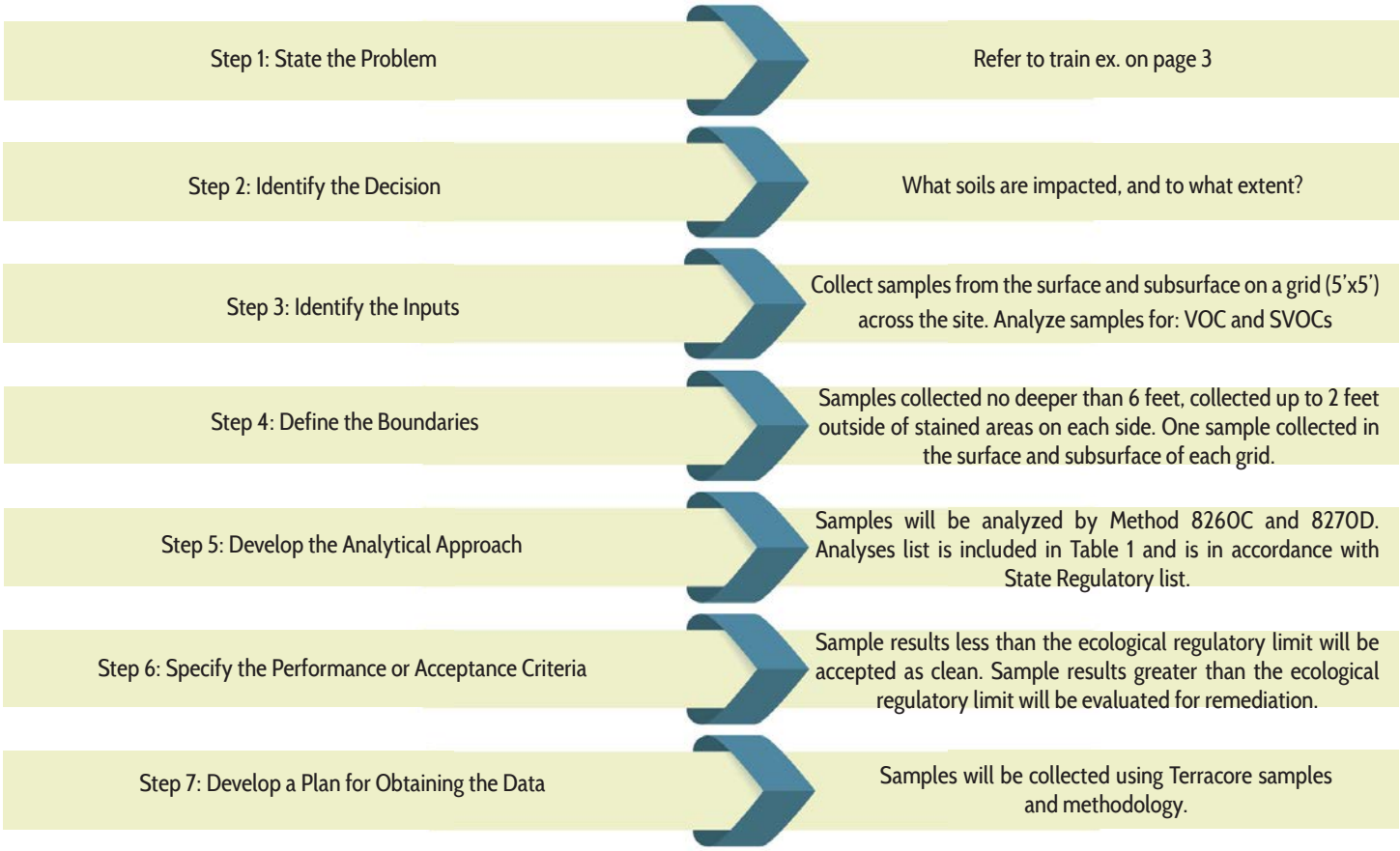
Developing planning documents is the key to documenting and communicating progress made during the definition and planning stage. The planning documents can include one or a combination of several documents and are usually included in the project work plan. Inclusion of laboratory and field personnel at this stage is a critical, but often missed, step toward planning for data defensibility. In addition, the planning documents need to be prepared in accordance applicable federal, state, and local guidelines. These can vary significantly, depending on the project location. Documents may include:

