

REGION 1 - EPA NEW ENGLAND

ENVIRONMENTAL DATA REVIEW SUPPLEMENT

For

Region 1 Data Review Elements and Superfund Specific Guidance/Procedures



REGION 1 - EPA NEW ENGLAND

**EPA Quality Assurance Branch & TechLaw Environmental
Services Assistance Team (ESAT) Contract Support**

Laboratory Services and Applied Science Division (LSASD)

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Preface

This document is intended to be used in conjunction with the *Region 1 - EPA New England Environmental Data Review Program Guidance* (1). As a regional implementation document, the *Region 1 - EPA New England Environmental Data Review Supplement*:

- Provides region-specific guidance for reviewing and reporting sample results generated for data collection activities (Note: review of previously collected or existing data is addressed in the *Region 1 - EPA New England Environmental Data Review Program Guidance*);
- Describes Superfund data review including:
 - use of the National Functional Guidelines for data review;
 - use of automated procedures;
 - incorporation of the *Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use*; and
 - use of a 2-Tiered data review approach dependent on project objectives.
- Includes instructions for using the Region 1 Performance Evaluation Sample Program.

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Chapter 1

Region 1 Data Review Elements

1.1 Introduction

The *Region 1 - EPA New England Environmental Data Review Program Guidance* (1) is applicable to all environmental data supporting EPA R1 decisions. This *Region 1 - EPA New England Environmental Data Review Supplement* (hereafter, *DR Supplement*) provides region-specific guidance for reviewing environmental data generated by or for the Region and is designed to augment guidance provided in the *Region 1 - EPA New England Environmental Data Review Program Guidance*.

The guidance supplements national or program guidance, including the Superfund *National Functional Guidelines* (NFG) available at: <https://www.epa.gov/clp/superfund-clp-national-functional-guidelines-data-review> whenever so directed. In addition, it may be used when national program guidance does not exist or when data review procedures are not specified in quality assurance project plans (QAPPs) or other quality assurance (QA) documentation. The *DR Supplement* establishes processes to ensure that region-specific quality control (QC) criteria and actions are applied consistently to data generated by and for the Region.

1.2 Data Review Using the Graded Approach

Basing the level of data review on project objectives and the needs of the data user, the Region applies a graded approach to review data. The Region encourages the use of professional judgment when reviewing measurement data. Data reviewers should be trained chemists and scientists experienced in and knowledgeable of the applicable analytical methods and data review procedures. Therefore, the Region anticipates that professional judgment applied by data reviewers to accept, qualify or reject sample results will be defensible and documented with scientific rationale.

Using the graded approach, the Region applies tiered procedures for reviewing Superfund data (refer to Chapter 3). In addition, the Region applies validation labels in accordance with the *Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use* (2), (refer to Chapter 3), to provide consistent review procedures and QA/QC activities evaluated for data review.

1.3 Region 1 Review Requirements

Region 1 expectations are that QA and QC sample results associated with project activities will be routinely evaluated to determine the quality of the sample data prior to decision making, and that procedures for reviewing data will be documented in a QAPP or equivalent QA documentation.

QC samples and QA activities provide information pertinent to the data quality elements, including precision, accuracy/bias, representativeness, comparability and sensitivity.

QA/QC samples and activities include but are not limited to:

- conducting a completeness check to confirm that all required sampling and analytical documents and records are present in the data deliverable to ensure sufficient documentation for data defensibility;
- applying preservation and holding time procedures to ensure sample integrity;
- submitting performance evaluation samples (PESs) for analysis with sample sets to assess bias and accuracy of the results;
- requiring procedures for calibration and calibration check samples to ensure the accurate quantitation of results;
- including and/or analyzing blanks (laboratory and equipment) with sample sets to assess contamination and bias of the results;
- sampling and analyzing duplicates (laboratory and field) to determine precision;
- including the use of spike samples (matrix, deuterated monitoring compounds, etc.) to assess accuracy and bias;
- including the use of instrument and system check samples to assess accuracy;
- including the use of sensitivity checks to assess detection and reporting limits; and,
- including the use of Method Detection Limit (MDL) determinations to establish quantitative reporting.

1.3.1 Method QC Acceptance Limits versus Project-Specific Acceptance Criteria for Data Review

In most cases, EPA-approved methods include QC acceptance limits that must be met to demonstrate that the measurement system is capable of producing scientifically acceptable data. When method QC acceptance limits are not achieved by the laboratory, the system is considered “out of control”. The laboratory may take corrective actions and re-prepare and/or reanalyze the samples as applicable; or it may qualify or reject sample results.

Note: For many projects, the method QC acceptance limits are used as data review criteria by the reviewers.

In addition to method QC acceptance limits, program and/or project-specific review criteria may be applied to sample results. These data review criteria and actions are provided in program procedures and guidance, and project-specific QA documentation. Based on data quality objectives (DQOs), project-specific data review procedures define acceptance criteria for QC samples (e.g., blanks, duplicates) and describe actions the reviewer should take when criteria are not met. Actions may include accepting, estimating (UJ or J) or rejecting (R) laboratory reported data. Qualification of data usually includes applying “flags” to laboratory reported results.

1.3.2 Region 1 Data Qualifier Flags

Data qualifiers or “flags” are applied by the reviewer to highlight the most significant aspect of a data point. During data review and the usability assessment, qualifiers are assessed to ensure that data are usable for their intended purpose. The Region uses the following data qualifiers:

- U** The analyte was analyzed for but was not detected. The associated numerical value is the sample quantitation limit (SQL) or Contract Required Quantitation Limit (CRQL). The SQL/CRQL accounts for sample specific dilution factors, percent solids results or sample sizes that deviate from those required by the method. SQLs are also referred to as Sample Reporting Limits (SRLs) and Contract Required Quantitation Limits (CRQLs) for Superfund CLP generated data.
- J** The associated numerical value is an estimated quantity. The analyte was positively identified and the associated numerical value is the approximate concentration (due either to the quality of the data generated because quality control criteria were not met, or the concentration of the analyte was below the SQL).
- J+** The associated numerical value is estimated; associated QC data indicate a positive bias.
- J-** The associated numerical value is estimated; associated QC data indicate a negative bias.
- Note:** J+ and J- qualifiers should only be used when QC results indicate an unambiguous direction of bias. For example, when all QC results are acceptable except for low spiked compound recoveries, then the data reviewer may qualify the associated data using “J-”. Also, there can be cumulative bias information, for example, when a PE compound has a low recovery and the compound is recovered low in the matrix spike. The data reviewer may apply “J-” to all the associated data and describe the cumulative low recoveries on the data summary table (DST) with a footnote.
- UJ** The analyte was analyzed for, but was not detected at a level greater than or equal to the SQL. The sample quantitation limit is an estimated quantity.
- NJ** The analysis indicates the presence of an analyte that has been “tentatively identified” and the associated numerical value represents an estimated quantity.
- R** The data are unusable (analyte may or may not be present). Re-sampling and analysis are necessary for verification. The R replaces the numerical value or SQL.
- C** This qualifier applies to pesticide and Aroclor results when the identification has been confirmed by Gas Chromatograph/Mass Spectrometer (GC/MS).
- X** This qualifier applies to pesticide and Aroclor results when GC/MS analysis was attempted but was unsuccessful.
- EB, TB, BB** An analyte that was identified in an aqueous equipment blank (EB), trip blank (TB), or bottle blank (BB) that was used to assess field contamination associated with soil/sediment samples. **These qualifiers should only be applied to soil/sediment sample results.**

If other data qualifiers are used, they must be defined in the generic program or project-specific QAPP and on the Data Summary Table (DST).

1.4 Data Review Reporting

The outcomes of data review are documented to support Agency actions. The documentation of data quality decisions (e.g., to use or not to use data) is an essential element of data review. The Region applies the graded approach when documenting the data review process.

For the Superfund Program, data review must be documented in a formal Data Review Report in accordance with the format specified in Chapter 2, Section 2.3.

For other programs, including the Water Program, the results of the data review process may be documented in a formal Data Review Report similar to the Superfund Program; or, data review may be presented in a narrative format as part of the final project report. If a narrative format will be used, it should be defined in the generic program or project-specific QAPP. The narrative should summarize the review procedures and outcomes; discuss the application of data qualifiers based on field and laboratory QA/QC results; and, identify any limitations on the use of the data.

1.5 Data Usability Reporting

Depending on the type and complexity of the environmental project, a formal, separate Data Usability Assessment Report may be required. Typically however, data usability is discussed in conjunction with data review results as part of the project final report. In either case, the QA planning document (e.g., QAPP, SAP) should define how data usability will be documented and reported.

Data usability reporting should include an evaluation and summary of data usability relative to the project objectives, and should include the following:

- description of the project QA/QC activities and DQOs;
- procedures used for reviewing and evaluating data, including acceptance criteria, the definition of data qualifiers, and the statistical methods of data analysis, if applicable;
- tabular summary of data used and not used, including the rationale for the data not used;
- narrative summary of the representativeness evaluation relative to the sampling design, data completeness, and matrix homogeneity; and,
- discussion of the limitations or restrictions of the data use regarding bias, precision, comparability and sensitivity and taking into consideration the general assessment factors as discussed in Section 12 of the *Region 1 - EPA New England Environmental Data Review Program Guidance* (1).

Statements regarding the use of the data are recommended. Examples include:

- *The data meet the project quality criteria and can be used without restriction;*
- *Data were rejected based on failure to meet project quality criteria and should not be used for project decisions/actions; or,*
- *Some data were qualified based on failure to meet project quality criteria and may contribute an unacceptable level of uncertainty to project decisions/actions and, therefore, the data should be used with caution.*

Note: These are example opening statements that must be followed by a summary of the specific data evaluated, the acceptance criteria, and the evaluation outcome. The rationale must be documented for using or not using data.

1.6 Supplemental Region 1 Data Review Procedures

Data review procedures are specific to the national program and/or project. The Region applies national program data review guidance where it exists, including Superfund Program guidance. The Region applies region-specific review criteria and actions described in the following Section to supplement national program data review guidance (e.g. Superfund NFGs). **Where noted, R1 data review criteria and actions supersede Superfund NFG procedures for data review.** Refer to Chapter 2 Region 1 Superfund Data Review Procedures for specific guidance.

Chapter 2

Region 1 Superfund Data Review Procedures

2.1 Introduction

Except where noted in this Chapter the Region adopts USEPA Contract Laboratory Program (CLP) NFG review criteria and actions for organic, inorganic and high resolution chemical Superfund data as described in the most recent guidance available at: <https://www.epa.gov/clp/superfund-clp-national-functional-guidelines-data-review>. The NFG should be followed, as applicable, for Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) data generated through national contracts and by non-CLP (e.g., Potential Responsible Party (PRP)) laboratories.