- **SAPs –** A SAP can be a simple to complex document outlining the elements of the field collection, data analysis, and data quality programs. The SAP should also include more complex information such as project objectives, sampling protocol and methods, shipping, custody, field quality control samples, and SOPs.
- **Standard Operating Procedures (SOP)** – SOPs are developed to provide specific procedures that are followed by samplers or lab personnel on each project they work on. These procedures usually have step by step instructions that standardize the steps used from start to finish for specific project tasks.
- **QAPPs –** A QAPP is a complex document that provides guidance for all quality aspects of sample collection, analysis, and use. The QAPP defines information such as project objectives, reporting limits, analytical methods, required quality control samples, communication between project members, field collaboration and laboratory provided documents. The laboratory Quality Assurance Manual and SOPs are included within the document appendices.
- **Field Sampling Plan (FSP) –** A FSP provides specific field procedures and may include sampling preparation, procedures, and decontamination processes. This can be in addition to the SAP, part of the SAP, or as a separate document, depending on the local regulations.
- **DMP –** A DMP is specific to the treatment of the data once it has been obtained from the laboratory. This plan may include data validation, data qualification, reporting, and data storage.



Planning documents are specific to the project or facility and should only include aspects relevant to that project or facility. For small projects, some planning documents may be combined to save time and repetitiveness. For example, if a project is small, it may not be necessary to develop a QAPP. Instead, planning can be completed using a SAP with a data quality section. Discretion of how to arrange the project documents is up to the project team and regulatory agency. To ensure understanding and alignment on quality objectives, the project team members (e.g. contractors, field, laboratory personnel) should review and sign-off on project planning documents.

3.5 Planning Checklist



Develop Data Quality Objectives

- ☐ Who will use the data?
- ☐ What will the data be used for?
- ☐ What data type is needed? (target analytes, analytical groups, field screening, on-site analytical or off-site laboratory techniques, sampling techniques)
- ☐ How "good" do the data need to be to support the environmental decision?
- ☐ How much data are needed? (number of samples for each analytical group, matrix, and concentration)
- ☐ Where, when, and how should the data be collected/generated?
- ☐ Who will collect and generate the data?

Choosing a Laboratory

- ☐ Is the laboratory certified under the local, state, or federal required accreditation programs (i.e. NELAC Institute, A2LA, etc...)?
- ☐ Is the laboratory able to meet the reporting limits needed in order to meet the project defined clean-up levels? Can the laboratory analyze the samples by the required analytical methodology? If not, can the subcontract the remaining analyses?
- ☐ Does the laboratory have sufficient capacity to manage the samples?

- [ ] Can the laboratory provide the required reporting output and electronic deliverables for your database?
- [ ] Can the laboratory provide the level of data report needed?
- [ ] Can the laboratory meet the required turn-around-times for sample analysis and reporting?

Choosing Field Personnel

- [ ] Are the field personnel trained on the sampling methods as defined in the SOP documents, SAP and/or FSP?
- [ ] Are the field personnel trained in general sampling procedures, chain-of-custody, decontamination documentation, and packing?
- [ ] Are the field personnel able to work on the entire project?
- [ ] Is a field personnel transition plan in place?
- [ ] Do the field personnel have the required corporate and client safety training?

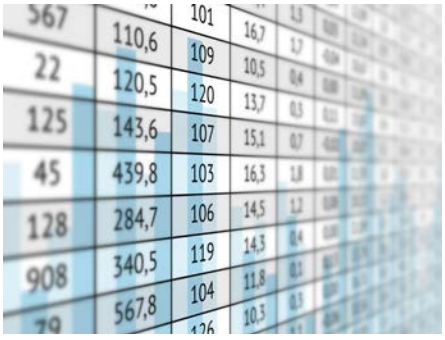
What planning documents are required for this project?