In addition, the Region adopts the *Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use*, OSWER Directive No. 9200.1-85, EPA 540-R-08-005 (2). This guidance provides consistent terminology and ensures that EPA decision makers can readily determine the data review procedures that have been applied to laboratory analytical data regardless of the region, program office, or contractor providing the review.

2.2 Manual versus Automated Data Review

The Region uses both manual and automated data review procedures. Data generated by non-CLP laboratories can be reviewed manually, however, electronic review should be incorporated to the greatest extent possible. Data review procedures applied to non-CLP data, including review criteria, actions and qualifiers, must be documented in the generic program or project specific QAPP and/or SAP. Reviewers of non-CLP data should document their review with worksheets/checklists as necessary, and generate a Data Review Report utilizing the format described in Section 2.3.

2.2.1 Automated Data Review of CLP Data and Associated EXES Reports

Data generated through national contracts (i.e., CLP) that produce Staged Electronic Data Deliverable (SEDD) formats will undergo automated data review and qualification by the Superfund National Program Office (NPO) based on the NFG criteria. Automated review generates Electronic Data Exchange and Evaluation System (EXES) Reports that electronically document the data review process for calibration and QC sample checks. EXES Reports are used to the extent possible for the review of CLP data.

EXES Reports may be accessed through the SMO Portal at <https://www.smoclps.com/uaa/login>. First time users will need to register for access which may take 24-48 hours. For assistance with registering or general questions contact the Contract Laboratory Program Support Services (CLPSS) Help Desk either by email at CLPSSHelpdesk@csra.com or by telephone M-F, 9-5 ET at (703) 461-2400.

2.2.2 Exceptions to Automated EXES Review Requiring Additional Manual Review

There are several types of QC samples and review criteria that are either not addressed in the EXES review or not adequately addressed. These parameters must be evaluated manually to meet EPA Region 1 (R1) requirements, depending on the DQOs. Tier levels of data review are specified in Section 3. They include the following and are addressed in the sections indicated:

- Performance Evaluation Samples (Chapter 4 and relevant NFG)
- Field Blanks (Section 2.5 and 2.6)
- Field Duplicates (Section 2.7)
- Percent Solids in Sediment and Soil Samples (Section 2.8)
- Pesticide and Aroclor Clean-up Procedures (Section 2.9)
- Organic Matrix Spike/Matrix Spike Duplicate (Section 2.10)
- Analyte concentration exceeding instrument calibration range (Section 2.11)
- Toxic Equivalent Determination (Section 2.12)

Tables 2-1, 2-2 and 2-3 provide summaries of region-specific guidance for data review.

2.2.2.1 Manual Review when Professional Judgment is Specified

When the NFG qualification procedures specify professional judgment, the reviewer must manually evaluate the data to determine whether to accept, estimate (J, UJ) or reject (R) sample results and document the qualification rationale on the associated worksheet/checklist or EXES Report.

2.2.2.2 Manual Review for CLP Modified Analyses

Manual review and data qualification may be necessary for some CLP Modified Analyses (MAs), depending on the specific modification. Generally, EXES performs all applicable checks for additional MA analytes as it does for the routine CLP target analytes, with the modified analysis requirements supplementing the SOW requirements. For example, MAs with adjusted CRQLs, EXES review procedures evaluate against the modified CRQLs. It is recommended to compare a percentage of the EXES and/or hard copy results with MA requirements.

Note: Wipe sample analyses require manual review of the calculations/final results as the data may not be captured in EXES.

2.2.2.3 Automated or Manual Review for Laboratory Resubmittals

When resubmittals are part of the data review process, the original automated EXES Reports may not be accurate. After additional data or a revised data package has been uploaded to EXES, the reviewer may request regenerated EXES Reports via the R1 CLP COR. However, it should be noted that regenerating the reports will eliminate any manual edits or other changes that may have been made previously through the EXES Data Manager.

In some situations it may not be necessary to regenerate EXES Reports, for example if a laboratory resubmission provided missing raw data. Based on the nature and extent of resubmissions, the reviewer may use professional judgment to manually validate the laboratory resubmittals.

Table 2-1: Summary of Region 1 Review Criteria, Evaluation and Actions for Superfund Data - Trace VOA, Low/Medium VOA, SVOA, Pesticides and Aroclors

(Trace VOA and Low/Medium VOA/SVOA by GC/MS; Pesticides and Aroclors by GC/ECD)

Evaluation Parameter	Tier 1 Organic Data Review Qualification	Tier 1 Plus & Tier 2 Organic Data Review Qualification			
		Trace VOA/ LM VOA	SVOA	Pesticides	Aroclors
Data Review Report	Section 2.3 ²	Section 2.3 ²			
Data Completeness	Section 2.4 ²	Section 2.4 ²			
Preservation and Holding Times	NFG ¹	NFG ¹			
Instrument Performance Check/ Instrument Stability	NFG ¹	NFG ¹			
Initial and Continuing Calibrations	NFG ¹	NFG ¹			
Blanks	NFG ¹ Only includes qualification of data based on Lab Blank results	NFG ¹ & Section 2.5 ² Includes Manual data review of Equipment, Trip and Bottle blank results			
Surrogates/DMCs	NFG ¹	NFG ¹			
Matrix Spike and Matrix Spike Duplicate Samples	NFG ¹	NFG ¹ & Section 2.10 ²			
Laboratory Control Sample	NFG ¹	NA	NA	NFG ¹	NFG ¹
Field Duplicates and Replicates and Oversight Split Samples	Data not qualified based on field duplicate precision	Section 2.7 ²			
Internal Standards	NFG ¹	NFG ¹	NFG ¹	NA	NA
Target Analyte Identification	NFG ¹	NFG ¹			
Target Analyte Quantitation ⁴ and SQLs	NFG ¹	NFG ¹ & Section 2.11 ²			
Percent Solids	Data not qualified based on % Solids	Section 2.8 ²			
TICs	Not evaluated	NFG ¹	NFG ¹	NA	NA
PE Samples	NFG ¹ & Chapter 4 ³	NFG ¹ & Chapter 4 ³			
System Performance	Not evaluated	NFG ¹			
GC/MS Confirmation	Not evaluated	NA	NA	NFG ¹	NFG ¹

Clean up Procedures	Florisil	NFG ¹	NA	NA	NFG ¹	NA
	Gel Permeation	NFG ¹	NA	NFG ¹	NFG ¹	NFG ¹
	Sulfur Removal	Not evaluated	NA	NA	Section 2.9 ²	Section 2.9 ²
Overall Assessment of Data	NFG ¹	NFG ¹				

¹ EPA National Functional Guidelines for Organic Superfund Methods Data Review, January 2017, OLEM 9355.0-136, EPA-540-R-2017-002 (3), or most recent update.

² *Region 1 - EPA New England Environmental Data Review Supplement*, Chapter 2 Sections, as indicated in the table.

³ *Region 1 - EPA New England Environmental Data Review Supplement*, Chapter 4 Performance Evaluation Sample Program

⁴ When multiple analyses, reruns, re-extractions, and dilutions, are performed on a sample, the reviewer should use professional judgment to determine which results to report and clearly identify the analyses with a footnote on the Data Summary Table.

NA – Not Applicable

Table 2-2: Summary of Region 1 Review Criteria, Evaluation and Actions for Superfund Data - Inorganics
(Metals by ICP-AES and ICP-MS, Mercury by CVAA, and Cyanide by Spectrophotometry)

Evaluation Parameter	Tier 1 Inorganic Data Review Qualification	Tier 1 Plus & Tier 2 Inorganic Data Review Qualification
Data Review Report	Section 2.3 ²	Section 2.3 ²
Data Completeness	Section 2.4 ²	Section 2.4 ²
Preservation and Holding Times	NFG ¹	NFG ¹
ICP-MS Tune Analysis	NFG ¹	NFG ¹
Calibration	NFG ¹	NFG ¹
Blanks	NFG ¹ Only includes qualification of data based on Laboratory Blank results	NFG ¹ & Section 2.6 ² Includes Manual data review of Equipment, and Bottle blank results
ICP Interference Check Sample (ICS)	NFG ¹	NFG ¹
Laboratory Control Sample	NFG ¹	NFG ¹
Duplicate Sample Analysis	NFG ¹	NFG ¹
Field Duplicates, Replicates and Split Sampling Oversight	Data not qualified based on field duplicate precision	Section 2.7 ²
Spike Sample Analysis	NFG ¹	NFG ¹
ICP Serial Dilution	NFG ¹	NFG ¹
ICP-MS Internal Standards (IS)	NFG ¹	NFG ¹
PE Samples	NFG ¹ & Chapter 4 ³	NFG ¹ & Chapter 4 ³
Percent Solids	Data not qualified based on % Solids	Section 2.8 ²
Overall Assessment of Data	NFG ¹	NFG ¹

¹ EPA National Functional Guidelines for Inorganic Superfund Methods Data Review, January 2017, OLEM 9355.0-135, EPA-540-R-2017-001 (4), or most recent update.

² *Region 1 - EPA New England Environmental Data Review Supplement*, Chapter 2 Sections, as indicated in the table.

³ *Region 1 - EPA New England Environmental Data Supplement*, Chapter 4 Performance Evaluation Sample Program

Table 2-3: Summary of Region 1 Review Criteria, Evaluation and Actions for Superfund Data - Dioxins/Furans and CB Congeners by HRGC/HRMS

Evaluation Parameter	Tier 2 Data Review	
	Dioxins/Furans	CB Congeners
Data Review Report	Section 2.3 ²	Section 2.3 ²
Data Completeness	Section 2.4 ²	Section 2.4 ²
Preservation and Holding Times	NFG ¹	NFG ¹
System Performance Checks	NFG ¹	NFG ¹
Initial Calibration	NFG ¹	NFG ¹
Continuing Calibration Verification	NFG ¹	NFG ¹
Blanks	NFG ¹ & Section 2.5 ²	NFG ¹ & Section 2.5 ²
Laboratory Control Sample/ LCS Duplicate	NFG ¹	NFG ¹
Field Duplicates and Replicates and Oversight Split Samples	Section 2.7 ²	Section 2.7 ²
Labeled Compounds	NFG ¹	NFG ¹
Target Analyte Identification	NFG ¹	NFG ¹
Target Analyte Quantitation	NFG ¹ & Section 2.11 ²	NFG ¹ & Section 2.11 ²
Second Column Confirmation and Isomer Specificity	NFG ¹	NFG ¹
Estimated Detection Limit (EDL) and Estimated Maximum Possible Concentration (EMPC)	NFG ¹	NFG ¹
Toxic Equivalent Determination	NFG ¹ & Section 2.12 ²	NFG ¹ & Section 2.12 ²
PE Samples	NFG ¹ & Chapter 4 ³	NFG ¹ & Chapter 4 ³
Percent Solids	Section 2.8 ²	Section 2.8 ²
Overall Assessment of Data	NFG ¹	NFG ¹

¹ EPA National Functional Guidelines for High Resolution Superfund Methods, April 2016, OLEM 9200.3-115, EPA-542- B-16-001 (5), or most recent update.

² *Region 1 - EPA New England Environmental Data Review Supplement*, Chapter 2 Sections, as indicated in the table.

³ *Region 1 - EPA New England Environmental Data Review Supplement*, Chapter 4 Performance Evaluation Sample Program

2.3 Data Review Reporting Guidance

2.3.1 Objective

Data review results must be reported using a standardized format to ensure consistent and accurate reporting for data users. A streamlined approach for reporting Superfund data has been developed and supersedes previous formats.

2.3.2 Data Review Report Format

Both automated and manual review processes use the streamlined data reporting format. The reporting procedure includes a “one page” Data Review Report with attachments (Refer to Section 2.3.2.2).

2.3.2.1 “One Page” Data Review Report

- Only one SDG, or group of samples, is documented in each report.
- The “one page” Data Review Report is formatted as a letter addressed and sent to the end user. The report contents are described below.
- The subject heading must include: the contractor Work Assignment (WA) or Task Order (TO) number, the case number and Sample Delivery Group (SDG) number, the laboratory name and location, the site name and location, the associated data SEDD Stage and R1 Tier level of Review (Refer to Chapter 3), the parameters evaluated, the total number of samples per matrix per parameter (parenthetically identify the field duplicates), the sample matrix and field sample numbers analyzed for each parameter, the parameter, matrix and sample number for each type of blank, and the parameter, matrix, and sample number for each PES. See the following example report included as Attachment 2-2.
- The first paragraph must include the name of the Field Sampling Contractor (FSC) , the reference information for the data review procedures, the title of the QAPP and/or SAP, or other project planning document, and the associated analytical method(s) and/or laboratory SOP(s).
- The second paragraph must list the QC parameters (checks) that were evaluated through review. QC parameters that met criteria should be asterisked (*) in the left hand margin of the parameter name. Similarly, QC parameters that were not applicable to the analytical methods should be noted with N/A (not applicable) in the left hand margin of the parameter name.
- Following the list of QC parameters the reviewer should indicate whether or not:
1) electronic data review reports were reviewed with notations for review findings documented, 2) data review worksheets/checklists were generated for a manual review of the data, or 3) a combination of electronic reports and

worksheets/checklists were used depending on the project objectives which may result in automated and manual data review procedures.

- The next paragraph is titled Overall Evaluation of Data and Potential Usability Issues.
 - The first element in this section is a list of the DQOs from the QAPP, SAP or other project planning document.
 - Following the list of objectives, include a statement listing the PESs and a brief summary of the score results, particularly the outliers.
 - Following the PES discussion, include a statement indicating the overall quality of the data. Include statements such as “*Data review indicated minor data quality problems*” or “*Data review indicated major data quality problems*”.
 - This introductory statement is then followed by a brief description of the elements which establish the basis for the statement. Expected statements include: “*All iron results were qualified due to method blank contamination*” or “*Acetone results were qualified due to an inaccurate calibration*”. Items included in this paragraph identify and summarize qualification on the Data Summary Tables which impact usability. This explanation provides an overview of data usability which combines analyte-specific statements and usability assessment. The descriptions should be listed by analytical parameter (i.e., Trace Volatiles, Semivolatiles, etc.; or ICP-AES, Mercury, etc.) Rejected results or technical decisions based on professional judgment to reject results should be included here.
 - The last sentence in the paragraph must indicate whether or not the results are usable for the site objectives. If the data are not usable, include the rationale and notify the end user immediately.

2.3.2.2 Data Review Report Attachments

Attachments to the data review report include:

1. Data Summary Tables (DST)

Data Summary Tables (DST), typically in spreadsheet format, include the results and qualifiers for the field samples. Sample results are displayed side by side which facilitates review by the end user. Qualifier footnotes must be provided for qualifiers which impact data usability. The qualifier footnotes must clearly identify the reason for qualification.

2. Data Review Documentation

The rationale for qualifying data must be documented in the Data Review Report or attachments to the Data Review Report. Data review must demonstrate that sample results have been assessed against evaluation parameters specific to the analytical method (e.g., Tables 2-1, 2-2, 2-3). Reviewers must ensure that method and review criteria are current, accurate and documented.

Various tools can be used to document data review; automated electronic reports such as EXES Reports, worksheets, checklists or other method-specific formats. EXES Reports should be used and attached to the Data Review Report whenever available. When manual review is performed, data review worksheets, checklists or an alternate recording format must be used to document data anomalies, rationale and decisions for data qualification. (Refer to Attachment 2-3 for example data review worksheets.) Depending on the data review procedures, a combination of electronic reports, worksheets, checklists or alternate recording format may be provided as applicable.

3. **Support Documentation**

Support documentation includes records of communication between the Region, the data reviewer, and the lab or the reviewer and the sampler (email messages and/or telephone logs); field notes; PES Scoring Evaluation Report (hereafter PES Score Report); and a copy of the CSF Audit (DC-2) Form as applicable.

2.3.3 Distribution and Archival of Data Review Documentation

2.3.3.1 Hardcopy Report

All hardcopy reports are submitted to the site manager when the data review is complete, including:

- The complete laboratory data package (if required and requested at sample scheduling), including additional laboratory data, revised data or resubmittals, and any other data not captured in the reports; and,
- The complete Data Review Report and Attachments, including the one-page report, DST, data review documentation, i.e. EXES reports and manual worksheets, and Support Documentation.

These complete data packages and Data Review Reports are ultimately maintained in the Federal Records Center (FRC) as applicable.

2.3.3.2 Electronic Reporting

Electronic reports are submitted via e-mail to the Site Manager, R1 CLP COR, and the CLP Project Officer (PO)/ASB, as noted below.

- The Site Manager receives all documents related to the Data Review Report. These data are maintained in the Superfund Enterprise Management System (SEMS) as applicable. The Site Manager receives the following documents:
 - The complete data package, additional laboratory data, revised data or resubmittals, and any other data not captured in the reports, in portable document format (.pdf); and,

- The complete Data Review Report and Attachments, including the one-page report, DST, data review documentation, i.e. EXES reports and manual worksheets, and Support Documentation, in .pdf format, with the exception of the DST which must be in MS Excel format.
- The R1 CLP COR receives the following documents (Refer to Attachment 2-1 for contact information):
- The complete Data Review Report and Attachments, including the one-page report, DST, data review documentation, i.e. EXES reports and manual worksheets, and Support Documentation, in .pdf format.
 - For Delivery of Analytical Services (DAS) activities, a completed Region 1 DAS/Tier 4 Actual Sampling Event (ASE) - Part 2 Form is also submitted, along with the chain-of-custody and Data Review Report.

The DAS/Tier 4 ASE Form contains the following information: FSC/Contract, Ship to Lab Date, Data Package Receipt Date, DAS Case #, SDG #, Data Turnaround Time (TAT), Site Name, Site Location (City & State), CERCLIS#, Site ID, Action Code, Operable Unit, Purpose Code, Lab Name, Lab Location, Lab Code, Number of Samples, Sample IDs, Case Complete (Y/N), Total Cost, and Sample Analysis and QC Summary by Parameter. See Attachment 2-4b for an example of a DAS/Tier 4 ASE Form.

- Note: The Tier 4 Projected Sampling Event – Part 1 Form is submitted by the FSC during the planning phase of the project. The form is submitted to the Remediation II Branch Chief for approval of analytical services which could not be provided via a higher tier of the Field and Analytical Services Teaming and Advisory Committee (FASTAC) Strategy. The FSC also sends the Part 1 form to the R1 CLP COR and the LSASD Chemistry Team Lead for their concurrence, which they forward to the Remediation II Branch Chief. The final signed/approved form is then returned to the R1 CLP COR, LSASD Chemistry Team Lead and the FSC. The analytical services can then be contracted by the FSC. See Attachment 2-4a for an example of a DAS/Tier 4 Projected Sampling Event – Part 1 Form.
- The laboratory's CLP PO/ASB receives the following documents if there are data concerns:
- The complete Data Review Report and Attachments, including the one-page report, DST, data review documentation, i.e. EXES reports and manual worksheets, and Support Documentation.

2.4 Complete Sample Delivery Group File Completeness Review Guidance

CSF completeness checks are conducted to ensure that laboratory documentation will be sufficient to assess and verify the quality of the data in terms of project objectives.

2.4.1 Complete Sample Delivery Group File (CSF)

The CSF consists of the original Sample Delivery Group (SDG) Package generated by the contract laboratory and all other related documentation including but not limited to original shipping documents, CLP DC-1 Form, and communication records (e.g., e-mails, telephone logs). The laboratory assembles the CSF and completes the CSF Inventory Sheet (DC-2 Form) to index all documents submitted. The laboratory submits the CSF, including the completed DC-2 Form, in accordance with the Report Deliverable Schedule of the relevant SOW. The DC-1 and DC-2 Forms may be found in the most recent Superfund CLP Analytical Statements of Work (SOWs) at <https://www.epa.gov/clp/superfund-clp-analytical-statements-work-sows>.

2.4.2 Region 1 CSF Tracking Procedure

Currently the hardcopy CSF is received by the Region from the laboratory under custody. When requested, signed and dated custody seals are affixed to the CSF for transfer by the CLP representative or designee. The CSF is considered transferred whenever it changes location upon shipment or hand-delivery; for example, when the CSF is shipped from the laboratory to the CLP representative or from the CLP representative to the Field Sampling Contractor (FSC). The FSC is responsible for tracking the CSF when CLP data packages are transferred. The hardcopy CSF files are organized by site, Case, and SDG in the LSASD QA central files and are archived by EPA as the FSCs are using the electronic copy for review.

2.4.3 Tracking Laboratory Resubmittals (Electronic)

For data generated under the Superfund CLP program, additional laboratory data, or resubmittals requested during the completeness check or data review, are electronically uploaded to the SMO Portal as described in the relevant statement of work (SOW).

For data generated under non-Superfund programs, electronic resubmittals are provided in various formats. Upon receipt of electronic resubmittals from a laboratory (e.g., corrected data reports or additional raw data), the reviewer should document receipt of the resubmittal and follow document control procedures as required by their organization to ensure that the proper data is used for data review. All laboratory electronic resubmittals should be provided to the Project Manager.

2.4.4 Completeness Review

2.4.4.1 CLP Data Packages

The CLP laboratory uploads a PDF of the laboratory data package to the SMO portal. The EPA Sample Management Office (SMO) performs a manual inspection of the electronic data package for completeness, ensuring that all items required by the SOW have been provided. A Contract Compliance Screening (CCS) Report is sent to the laboratory within 72 hours of data submission detailing the findings of the review and is

available in the EXES Data Manager (EDM). The CCS Report should be utilized by the validator as the completeness check. If any missing items or discrepancies were noted in the CCS Report then the validator should determine whether or not the laboratory submitted additional or corrected data. If the lab responds to the CCS report with additional or corrected data, there will be an additional CCS Report evaluating the updated laboratory submission in EDM.