- [ ] Work plan
- [ ] Quality Assurance Project Plan
- [ ] Sampling Analyses Plan
- [ ] Data Management Plan
- [ ] Field Sampling Plan
- [ ] Health and Safety Plan
- [ ] Others: _____

4.0 PREPARATION

The USEPA provides guidance for sample preparation in the Contract Laboratory Program Guidance for Field Samplers. Communication between the teams proves critical at this stage of the project.

4.1 Laboratory Preparation



The laboratory project manager and the site project manager should work together to schedule sampling and analyses. Contacting the laboratory manager well in advance of an upcoming sampling event will help ensure they are adequately prepared for the volume and scope of the sampling event (e.g., do they have the proper constituents within their calibration standards and do they have sufficient personnel and instruments available to complete the analyses within the required times). A defensible practice is to provide necessary project planning documents (i.e., QAPPs) to the laboratory before the submittal. This allows the laboratory to review and provide edits, where needed. Then, the formal bottle order should provide expectations on communication methods and frequency. Some examples include:

- Missing or incomplete chain-of-custody (CoC) documents or custody seals
- Missing or damaged sample containers
- Switched, missing, or illegible sample container labels
- Sample temperatures outside the method acceptable range of 2.0 to 6.0˚C or other Method specific preservation requirements

- Inadequate sample volume(s) to perform the required analyses and/or quality control tests
- Samples received outside of holding times or too close to the holding times for the laboratory to complete the analyses within the required timeframe
- Any other physical conditions relating to the samples which might adversely affect the final quality of the analytical results

The formal bottle order and laboratory purchase orders or contracts should include how data shall be reported to the client (i.e., electronically, hard copy, or both), and what level and types of reports are expected (i.e., electronic data deliverable, paginated report, or both). Other items to communicate are when and where bottles should arrive, contact information for field personnel, and payment information. The laboratory should also be aware of their responsibilities for filtering and compositing, if necessary. Additionally, the formal bottle order or communication before the sampling event should include information applicable to how dilutions should be handled and reported. The laboratory will require time to set up reporting dilutions and reporting limits before commencement of sampling. Therefore, as discussed above, proper communication with the laboratory is essential to preparing the laboratory for project work.

4.2 Field Personnel

Communication between the site project manager and field personnel is essential. Additionally, proper training for field personnel will help ensure defensibility of data produced by the laboratory. This training may include proper field equipment use and calibration, proper collection techniques, techniques for preventing cross-contamination, techniques for proper packaging and shipping, techniques for maintaining custody, and proper decontamination techniques.

Field personnel should be comfortable communicating with the site project manager. Some of the worst data usability problems come from improper field data collection due to complacency, shortcutting, covering up a problem, or inadequate training. Field problems are easy to fix if they are discovered early. However, resampling can be expensive if you find a mistake later in the process or during review. Chain-of-custody discrepancies can be corrected/clarified using a signed custody confirmation form, or a signed and notarized affidavit.

4.3 Preparation Checklist

Laboratory

- ☐ Provide laboratory a formal contract
- ☐ Notify laboratory of sampling dates
- ☐ Notify laboratory of number of samples
- ☐ Create or use a laboratory bottle order form to order bottles
- ☐ Notify laboratory of the report style/level/type and Electronic Data Deliverables (EDD) style/level/type required for your project

Field

- ☐ Utilize form H-1 of the Samplers Guide

5.0 EXECUTION

Execution of the field event involves actual data collection. The USEPA provides data collection tips in the Contract Laboratory Program Guidance for Field Samplers where collection, preservation, sample volume, decontamination, and shipping are covered in detail.

5.1 Laboratory Execution

The laboratory execution of the samples starts when a bottle order is placed. The laboratory will need to confirm they are able to meet capacities, reporting limits, and any other planning document requirements communicated during the planning process. The bottles will need to be packed and shipped to the sampling crew with the correct number of bottles and preservatives for each analysis. Depending on the method, they may also ship tools, canisters, or equipment required by the Meathod.