2.4.4.1 Non-CLP Data Packages

The validator must perform a completeness check for non-CLP laboratory data packages. The laboratory may include a form similar to the CLP DC-2 Form or a table of contents which can be utilized as an inventory checklist for the data, or the validator may generate a form documenting the completeness check. The validator must confirm that the package is complete based on the method, QAPP/SAP requirements and data deliverable requested.

2.5 Organic - Blank Contamination Data Review Guidance

All blank sample results should be evaluated manually for contamination in accordance with the most recent NFG blank criteria. EXES electronic validation will evaluate an SDG for method blank qualifications only.

Apply the NFG criteria and actions based on the highest blank contamination associated with the samples. PES contamination is not used to qualify data.

- In determining the highest blank contamination, evaluate all blanks including method, clean-up, instrument, storage, bottle, trip and equipment rinsate blanks.
- If the blank action for an analyte is determined using the concentration from a field blank (i.e. equipment, trip or bottle blank), then the positive values in the equipment, trip or bottle blank should be reported unqualified on the Data Summary Tables. However, if the blank action is determined from a laboratory blank (e.g., method, clean-up, storage, or instrument blank), then the positive values in the equipment, trip or bottle blanks should be qualified.
- For aqueous field blanks, if an analyte is present in the non-aqueous sample and is also present in the associated aqueous equipment blank, trip blank or bottle blank, then flag that sample result as EB, TB, or BB, respectively, to indicate to the end user that an indeterminate amount of sampling error has potentially impacted the sample results.

In the event that an affected sample result is much greater than (i.e. 100x) the equivalent field blank result (using the same units for comparison, i.e. total pg), professional judgment may be used to accept the sample result without qualification. This decision should be documented on the data review worksheets and the Data Review Report as appropriate.

2.6 Inorganic - Blank Contamination Data Review Guidance

All blank sample results should be evaluated manually for contamination in accordance with the most recent NFG blank criteria. EXES electronic validation will evaluate an SDG for method blank qualifications only.

Apply the NFG criteria and actions based on the highest blank contamination associated with each sample. PES contamination is not used to qualify data.

- In determining the highest blank contamination, evaluate all blanks including preparation/method, calibration/instrument, bottle, and equipment rinsate blanks.
- Initial and continuing calibration blank contamination within an analytical sequence applies to all samples analyzed in that sequence. Use professional judgment to apply contamination only to a specific subset of samples.
- If the blank action for an analyte is determined using the concentration from a field blank (i.e. equipment or bottle blank), then the positive values in the equipment or bottle blank should be reported unqualified on the Data Summary Tables. However, if the blank action is determined from a laboratory blank (e.g., preparation or calibration blank), then the positive values in the equipment and bottle blanks should be qualified.
- For aqueous field blanks, if an analyte is present in the non-aqueous sample and is also present in the associated aqueous equipment blank or bottle blank, then flag that sample result as EB or BB, respectively, to indicate to the end user that an indeterminate amount of sampling error has potentially impacted the sample results.

In the event that an affected sample result is much greater than (i.e. 100x) the equivalent field blank result (using the same units for comparison), professional judgment may be used to accept the sample result without qualification. This decision should be documented on the data review worksheets and the Data Review Report as appropriate.

2.7 Field Duplicates, Field Replicates and Oversight Split Sampling Data Review Guidance

2.7.1 Objective

Field duplicates measure the cumulative effects of both field and laboratory precision and hence provide an indication of overall precision. Duplicate precision is evaluated by calculating a Relative Percent Difference (RPD) in accordance with the *Quality Assurance and Quality Control Environment Data Standard (7)*; a low RPD demonstrates greater precision. It is expected that non-aqueous matrices will have a greater variability than aqueous matrices due to the heterogeneity of most non-aqueous samples (e.g., soil and sediment samples), which can result in higher RPD values.

Occasionally project objectives require additional precision data. This may include the collection of three or more field replicate samples. Replicate precision is evaluated by calculating the Relative Standard Deviation (RSD), also referred to as the coefficient of variation (V); a low RSD represents greater precision. RSD requirements and criteria should be specified in the QAPP, SAP or other project documents.

Oversight split sampling analysis may be performed to monitor performance of another organization or contractor. Split sampling analyses are evaluated by calculating a Relative Percent Difference (RPD) similar to duplicates. **Note:** This equation assumes that values generated by EPA and those values generated by equivalent methods used by the PRP (or other entities) are equally accurate. The RPD calculation is used to assess data comparability.

2.7.2 Criteria

2.7.2.1 The frequency of field duplicate analysis must support the site-specific quality objectives and be documented in the EPA-approved QAPP or SAP. The following R1 criteria for field duplicates are provided as guidance. Site specific criteria may be established and applied as necessary.

Aqueous Field Duplicates

- a. For all analytes detected at concentrations greater than or equal to five times the sample quantitation limit (SQL) in both field duplicate samples of aqueous matrices, the absolute RPD should be less than or equal to 30 percent ($RPD \leq 30\%$).
- b. For all analytes detected at concentrations less than five times the SQL, including non-detects, in either field duplicate sample of aqueous matrices, the absolute difference between the sample concentrations should be less than or equal to twice the SQL.

Non-Aqueous Field Duplicates

- a. For all analytes detected at concentrations greater than or equal to five times the SQL in both field duplicate samples of non-aqueous matrices, the absolute RPD must be less than or equal to 50 percent ($RPD \leq 50\%$).

- b. For all analytes detected at concentrations less than five times the SQL, including non-detects, in either field duplicate sample of non-aqueous matrices, the absolute difference between the sample concentrations must be less than or equal to four times the SQL.

2.7.2.2 The frequency and evaluation criteria and actions of field replicate analysis and split sampling analysis must support the site-specific quality objectives and must be documented in the EPA-approved QAPP or SAP.

2.7.3 Evaluation and Actions

All potential impacts on the sample data resulting from field duplicate anomalies should be noted on data review worksheets/checklists. If technical decisions result in rejection of the data, then the reviewer should also document and justify the technical decisions made based on professional judgment in the Data Review Report.

For a field duplicate sample analysis that does not meet the technical criteria, apply the action to all samples of the same matrix if the samples are considered sufficiently similar. Exercise professional judgment in determining sample similarity making use of all available data including site and sampling documentation.

2.7.3.1 Identify the samples which are field duplicates from the Chain-of-Custody Record and/or the Traffic Report. If field duplicates are not listed on the Chain-of-Custody Record or the Traffic Report, then the reviewer should:

- Contact the sampler to ascertain if field duplicates were collected. If the forms were completed incorrectly, or if field duplicates were not collected, then the reviewer should document this in the Data Review Report.

2.7.3.2 Verify that the appropriate number of field duplicates per matrix sampled were collected and analyzed to support project quality objectives. If field duplicates were not collected at the required frequency to support project objectives, then the reviewer should:

- Record the absence of field precision data in the Data Review Report and discuss how the lack of field precision data might potentially increase uncertainty surrounding site decisions.

2.7.3.3 Aqueous Field Duplicates

- a. Calculate the RPD for all analytes detected at concentrations greater than or equal to 5x the SQL in the aqueous field duplicate pair. If any analyte is detected at concentrations greater than or equal to 5x the SQL in both aqueous field duplicate samples and has an absolute RPD greater than 30%, then the reviewer should:
 - Estimate (J) positive detects and estimate (UJ) non-detects for the affected analyte in all samples of the same matrix prepared and analyzed by the same method.

- b. Calculate the absolute difference for all analytes detected at concentrations less than 5x the SQL in either one or both of the aqueous field duplicate samples (including the case where one duplicate sample result is a non-detect and the other result is a positive detect). If any analyte is detected at concentrations less than 5x the SQL in either one or both of the aqueous field duplicate samples and the absolute difference is greater than 2x the SQL, then the reviewer should:
 - Estimate (J) positive detects and estimate (UJ) non-detects for the affected analyte in all samples of the same matrix prepared and analyzed by the same method.
- c. If any analyte is detected at concentrations less than the SQL in both of the field duplicate samples, or if any analyte is a non-detect in both of the field duplicate samples, then no action is taken.

2.7.3.4 Non-Aqueous Field Duplicates

- a. Calculate the RPD for all analytes detected at concentrations greater than or equal to 5x the SQL in both non-aqueous field duplicates. If any analyte is detected at concentrations greater than or equal to 5x the SQL in both non-aqueous field duplicate samples and has an absolute RPD greater than 50%, then the reviewer should:
 - Estimate (J) positive detects and estimate (UJ) non-detects for the affected analyte in all samples of the same matrix prepared and analyzed by the same method.
- b. Calculate the absolute difference for all analytes detected at concentrations less than 5x the SQL in either one or both of the non-aqueous field duplicate samples (including the case where one duplicate sample result is a non-detect and the other result is a positive detect). If any analyte is detected at concentrations less than 5x the SQL in either one or both of the non-aqueous field duplicate samples and the absolute difference is greater than 4x the SQL, then the reviewer should:
 - Estimate (J) positive detects and estimate (UJ) non-detects for the affected analyte in all samples of the same matrix prepared and analyzed by the same method.
- c. If any analyte is detected at concentrations less than the SQL in both of the field duplicate samples, or if any analyte is a non-detect in both of the field duplicate samples, then no action is taken.

Note: When applying the criteria of 4x the SQL, the SQL is calculated using the sample weight, volume, and percent solids for the sample versus the duplicate sample.

- 2.7.3.5** Check and recalculate the analytical concentrations for at least one positive detect and one SQL (for a diluted sample or soil sample) for each analytical method in each field duplicate sample. If calculation and/or transcription errors are detected, then the reviewer should:
- Contact the laboratory via the R1 CLP COR to evaluate the data accuracy and possible need to re-quantitate and resubmit all corrected raw data and forms. If a discrepancy remains unresolved, the reviewer must use professional judgment to decide which value is accurate. Under these circumstances, the reviewer may determine that the sample data should be qualified or rejected. A discussion of the rationale for data qualification and the qualifiers used should be documented on the worksheets/checklists and in the Data Review Report.
- 2.7.3.6** If there is information to indicate that the matrix heterogeneity and/or potential sampling error are limited to the field duplicate samples or to a specific subset of samples of the same matrix, then the reviewer should use:
- Professional judgment to apply the action only to the field duplicate samples or to a specific subset of samples of the same matrix. The reviewer should discuss the justification for limiting the qualification to specific samples in the data review worksheets and the Data Review Report as appropriate.
- 2.7.3.7** Evaluate field duplicate precision data to assess overall precision and to verify the field sampler’s ability to collect representative duplicate samples. Laboratory duplicate sample data should be evaluated to verify the laboratory’s ability to generate precise data. Matrix spike data can also be evaluated to identify overall matrix issues. If field duplicate data indicate poor field precision and general sample heterogeneity and/or possible sampling error, then the reviewer should use:
- Professional judgment to determine whether additional validation action is warranted. The reviewer should discuss this problem in the data review worksheets and the Data Review Report, *Overall Evaluation of Data and Potential Usability Issues* section where the potential impact on the representativeness and usability of the data for project DQOs is documented.

See Equation 2-1: Relative Percent Difference and Equation 2-2: Relative Percent Standard Deviation for details on these equations.

Equation 2-1: Relative Percent Difference

Field duplicate and split sampling analysis precision is evaluated by calculating a Relative Percent Difference (RPD). The following equation from the *EPA Environmental Data Standards (7)* measure of duplicate precision is applied; the lower the RPD value, the greater the precision:

$$d_i = \frac{Y - X}{(Y + X) / 2} \times 100$$

Relative Percent Difference (RPD or d_i), where X is the primary value and Y is the duplicate. Note: this equation retains the sign of the difference. Absolute values may be used based on the needs of the project.

Equation 2-2: Relative Standard Deviation

Replicate precision is evaluated by calculating the Relative Standard Deviation (RSD), also referred to as the coefficient of variation (CV), of the samples using the following equation (the smaller the RSD, the greater the precision):

$$\%RSD = \frac{S}{\text{mean}} \times 100\%$$

Where,

$$S = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1}}$$

x_i = each individual value used for calculating the mean

\bar{x} = the mean of n values

n = the total number of values

S = standard deviation

**Table 2-4: Qualification of Analytes Based on Field Duplicates -
 Aqueous Matrices**

Sample Results	Aqueous Field Duplicate Sample Results			
	Both Duplicates $\geq 5 \times \text{SQL}$		One or Both Duplicates $< 5 \times \text{SQL}^1$	
	RPD $\leq 30\%$	RPD $> 30\%$	Abs. Diff. $\leq 2 \times \text{SQL}$	Abs. Diff. $> 2 \times \text{SQL}$
Detects	A	J	A	J
Non-detects	A	UJ	A	UJ

¹ No action is taken when both field duplicate results are positive detects $< \text{SQL}$ or are non-detects.

Note: Qualification refers to the affected analyte in all samples of the same matrix prepared and analyzed by the same method. Professional judgment may be used, with rationale provided, to limit duplicate actions only to the field duplicate sample results or to a subset of samples of the same matrix for the affected analyte.

**Table 2-5: Qualification of Analytes Based on Field Duplicates -
 Non-Aqueous Matrices**

Sample Results	Non-Aqueous Field Duplicate Sample Results			
	Both Duplicates $\geq 5 \times \text{SQL}$		One or Both Duplicates $< 5 \times \text{SQL}^1$	
	RPD $\leq 50\%$	RPD $> 50\%$	Abs. Diff. $\leq 4 \times \text{SQL}$	Abs. Diff. $> 4 \times \text{SQL}$
Detects	A	J	A	J
Non-detects	A	UJ	A	UJ

¹ No action is taken when both field duplicate results are positive detects $< \text{SQL}$ or are non-detects.

Note: Qualification refers to the affected analyte in all samples of the same matrix prepared and analyzed by the same method. Professional judgment may be used, with rationale provided, to limit duplicate actions only to the field duplicate sample results or to a subset of samples of the same matrix for the affected analyte.

2.8 Percent Solids in Non-Aqueous Samples Data Review Guidance

2.8.1 Objective

The objective is to ensure that percent (%) solids are appropriately considered when evaluating analytical results for non-aqueous samples.

2.8.2 Criteria

Representative soil/sediment sample matrices should have percent solids greater than or equal to 30 percent.

Sampling and analytical methodologies must be determined during project scoping processes and must be based on the data objectives. Most analytical methods for soil-type matrices are applicable to both soils and sediments with no preparation and analysis differences. Since a definition for soil and sediment matrices is not provided in most analytical methodologies, for many years EPA R1 has used the definition by the Office of Water Regulations and Standards Industrial Technology Division, Method 1620, Section 14.16, Draft September 1989 (6). Soil samples are defined as: "soils, sediments, and sludge samples containing more than 30% solids".

Sediments with high moisture content may or may not be successfully analyzed by routine analytical methods. Additional sampling and analytical preparation steps may need to be employed to ensure a representative amount of sample is prepared and analyzed. To enhance sampling procedures, standing water may be decanted from field samples, and/or the sample may be centrifuged or filtered to remove excess water. To achieve the dry weight quantitation limits, the laboratory must perform a percent solids determination prior to preparation and the initial volume of sample prepared must be increased accordingly. This presumes that the samplers have collected sufficient volume, above the routine volume requirements, so that additional sample can be prepared.

2.8.3 Evaluation and Actions

2.8.3.1 Verify that all non-aqueous samples contain solids greater than or equal to 30%.

- If a non-aqueous sample contains less than 30% solids (<30% solids) but 10% solids or greater (\geq 10% solids), then estimate (J, UJ) positive detects and non-detects.
- If a non-aqueous sample contains less than 10% solids (< 10% solids), then reject (R) detects or use professional judgment to estimate (J) detects when analytes are detected in high concentrations, and reject (R) non-detects.

2.8.3.2 If sampling and/or analytical preparation steps were employed to address high moisture soil/sediment/solid samples, such as removing the aqueous portion or increasing the sample size, then the reviewer should use professional judgment to determine whether the associated sample data should be accepted, qualified as estimated, or rejected (UJ, J or R).

The reviewer should determine whether or not project objectives were achieved, such as required detection limits. Dry weight quantitation limits and whether or not the sampling and analytical methods were appropriate for the sample matrix should be considered. The rationale for data qualification should be documented on data review worksheets/checklists and discussed in the *Overall Evaluation of Data and Potential Usability Issues* section of the Data Review Report.

Table 2-6: Qualification of Non-Aqueous Samples Based on Sample Percent Solids

CRITERIA	ACTION	
	Detected Analytes	Non-Detected Analytes
% Solids \geq 30%	No qualification	
10% \leq % Solids < 30%	J	UJ
% Solids < 10 %	R*	R

*Professional judgment may be used to estimate (J) data in samples with high percent moisture content.

2.9 Pesticides and Aroclor Sulfur Removal Clean-up Data Review Guidance

2.9.1 Objective

Pesticide/Aroclor sulfur cleanup procedures remove elemental sulfur from sample extracts prior to analysis. If not removed, sulfur may cause a rise in the chromatographic baseline preventing accurate analyte identification and quantitation.

2.9.2 Criteria

2.9.2.1 Sulfur removal procedures should be performed on all field sample extracts suspected of containing elemental sulfur which may interfere with GC analysis.

2.9.2.2 Sulfur removal procedures must also be performed on associated QC sample extracts, and method blank extracts. When only a subset of samples requires sulfur removal, a separate sulfur blank is prepared.

2.9.2.3 The sulfur blank must meet all method blank QC criteria.

2.9.3 Evaluation and Actions

2.9.3.1 Review Pesticide and Aroclor results (Form Is), laboratory bench sheets, and/or data package narrative to determine if sulfur cleanup was performed on any sample extracts, associated QC samples and method blanks.

- If a manual review is performed, then the reviewer should note that sulfur cleanup was performed and that reducing conditions may exist at the sample site location.

2.9.3.2 Check the field sample GC chromatograms to determine whether or not there is a flat baseline. A rising baseline may indicate the presence of sulfur. Confirm that all pesticide/Aroclor peaks are adequately resolved and are symmetrical.

- If a method-required sulfur cleanup was not performed on sample extracts that contain sulfur or adequate sulfur removal was not achieved, which is demonstrated by a rising baseline or interference determining late eluters, then the reviewer should carefully assess the impact on the sample data. If only minor sulfur interference is observed, then the reviewer should use professional judgment to estimate (J) positive detects for analyte(s) that co-elute with sulfur and reject (R) non-detects.
- If the sulfur contamination obscures a limited, discrete portion of the chromatogram, then the reviewer should use professional judgment to reject (R) the positive detects and non-detects for analytes co-eluting with sulfur and accept the unaffected sample results.

- If the sulfur contamination is gross and the majority of the chromatogram is obscured, then the reviewer should use professional judgment to reject (R) the entire pesticide/PCB analysis for that sample. The reviewer should request sample reanalysis that includes sulfur removal.

2.9.3.3 Confirm from the raw data, laboratory bench sheets, or SDG Narrative, that a method-required cleanup technique was used to remove sulfur present in the samples.

- If a method-required sulfur cleanup technique was not used for sulfur removal, then the reviewer should request sample cleanup and reanalysis and document all technical decisions in the data review worksheets and the Data Review Report as appropriate.

2.9.3.4 Verify from Form IV PEST and Form IV ARO that a sulfur cleanup blank was prepared and analyzed along with the samples, or that the associated method blank was also sulfur cleaned.

- If a sulfur cleanup blank was not prepared and/or analyzed with the samples, or the associated method blank was not also sulfur cleaned, then the reviewer should use professional judgment to qualify sample data.

2.9.3.5 Verify that the sulfur cleanup blank met all method QC acceptance criteria specified for the method blank contamination.

- If the sulfur cleanup blank does not meet QC criteria after sulfur cleanup, then the reviewer should refer to Section 2.5, and use professional judgment to qualify sample data.

2.9.3.6 Verify from the raw data that there are no target analytes greater than the quantitation limit present in the sulfur cleanup blank.

- If any target analytes are detected in the sulfur cleanup blank greater than or equal to the SQL, then the sulfur cleanup may be a source of contamination. The reviewer must use professional judgment in conjunction with guidance provided in Section 2.5 to qualify sample data.

2.9.3.7 Compare the raw data to the reported results, if available, and verify that no calculation and/or transcription errors have occurred.

- If discrepancies between the raw and reported data are found, the reviewer should have the laboratory evaluate the discrepancy and recalculate and resubmit all corrected raw data and forms as applicable. If a discrepancy remains unresolved, the reviewer must use professional judgment to decide which value is more accurate. The reviewer may determine that the sample data should be estimated (J) or rejected (R). The rationale for data qualification and the qualifiers used should be documented on the worksheets/checklists and in the Data Review Report.

Table 2-7: Qualification of Pesticides/PCB Analytes Based on Sulfur Cleanup

Minor Sulfur Interference	Sample Result	Discrete Sulfur Interference	Gross Sulfur Interference
Estimate (J) positive detects that co-elute with sulfur.	Detects	Accept analytes not impacted by sulfur interference. Reject (R) positives detects that co-elute with sulfur.	Reject (R) all analytes and request re-analysis.
Reject (R) non-detects that co-elute with sulfur.	Non-detects	Accept analytes not impacted by sulfur interference. Reject (R) non-detects that co-elute with sulfur.	Reject (R) all analytes and request re-analysis.