Once the laboratory receives the samples from the field, you will not have much control over the data quality. Therefore, be sure to maintain an open dialogue with the laboratory. As previously noted, depending on the regulatory requirements, the laboratory must follow either the methodology or the SOPs. The laboratory will be required to meet quality assurance objectives outlined by the methods, SOPs, and certifying bodies. They may also be required to meet other quality objectives outlined in the planning documents, which will be verified during the data review.

5.2 Field Execution

Major data defensibility problems can be found from the practices of field personnel. Therefore, correct sample collection is important. Some collection tips include:

- **Collection Method:** Field personnel should verify the lab shipped all correct bottles and preservatives before beginning sampling activities. Samples should be collected in accordance with method requirements. Some methods require sampling with specific equipment, preparation, filtration, or even specific temperature requirements. Each method requires differences in sample volume and preservation requirements that must be met and clearly documented.
- **Collection Order:** The order in which wells are sampled can cause problems with contaminate carry over. To the extent possible, samples should be collected in order of cleanest to dirtiest to prevent cross-contamination. Samples should be collected in order of bacteriological, volatiles, semi-volatiles, inorganics, and then metals.
- **Decontamination:** Decontamination of equipment between samples to ensure contaminants are not carried from one location to the next.
- **Quality Assurance Samples:** Quality assurance samples can be expensive and are often eliminated from sample collection events. However, each quality assurance sample has a specific function in determining data validity. Some quality assurance samples include:
    - **Field blanks –** Collected to check for possible ambient contaminants present within the sample collection area.
    - **Equipment Blanks/Rinsate Blanks –** Collected to check for residual carryover in the equipment following decontamination or other residual contamination.
    - **Trip Blanks –** Collected to verify samples are not contaminated during transportation activities. Trip blank samples are prepared in the laboratory and travel with the sample coolers. These samples are usually provided in coolers containing volatile samples.

  - **Matrix Spikes –** Collected in pairs and are used to determine how the instrumentation at the laboratory responds to the specific site matrix.
  - **Field Duplicates –** Collected to determine precision between field and laboratory procedures (i.e., how homogenous the samples are).

- **Documentation:** Similar to the laboratory, sample collection should be documented at each step. As many factors can affect sample quality, notable concerns should be documented and may include, but are not limited to: weather, location, and visual inspection of the samples. The field personnel should also take notes of any major collection issues (e.g. buffering or sedimentation) on the CoC form. Noting major field concerns on the CoC form will help the laboratory make proper decisions regarding the analyses before sample receipt. Documentation can also be completed by taking photographs.
- **Sample Custody:** Sample custody should be maintained from the moment of collection. To maintain custody, the CoC form should be filled out correctly, fully, and legibly by the sampler, released to the shipper, and then to the laboratory. The final custody form should be kept in the project files. Also, the coolers and sample bottles (if required) should have custody seals to ensure sample coolers were not opened during shipping/transport.
- **Packing/Shipping:** The samplers should pack the coolers in a way that prevents breakage but allows the samples to stay cool. Coolers should be clean, the cooler contents should match the CoC, the cooler should be completely sealed to prevent leaks, and the laboratory should be notified when the cooler ships.

While collecting samples, communication with the laboratory about changes in the field conditions (e.g. fewer samples collected, different analyses required, delay in shipping, etc.) can prevent shipping and analyses problems.

5.3 Execution Checklist

- ☐ Did you contact the laboratory to ensure that the bottles were shipped?
- ☐ Did you call the laboratory when you shipped samples?
- ☐ Did you verify samples arrived at the laboratory?
- ☐ Did you notify the laboratory of everything they need to notify you about during analyses?
  - ☐ Did samples arrive in good condition?
  - ☐ Were holding times met?
  - ☐ Were any quality issues identified?
  - ☐ What is the due date and will they meet that date?
  - ☐ Were limits met?

Field:

- ☐ Utilize forms H-2, H-3, H-4, H-5, H-6 of the Samplers Guide

6.0 REVIEW

The data review process involves several steps and may vary based on the project and laboratory. The field data are reviewed by field personnel and then by the project manager.