2.10 Organic Matrix Spike/Matrix Spike Duplicate Guidance

Matrix spike and matrix spike duplicate sample results should be evaluated in accordance with the most recent NFG Matrix Spike/Matrix Spike Duplicate criteria. For organic matrix spike and matrix spike duplicate sample analysis that does not meet the technical criteria, apply the action to all samples of the same matrix if the samples are considered sufficiently similar. Exercise professional judgment in determining sample similarity making use of all available data including site and sampling documentation.

2.10.1 If there is information to indicate that the matrix heterogeneity are limited to the native sample, matrix spike, and matrix spike duplicate or to a specific subset of samples of the same matrix, then the reviewer should use:

- Professional judgment to apply the action only to the native sample or to a specific subset of samples of the same matrix. The reviewer must document the justification for limiting the qualification to specific samples in the data review worksheets and the Data Review Report as appropriate

2.11 Analyte Concentration Exceeding Instrument Calibration Range Guidance

Analyte concentrations that are greater than the initial calibration high standard should be considered uncertain. EXES automated evaluation and qualification procedures do not assess the concentration of results. For organic CLP data, the affected analyte concentrations are typically flagged with an “E” qualifier on the Form I. For inorganic CLP data, a laboratory defined qualifier may be used. An analyte reported above the instrument calibration range should be considered an estimated value, and qualified with a “J”.

If an analyte has saturated the detector, the result should be rejected (R). However, the validator can use professional judgment to evaluate whether or not the data can be used for reporting purposes, as an estimated (J) value. The validator should also review whether or not there are interferences from the high concentrations and evaluate for any adverse effects on identification or quantitation of other analytes, or samples analyzed after the detector was saturated.

2.12 Toxic Equivalent Determination Guidance

There are multiple approaches to determining the Toxic Equivalents (TEQ) for Dioxins/Furans and CB Congeners. The NFG describes two common approaches. The R1 approach is to calculate TEQs and Total TEQ based on the final validated results. TEQs are recalculated after applying all validation qualifications (i.e. blank-qualifications or analyte identification qualifications).

The TE calculations include the positive results, estimated values, and reported EMPC values. The TE calculations do not include the EDL, MDL, or validator qualified non-detect values (i.e. blank-qualified non-detect or analyte identification non-detect). The TEQs and Total TEQ are estimated (J) when any individual congener is estimated.

For Dioxins/Furans, if 2,3,7,8-TCDF was reported from a required second column confirmation (DB-225), then the TEQ determined from the confirmation column is summed with the TEQs determined from the primary column (DB-5) to obtain the Total TEQ for a sample.

The Toxic Equivalent Factor (TEF) values used to calculate the TEQs are published in "The 2005 World Health Organization Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds", Society of Toxicology, July 7, 2006.

Chapter 3

Tiered Superfund Organic and Inorganic Data Review

3.1 Introduction

Automated data review performs many verification and validation checks routinely for CLP data. The region has adopted a 2-Tiered approach for data review.

3.2 Selection of Data Review Tier

When planning data collection activities, the EPA project manager can select between two data review tiers based on the project objectives (Table 3-1). Data review tiers may always be modified to accommodate modified analyses and project-specific technical specifications such as non-routine project contaminants of concern, lower quantitation limits, and/or unusual matrices. **Note: Tier 1 Data Review is the minimum level of review that Superfund data must undergo prior to use by the Region.**

Tier 1 Data Review provides basic information about the completeness of the data package, PES score results, and qualifies sample results based on reported laboratory quality control results, including laboratory contamination. For CLP data, Tier 1 is performed electronically, and PES results must be scored. CLP electronic data review does not qualify data based on PES score results. The PES score results must be manually evaluated and qualifications considered in the Tier 1 data review report. Tier 1 does not include the qualification of sample results based on field duplicate sample precision; equipment, trip or bottle blank contamination; percent solids; organic MS/MSD results; instrument calibration range; or sulfur clean-up in pesticides and Aroclor analyses.

A *Tier 1 Plus Data Review* provides a Tier 1 review plus a review and qualification of sample results based on R1 QC that are not part of the Tier 1 review (e.g., field duplicate sample precision; equipment, trip or bottle blank contamination; % solids; organic MS/MSD; instrument calibration range; or pesticide and Aroclor sulfur clean-up). For CLP data, Tier 1 Plus Data Review is partially performed electronically with additional manual review per the guidance provided in Chapter 2 of this R1 DR Supplement.

Tier 2 Data Review includes the Tier 1 Plus review and additional levels of raw data review for enhanced accuracy checks. For CLP data, Tier 2 is performed electronically with additional manual review. **Note: Tier 2 is the preferred level of review for human health and ecological risk assessment and is typically required for Dioxins/Furans and PCB Congener analyses.**

Table 3-1: Data Review Tiers/Electronic CLP Data Validation Stages

Region 1 Data Review Tiers**	Use	Data Review and Qualification Activities		Stages Electronic/Manual
Tier 1	Minimum Data Review Tier for Superfund Data used by the Agency.*	Review and qualification of sample results based only on completeness and compliance of sample receipt condition checks		Stage 1 Electronic
			AND sample-related QC results	Stage 2A Electronic
			AND instrument-related QC results	Stage 2B Electronic
Tier 1 Plus	Use when R1 field precision, field contamination, PES checks on laboratory accuracy, and R1 % solids criteria are required to meet DQOs; and higher Tier is neither warranted nor cost effective.	Tier 1	PLUS R1 QC sample results and activities (field duplicate samples, PESs, field contamination, percent solids, organic MS/MSD, instrument calibration range and pesticide and Aroclor sulfur clean-up) in accordance with DR Supplement Section 2.	Electronic & Manual for R-1 QC
Tier 2	Use to ensure data quality for risk assessments, Dioxin and CBC analyses and when project DQOs specify.	Tier 1 Plus	AND recalculation checks [including recalculation of TEQs (Dioxin and CBC only), in accordance with DR Supplement Section 2]	Stage 3*** Electronic/Manual
			AND review of instrument outputs	Stage 4 Manual

* PE samples must be scored. CLP electronic data review does not qualify data based on PES score results. The PES score results must be manually evaluated and qualifications considered in the Tier 1 data review report.

** Tiers may be modified to accommodate modified analyses including non-routine project contaminants of concern, matrices, etc.

*** Stage 3 electronic review deliverables includes recalculation checks for CLP Organic and Inorganic RAS analyses.

Note: Organic and Inorganic CLP data are electronically validated to Stage level 3 (S3VE), while High Resolution Dioxins/Furans and CBCs are electronically validated to Stage level 2A (S2AVE).

3.3 Tier 1 Data Review

A Tier 1 Data Review is required for all Superfund data that will be used by the Region. Tier 1 includes evaluation of the PE score reports (refer to Chapter 4 & relevant NFG), as well as the review and qualification of sample results in accordance with the NFGs based on: (refer to Tables 2-1, 2-2, and 2-3 for additional information)

- Delivery of required data package documents by the laboratory. A completeness check is performed in accordance with Section 2.4 of this guidance and ensures evidentiary documentation is included in the data package;
- Sample-related QC results and QC acceptance criteria (e.g., method blanks, DMC recoveries, deuterated monitoring compounds (DMC) recoveries, laboratory control sample (LCS) recoveries, duplicate analyses, matrix spike and matrix spike duplicate recoveries, serial dilutions, post digestion spikes). **Note: Only laboratory contamination is assessed with a Tier 1 review. See Tier 1 Plus Data Review for the evaluation of field contamination.**
- Instrument-related QC results (e.g., initial and continuing calibrations, instrument performance checks).

Tier 1 Documentation:

Organic and Inorganic CLP data are electronically reviewed at the SEDD Stage 3 level and High Resolution (Dioxins/Furans & CBCs) CLP data are currently reviewed electronically at the Stage 2A level in accordance with *Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use*, OSWER No. 9200.1-85, EPA 540-R-08-005, January 13, 2009, <https://www.epa.gov/clp/superfund-clp-analytical-services-guidance-documents>. Refer to Tables 3-3 and 3-4. It is expected that data reviewers will utilize electronic data reports whenever available. In the case of non-CLP data, data reviewers will use organization-specific worksheets/checklists as applicable (Refer to Attachment 2-3).

The Data Review Report documents missing data/information; provides a brief description of significant data quality issues regarding the reported laboratory QC results; and, includes a Data Summary Table (DST). Electronic data review reports, worksheets/checklists, PES score results and Support Documentation are attached to the Data Review Report. Refer to Section 2.3 for guidance on formatting the Data Review Report.

Note: Sample results are qualified based on the NFGs.

3.4 Tier 1 Plus Data Review

Tier 1 Plus builds on the Tier 1 Data Review and includes manual review and qualification of sample results based on R1 QC results and guidance provided in the following Sections (refer to Tables 2-1, 2-2, and 2-3 for additional information):

- PES results to evaluate laboratory accuracy (Refer to Chapter 4 & NFG);
- Field blanks (equipment, trip and bottle blanks) to evaluate field contamination (Refer to Sections 2.5 and 2.6);
- Field duplicate samples to evaluate field precision (Refer to Section 2.7);

- Percent Solids (Refer to Section 2.8);
- Pesticide and Aroclor Clean-up Procedures (Refer to Section 2.9);
- Organic MS/MSDs (Refer to Section 2.10); and
- Analyte concentration exceeding instrument calibration range (Refer to Section 2.11)

Tier 1 Plus Documentation:

Includes Tier 1 documentation (Data Review Report, DST, electronic data review reports/worksheets, PES score results evaluation, Support Documentation), plus the results of the additional review of R1 QC samples and activities (manual review worksheets and qualification of results based on the R1 QC reviewed).

Note: Sample results are qualified based on the NFGs and the R1 DR Supplement.

3.5 Tier 2 Data Review

Tier 2 Data Review builds on a Tier 1 Plus review and includes the review and qualification of sample results in accordance with NFGs based on (refer to Tables 2-1, 2-2, and 2-3 for additional information):

- recalculation checks (performed electronically for Stage 3 deliverables);
- recalculation of Toxic Equivalents (TEQs) (Dioxin/CBC only); and
- instrument outputs (e.g., gas chromatograms, mass spectra)

Tier 2 Documentation:

Includes Tier 1 Plus documentation (Data Review Report, DST, electronic data review reports/worksheets, manual review worksheets, PES score results evaluation, Support Documentation), plus the results of the Tier 2 data review of calculations and raw data (documented with additional worksheets as necessary).

Note: Sample results are qualified based on the NFGs and the R1 DR Supplement.

3.6 Tier 1, Tier 1 Plus, or Tier 2 Modified Analysis Data Review

When non-routine analytes, quantitation limits, matrices, etc. are required for project activities, data review procedures should be modified to accommodate the non-routine parameter. A Modified Analysis Data Review includes the required Tier level of review, utilizing electronic data review where possible, and manual review of non-routine sample data according to the Modified Analysis requirements in the QAPP.

Modified Analyses Data Review Documentation:

Includes appropriate Tier level documentation, and the results of the review of data quality issues regarding requested non-routine analytes, quantitation limits, and matrices, etc.

3.7 Documenting the Label and Tier for the Data Review Process

The data reviewer documents the Stage and Tier of validation for each laboratory analytical data package in the Data Review Report and DST. Stage labels are applied in accordance with the

Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use, OSWER No. 9200.1-85, EPA 540-R-08-005, January 13, 2009, <https://www.epa.gov/clp/superfund-clp-analytical-services-guidance-documents>. The label of the stage is documented in the Data Review Report subject area of the report. The labels of the various Stages are listed below:

Table 3-2: Stage Labels for Externally Validated Laboratory Analytical Data

Label	Corresponding Label Code
Stage_1_Validation_Electronic	S1VE
Stage_1_Validation_Manual	S1VM
Stage_1_Validation_Electronic_and_Manual	S1VEM
Stage_2A_Validation_Electronic	S2AVE
Stage_2A_Validation_Manual	S2AVM
Stage_2A_Validation_Electronic_and_Manual	S2AVEM
Stage_2B_Validation_Electronic	S2BVE
Stage_2B_Validation_Manual	S2BVM
Stage_2B_Validation_Electronic_and_Manual	S2BVEM
Stage_3_Validation_Electronic	S3VE
Stage_3_Validation_Manual	S3VM
Stage_3_Validation_Electronic_and_Manual	S3VEM
Stage_4_Validation_Electronic	S4VE
Stage_4_Validation_Manual	S4VM
Stage_4_Validation_Electronic_and_Manual	S4VEM
Not_Validated	NV

**Table 3-3: Summary of Organic Data Review Tiers
for Electronic and Manual Review**

Data Review Tier	Review Activities	CLP Electronic Review (Stage 3 Deliverable) (Stage 2A for CBC & D/F)	Non-CLP Manual Review
Tier 1 Purpose: Minimum Data Review Tier for Superfund data used by the Agency.	Review Tasks	Completeness check per DR Supplement (Section 2.4) & PES Score Report check. Electronic review of sample results per NFGs based on - laboratory QC sample results; - instrument-related QC results; and - recalculation checks.	Completeness check per DR Supplement (Section 2.4) & PES Score Report check. Manual review of sample results per NFGs based on - summarized laboratory QC sample results; and - instrument-related QC results.
	Data Qualification	Electronic application of data qualifiers per NFG based on summarized QC results and recalculations.	Manual application of data qualifiers per NFG criteria and actions based on summarized QC results.
	Documentation	Data Review Report Attachments: Data Summary Table Relevant Electronic data review reports (e.g. “Data Review Results”)	Data Review Report Attachments: Data Summary Table Worksheets/checklists
Tier 1 Plus Purpose: Used to review R1 QC samples to assess field precision, field contamination, PES checks on laboratory accuracy, and when R1 % solids criteria are required to meet DQOs; and when a	Review Tasks	Tier 1 Electronic review PLUS Manual review of R1 QC in accordance with DR Supplement, Section 2: <ul style="list-style-type: none"> • PES results; • Field contamination; • Field duplicate sample results; • % Solids; • Pesticide & Aroclor Sulfur Clean-up; • Organic MS/MSD; and • Instrument calibration range. 	Tier 1 Manual review PLUS Manual review of R1 QC in accordance with DR Supplement, Section 2: <ul style="list-style-type: none"> • PES results; • Field contamination; • Field duplicate sample results; • % Solids; • Pesticide & Aroclor Sulfur Clean-up; • Organic MS/MSD; and • Instrument calibration range.
	Data Qualification	Electronic and Manual application of data qualifiers* per NFGs and R1 DR Supplement.	Manual application of data qualifiers* per NFGs and R1 DR Supplement.

**Table 3-3: Summary of Organic Data Review Tiers
for Electronic and Manual Review**

Data Review Tier	Review Activities	CLP Electronic Review (Stage 3 Deliverable) (Stage 2A for CBC & D/F)	Non-CLP Manual Review
higher Tier is neither warranted nor cost effective.	Documentation	Data Review Report & Attachments: Data Summary Table Relevant Electronic data review reports (e.g. “Data Review Results”) Manual worksheet/checklists per R1 DR Supplement and/or QAPP.	Data Review Report & Attachments: Data Summary Table Manual worksheets/checklists per R1 DR Supplement and/or QAPP.
Tier 2 Purpose: Use to review Ecological or Human Health risk assessment data and when project DQOs specify. Note: Tier 2 review is routinely performed for Dioxins/Furans & CB Congener analyses.	Review Tasks	Tier 1 Plus Data Review <u>AND</u> Electronic and Manual recalculation checks [including manual recalculation of Toxic Equivalents (Dioxin/CBC only), in accordance with DR Supplement, Section 2] <u>AND</u> Manual review of instrument outputs (e.g., chromatograms).	Tier 1 Plus Data Review <u>AND</u> Manual recalculation checks [including manual recalculation of Toxic Equivalents (Dioxin/CBC only), in accordance with DR Supplement, Section 2] <u>AND</u> Manual review of instrument outputs.
	Data Qualification	Electronic and Manual application of data qualifiers.	Manual application of data qualifiers.
	Documentation	Data Review Report & Attachments: Data Summary Table Relevant Electronic data review reports (e.g. “Data Review Results”) Manual worksheets/checklists per R1 DR Supplement and/or QAPP.	Data Review Report & Attachments: Data Summary Table Manual worksheets/checklists per R1 DR Supplement and/or QAPP.

* Use of alternate data flags should be documented in the QAPP or equivalent document.

Table 3-4: Summary of Inorganic Data Review Tiers for Electronic and Manual Review

Data Review Tier	Review Activities	CLP Electronic Review (Stage 3 Deliverable)	Non-CLP Manual Review
Tier 1 Purpose: Minimum Data Review Tier for Superfund data used by the Agency.	Review Tasks	Completeness check per DR Supplement (Section 2.4) & PES Score Report check. Electronic review of sample results per NFGs based on - laboratory QC sample results; and - instrument-related QC results. - recalculation checks.	Completeness check per DR Supplement (Section 2.4) & PES Score Report check. Manual review of sample results per NFGs based on - summarized laboratory QC sample results; and - instrument-related QC results.
	Data Qualification	Electronic application of data qualifiers per NFG based on summarized QC results and recalculations.	Manual application of data qualifiers per NFG criteria and actions based on summarized QC results.
	Documentation	Data Review Report Attachments: Data Summary Table Relevant Electronic data review reports (e.g. “Data Review Results”)	Data Review Report Attachments: Data Summary Table Worksheets/checklists
Tier 1 Plus Purpose: Used to review R1 QC samples to assess field precision, field contamination, PES checks on laboratory accuracy, and when R1 % solids criteria are required to meet DQOs; and when a higher Tier is neither warranted nor cost effective.	Review Tasks	Tier 1 Electronic review PLUS Manual review of R1 QC in accordance with DR Supplement, Section 2: <ul style="list-style-type: none"> • Field contamination; • Field duplicate samples; • PES results; • % Solids; and • Instrument calibration range. 	Tier 1 Manual review PLUS Manual review of R1 QC in accordance with DR Supplement, Section 2: <ul style="list-style-type: none"> • Field contamination; • Field duplicate samples; • PES results; • % Solids; and • Instrument calibration range.
	Data Qualification	Electronic and Manual application of data qualifiers* per NFGs and R1 DR Supplement.	Manual application of data qualifiers* per NFGs and R1 DR Supplement.
	Documentation	Data Review Report & Attachments: Data Summary Table Relevant Electronic data review reports (e.g. “Data Review Results”)	Data Review Report & Attachments: Data Summary Table Manual worksheets/checklists per R1 DR Supplement and/or QAPP.

**Table 3-4: Summary of Inorganic Data Review Tiers
 for Electronic and Manual Review**

Data Review Tier	Review Activities	CLP Electronic Review (Stage 3 Deliverable)	Non-CLP Manual Review
		Manual worksheet/checklists per R1 DR Supplement and/or QAPP.	
Tier 2 Purpose: Use to review ecological and health risk assessment data; and when project DQOs specify.	Review Tasks	Tier 1 Plus Data Review <u>AND</u> Electronic and Manual recalculation checks <u>AND</u> Manual review of instrument outputs.	Tier 1 Plus Data Review <u>AND</u> Manual recalculation checks <u>AND</u> Manual review of instrument outputs.
	Data Qualification	Electronic and Manual application of data qualifiers.	Manual application of data qualifiers.
	Documentation	Data Review Report & Attachments: Data Summary Table Relevant Electronic data review reports (e.g. “Data Review Results”) Manual worksheets/checklists per R1 DR Supplement and/or QAPP.	Data Review Report & Attachments: Data Summary Table Manual worksheets/checklists per R1 DR Supplement and/or QAPP.

* Use of alternate data flags should be documented in the QAPP or equivalent document.

Chapter 4

Performance Evaluation Sample Program

4.1 Introduction

This guidance provides implementation details for the use of PESs for environmental data operations conducted within the region. The use of single and/or double blind PESs helps to ensure that environmental data collection activities result in the delivery of analytical data of known and documented quality, which are suitable for the intended use.

4.2 Purpose of the PES Program

EPA R1 supports the routine use of PESs to:

- identify a community of technically capable laboratories during laboratory pre-award evaluation;
- evaluate the performance of analytical laboratories over a period of time; and,
- provide information on a laboratory's ability to accurately identify and quantitate analytes of interest during the period of sample preparation and analysis.

The EPA R1 PES Program works in conjunction with the graded data review approach described in previous Chapters.

4.3 Use of PESs

The EPA R1 PES program can be used for programs described below.

4.3.1 Superfund Program

The EPA R1 PES Program applies to all Superfund fixed laboratory, field laboratory, and field screening analyses. Regardless of the mechanism used to obtain the analytical data, the project funding source, or the lead, EPA or non-EPA entity, the EPA R1 PES Program applies.

4.3.1.1 EPA Fund-lead, Potentially Responsible Parties (PRPs) and Federal Facility Oversight Projects

For EPA Fund-lead, PRP and Federal Facility Oversight Superfund projects, the EPA R1 PES Program applies to all analytical services obtained through the Contract Laboratory Program (CLP) and non-CLP vehicles. Non-CLP vehicles include fixed laboratories, field laboratory and field screening analytical services provided directly by EPA or by EPA lead contractors and/or subcontractors. EPA-provided PESs, which support project DQOs, should be utilized when available as described in Section 4.4 of this guidance document. If appropriate PESs which support the project DQOs are not available through EPA, then PESs should be obtained from commercial vendors.