6.1 Laboratory Review

Laboratory data review procedures vary but are typically done using a tiered approach with two or more reviews following the analyst review. First, the analyst reviews the data at the bench level. Second, the department manager and/or quality department official reviews the data. The laboratory project manager often completes the third review for completeness and prepares a summary of non-conformances for the case narrative. Qualifiers are applied to data and reviewed as part of this process. In many cases, the laboratory project manager prepares a case narrative (or similar) and signs the legal copy before sending the data to you. The laboratory review is extensive and primarily focuses on analytical data quality. However, a third-party review is necessary to validate the data from your project's standpoint.

6.2 Project Data Review

Project data review should be conducted to determine if the data meet project objectives. This review is sometimes referenced as a Tier I data validation or a data verification review. The Tier I data package is checked to document that all samples in the data set were analyzed according to project requirements, and that the laboratory analytical report is complete. This initial review is specific to the usability of the data from your perspective. For example, you will be most concerned with the data being consistent with your expectations. You will also be concerned with the reporting limits and how those measure up to required clean-up levles or regulatory limits. You should confirm that what you received is the same as what was requested. The following questions will help you determine the usability of the data:

- Were any non-conformances noted by the laboratory that may affect the quality and usability of the data?
- Were the CoC forms and sample receipt logs complete?
- Were samples received in good condition, within temperature requirements, and properly preserved?
- Did you receive the samples and analyses that were requested on the CoC?
- Will the reporting limits meet your project requirements? If not, explain.
- Is the data consistent with previous sample events?
- Specify any project specific data validation objectives or information that need to be met in the validation process or in the addition of qualifiers.
- Was a quality control section included with the lab report?
- Were blind duplicates collected?
- Were sample holding times met?
- Were the correct concentration units reported?
- Were compounds detected in the field blanks, equipment blanks, or trip blanks?
- Spot check that the laboratory report and eEDD match.

This level of review should always be completed and is not usually standalone except for some applications like non-chemical data (e.g. engineering analysis and light non-aqueous phased liquid [LNAPL] characterization data).

6.3 Third Party Review

Regulatory agencies and data users often require third party data validation reviews. A third party data validation can be simple or complex. This portion of the review provides an independent data verification against the environmental analysis method or applicable guidelines such as the EPA Contract Laboratories National Functional Guidelines. Chemical data validation is conducted in accordance with the following guidance documents or the specific methods, as applicable. State and program guidance documents may also be used, depending on the regulatory or state requirements:

- USEPA Contract Laboratory Program (CLP) National Functional Guidelines for organic and inorganic analyses or by the appropriate method if not covered in the National Functional Guidelines.
- USEPA CLP National Functional Guidelines for Superfund Organic Methods Data Review, document number USEPA-540-R-2017-002, January 2017 (USEPA 2017) with additional reference to the USEPA CLP National Functional Guidelines for Organic Data Review, document number EPA 540/R-99-008, October 1999. (USEPA 1999)
- USEPA CLP National Functional Guidelines for High Resolution Superfund Methods Data Review, document number EPA 542-R-B-16-001, April 2016. (USEPA 2016).
- USEPA Hazardous Waste Support Branch Validating Air Samples Volatile Organic Analysis of Ambient Air in Canister by Method TO-15, standard operating procedure number HW-31 revision 6, June 2014. (USEPA 2014)
- USEPA CLP National Functional Guidelines for Inorganic Superfund Data Review, document number EPA 540-R-2017-001, January 2017. (USEPA 2017) with additional reference to the USEPA CLP National Functional Guidelines for Inorganic Data Review, document number EPA 540-R-04-004, October 2004.
- Review of field duplicates is conducted according to the USEPA Region 1 Laboratory Data Validation Functional Guidelines for Evaluation of Organic Analysis, December 1996. (USEPA 1996)

Multiple other guidance documents exist depending on Meathod and regulatory program. Data validation can be completed in several different ways including by method, samples, analytical batch, data set, or even by project. The validation can include a limited, to a detailed review. However, level of validation should be described in the planning documents.

A data validation is more detailed and occurs from a different perspective than your review. A validation review includes a review of the analytical procedure results, a review of field and laboratory quality control data, assessment of duplicate sample repeatability, and a description of any qualified or rejected data. An even more detailed review may include checking a specified percentage of the raw analytical data. This detailed review may check for correctness of concentration calculations, compound identification, and anomalies in the data. The validation review should provide enough detail for you to have an accurate idea of the data quality and reliability, and an understanding of how well the project objectives were met.

The data validation specifically reviews the precision, accuracy, method compliance, completeness, and representativeness of the data. Precision is determined by evaluating the calculated relative percent difference (RPD) values of samples from field duplicate pairs; laboratory duplicate pairs; matrix spike (MS) and matrix spike duplicate (MSD) pairs; and laboratory control sample (LCS) and laboratory control sample duplicate (LCSD) pairs. Laboratory accuracy was established by reviewing the demonstrated percent recovery of matrix spike MS/MSD samples, LCS/LCSD samples, and organic system monitoring compounds (surrogates) to verify that data are not biased. Field accuracy is established by collecting trip blank, field blank, and equipment blank/rinsate blank samples to monitor for possible ambient or cross contamination during sampling and transportation. Method compliance is established by reviewing sample integrity, holding time, system performance checks, initial and continuing instrument calibrations, laboratory blanks, internal standards, and target analyte identification against method specified requirements. Completeness is evaluated by determining the overall ratio of the number of samples and analyses planned versus the number of samples with valid analyses. Determination of completeness includes a CoC review, laboratory analytical methods, and other laboratory and field documents associated with this analytical data set.

Data validations should be customized to the project and specified in the planning documents. The more scrutiny the data could have, the higher the validation level. However, it is important that the validations are in accordance with the data users and regulators requirements.

The data validation may result in qualification of data. However, the laboratory may have added qualifiers to the data. For example, a "J" flag may be added to a data point to indicate that the result is estimated between the PQL and MDL. The data validation will review these qualifiers and then revise them to be consistent with the qualifiers specified by the USEPA in the National Functional Guidelines (NFGs) or other applicable guidance documents. Depending on how the planning documents treated the qualifiers, it is common for estimated data to be accepted for qualitative use and rejected data to not be used. Maintaining these qualifiers with any data tables or reports is important so that the validity and usability are known by any user.

6.4 Review Checklist

- ☐ Were field forms filed and stored correctly?
- ☐ Were data entered into the database from field forms and quality-control checked (QC'd)?
- ☐ Were data packages and EDDs received from the laboratory?
- ☐ Was the appropriate level of validation completed?
- ☐ Were any major nonconformances identified?
- ☐ Were the laboratory data correctly loaded to the database?
- ☐ Were duplicates and blanks correctly identified and recorded?
- ☐ Were data deliverables checked against the planning documents?
- ☐ Have you used an auditing system to ensure data are not changed accidently?
- ☐ Have you had any handmade tables or figure QC'd?

7.0 MANAGEMENT & MAINTENANCE

The final step in defensible data is management and maintenance of the data. You should obtain all required information from the laboratory including the standard laboratory report, expanded laboratory report, EDD, field personnel notes, field data, data validations, or any other documents specified in the planning documents. Be sure to store these documents in a central location.

You should be aware that the EDD is not the legal copy of the data. While the EDD is convenient for creating tables, the signed laboratory report is the legal copy of the data. The data validation may result in data validation flags or qualifiers that should also be maintained with the data. Additionally, the data validation could result in changed values (e.g. if cross contamination is evident from the laboratory or field blank detections, the validator may revise a detected result to be an undetected result if determined necessary). As you work with the data, the revised result should be used. However, revising the data, even in the EDD, can result in less defensible data. Therefore, it is important to have a data management system that not only stores and tracks the data but audits changes to the data. You should also be aware of any changes made to the data so that if the EDD is compared to the legal laboratory report, the data will not appear to be tampered with or in error.

7.1 Management & Maintenance Checklist

- ☐ Have all records been filed?
- ☐ Have all reports been filed in an accessible location?
- ☐ Are documents easily accessible to anyone in the company?
- ☐ Are data and documents locked down once finalized?
- ☐ Are the lab reports, EDDs, validations, and qualifiers stored together as one package?
- ☐ Are the field forms stored together with the electronic tables?

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