4.3.1.2 Fund-lead Projects Performed by States or other Federal Agencies

For Fund-lead projects performed by States (under Cooperative Agreements) or other Federal Agencies (under Interagency Agreements) that utilize the CLP to obtain analytical services, EPA-provided PESs should be utilized. When non-CLP mechanisms are used for fixed laboratory, field laboratory, or field screening analytical services for Superfund projects, EPA-provided PESs, which support project DQOs should be utilized when available as described in this guidance. If appropriate PESs which support the project DQOs are not available through EPA, then PESs should be obtained from commercial vendors.

4.3.1.3 Non Fund-lead Projects

For Non Fund-lead Superfund projects performed by Potentially Responsible Parties (PRPs) or other Federal Agencies, the EPA R1 PES Program applies to all fixed laboratory, field laboratory, and field screening analytical services utilized for these projects. Appropriate PESs which support the project DQOs must be utilized whenever environmental samples are collected. If appropriate PESs which support the project DQOs are not available through EPA, then PESs should be obtained from commercial vendors.

4.3.1.4 EPA R1 PES Program Requirements for Superfund Projects

The following EPA R1 PES Program requirements apply to all Superfund projects:

- One single or double blind PES should be used for each sample matrix, analysis parameter, and concentration level for each Sample Delivery Group (SDG) that is sent to a laboratory. An SDG is generally defined as a group of 20 or fewer field samples within a project, received over a period of up to 7 calendar days. The PES should not be counted as field samples in the 20 sample SDG total.
Note: The sampling schedule and/or project objectives may necessitate the use of an alternate PES frequency.
- PESs are required for analytical testing when they are available from EPA or commercial vendors in the appropriate matrix and at the proper concentration level to support the project objectives.
- PESs should contain as many target analytes as possible, but they must contain at least one of the target analytes, preferably a site contaminant of concern; and,
- For soil/sediment/solid sampling events, it is not necessary to include an aqueous PES when the only aqueous samples are equipment and/or trip blanks **and** when a PES exists (from either EPA or a commercial vendor) for the soil/sediment/solid samples. However, an aqueous PES should be included with soil/sediment/solid samples when a soil/sediment/solid PES (from either EPA or a commercial vendor) does not exist for the analytical parameter.

Note: The frequency and/or type of PESs should be chosen to support the project DQOs.

4.3.2 Non-Superfund Programs

The EPA R1 QA Unit recommends that Non-Superfund programs utilize PESs whenever environmental samples are collected. PESs are not available through EPA for non-Superfund activities; and must be obtained from commercial vendors (refer to Section 4.8). This recommendation applies to environmental sampling performed by EPA (LSASD, OEP, etc.) and non-EPA entities (facilities, manufacturers, generators, States, other Federal Agencies, etc.) which support non-Superfund federal regulations such as RCRA, UST, CWA, NPDES, CAA, TSCA, FIFRA, etc.

The following PES Program recommendations should apply to all Non-Superfund projects:

- One single or double blind PES should be used for each sample matrix, analysis parameter, and concentration level for each Sample Delivery Group (SDG) that is sent to a laboratory. An SDG is generally defined as a group of 20 or fewer field samples within a project, received over a period of up to 7 calendar days. The PESs should not be counted as field samples in the 20 sample SDG total.
Note: The sampling schedule and/or project objectives may necessitate the use of an alternate PES frequency.
- It is suggested to include PESs from commercial vendors in the appropriate matrix and at the proper concentration level to support the project objectives.
- PESs should contain as many target analytes as possible, but they must contain at least one of the target analytes, preferably a site contaminant of concern; and,
- For soil/sediment/solid sampling events, it is not necessary to include an aqueous PES when the only aqueous samples are equipment and/or trip blanks **and** when a PES exists from a commercial vendor for the soil/sediment/solid samples. However, an aqueous PES should be included with soil/sediment/solid samples when a soil/sediment/solid PES does not exist for that analysis parameter.

Note: The frequency and/or type of PESs should intentionally be chosen to support the project DQOs.

4.4 Application of PESs

Contact the R1 CLP COR for a current Superfund PES catalog. PESs can be used for multiple analyses, for example, #95-001 or #98-002, Low/Medium Volatiles in Water, could be used for analysis by the CLP Statements of Work, SW-846 Method 8260, or 40 CFR Method 624, etc. Note that several catalog numbers may exist for a particular method description and matrix.

The catalog numbers indicate several different concentrations and analyte mixes. When requesting PESs, the FSC or EPA Field Sampling Personnel must clearly identify the necessary analytes and concentration range(s).

Note: If an aqueous mercury PES is needed, order PES #06-003 as the aqueous #99-004 PES contains metals but does **not** contain mercury.

Note: The CDD/CDF and CB Congener parameters have a Blank PES for both soil and water matrices. The Blank PES should always be included with the spiked PES for these parameters.

The Superfund PES program can accommodate special requests or site-specific PESs containing analytes and/or concentrations designed to support project objectives. Site-specific PESs can be single-blind or double-blind full-volume PESs. Special-order PESs can usually be filled in the same time frame as the ampulated PESs listed in the catalog.

PESs and Standard Reference Materials (SRMs) are available from commercial vendors for use in Fund-lead Superfund projects, for Non Fund-lead Superfund projects, as well as for Non-Superfund projects. SRMs can be utilized as PESs. Individual vendors should be contacted directly to obtain current catalog information to ensure that PESs will meet project DQOs for specific compounds/parameters, matrices and concentration levels. Table 4-1 provides vendor contact information but is not inclusive of all potential PES/SRM vendors and does not constitute an endorsement by EPA for any particular vendor. It is provided solely for reference in identifying potential commercial PES sources.

4.5 Planning for PES Use

Project Planning should include the use of PESs as an analytical Quality Control tool. The utilization of PESs in accordance with this guidance should be referenced in the Quality Assurance Project Plan (QAPP) and/or Sampling and Analysis Plan (SAP) along with the frequency, analytical parameters, matrices, and concentration levels for each PES. The origin of the PES (EPA-provided or commercial vendor) should be documented in the QAPP and/or SAP.

PESs are not included in the sample count for a CLP SDG. For example, 20 field samples and two PESs would be one SDG assuming the samples are received within seven days and the shipment is complete even though 22 (total) samples were submitted for analysis. **Note:** The sampling schedule and/or project objectives may necessitate an alternate PES frequency, as appropriate to achieve project objectives.

4.6 Roles and Responsibilities

4.6.1 Superfund Program

The process is summarized with a flow chart, see Figure 4-1. The process roles/responsibilities, time frames for planning, obtaining, analyzing, scoring, and evaluating results for EPA-provided and commercial PESs used in Superfund projects is captured in Figure 4-1.

4.6.1.1 EPA R1 CLP COR

The R1 CLP COR of the EPA R1 Quality Assurance Unit (Refer to Attachment 2-1 for contact information) is responsible for the following activities:

- Providing the current PES Catalogue upon request;
- Supplying EPA PESs to requestors;
- Scoring EPA PES analytical results;
- Providing EPA PES Score Reports to EPA PES requestors;
- Assists with choosing appropriate PESs if needed, handling Special-Request/Site-Specific PE orders and consultation when evaluating resultant data quality;
- Providing PES trend reports based on EPA PES score results by lab or sample type; and,
- Communicating between the PES provider and user.

4.6.1.2 EPA Field Sampling Contractors and EPA Field Sampling Personnel

EPA FSC and EPA Field Sampling Personnel are responsible for the following activities (when CLP and/or non-CLP mechanisms are used to obtain analytical services for EPA Fund-lead, PRP and Federal Facility Oversight projects):

- Determining PES needs during the project planning phase (scoping meetings, QAPP and/or SAP development);
- Identifying PES sources (EPA and commercial);
- Procuring commercial PESs if necessary;
- Requesting EPA PESs from the R1 CLP COR according to the procedures outlined in Section 4.7;

- Ensuring that every laboratory analyzing project samples receives and analyzes appropriate PESs according to the frequency requirements described in this guidance or as established by the project objectives/procedures;
- Obtaining PES score results from EPA and/or commercial PES vendors;
- Evaluating PES score results in accordance with the relevant NFG and documenting the evaluation on the data review worksheets/checklists and the Data Review Report as appropriate; and,
- Notifying the R1 CLP COR if the EPA PES performance necessitated the need for reduced payment or rejection of CLP data.

4.6.1.3 States and Other Federal Agencies

4.6.1.3.1 Fund-lead CLP Projects

For Fund-lead projects performed by States or other Federal Agencies that utilize the CLP or methods similar to CLP, to obtain analytical services, the States and other Federal Agencies are responsible for performing the activities described in Section 4.6.1.2 of this guidance.

4.6.1.3.2 Other Projects or Programs

When commercial PESs are used for Fund-lead Non-CLP Projects, Non Fund-lead Projects, as well as projects under Non-Superfund Programs, then the EPA or non-EPA entity (PRP, States or other Federal Agencies) is responsible for the following activities:

- Determining PES objectives and use for the project planning phase (scoping meetings, DQO development, QAPP and/or SAP development);
- Identifying commercial PES sources;
- Procuring commercial PES;
- Ensuring that every laboratory analyzing project samples, receives and analyzes appropriate commercial PESs according to the frequency requirements described in Section 4.3.2 of this guidance document;
- Obtaining score results for commercial PES; and,
- Evaluating commercial PES score results in accordance with the relevant NFG and documenting the evaluation on the data review worksheets/checklist and the Data Review Report as appropriate.

4.7 Detailed Procedures for the PES Program

4.7.1 Superfund Program

Specific procedures for obtaining and utilizing EPA R1-provided PES are provided below. These procedures must be followed by EPA FSC and EPA Field Sampling Personnel (whenever CLP and/or non-CLP mechanism are used to obtain analytical services for EPA Fund-lead, PRP, and Federal Facility Oversight projects) and by States or other Federal Agencies that utilize the CLP or methods similar to CLP to obtain analytical services for Superfund projects.

1. The EPA FSC (START, RACS, etc.), State, Federal Agency (ACOE, etc.) or EPA Field Sampling Personnel send (via email) the EPA R1 Superfund PES Request Form (See Attachment 4-1) to the R1 CLP COR (Refer to Attachment 2-1 for contact information) one week prior to sampling.
2. The R1 CLP COR will confirm receipt of the PES request by email.

Note: In an emergency, PESs can be requested within 24 to 48 hours of ordering, but this service cannot be guaranteed.

3. The EPA R1 Superfund PES Request Form may specify the catalog number for the requested PES, number of PESs ordered, method description, applicable matrix, exact reference title or number for the analytical method which will be used to prepare and analyze the PES and field samples.
4. Identify specific analytes and concentration ranges in the "Required Analyte & Concentration" field on the request form. If a specific analyte or concentration, as requested by the FSC or EPA Field Sampling Personnel in the "Required Analyte & Concentration" field, cannot be provided by an existing EPA PES, then the R1 CLP COR will notify the requestor. The FSC or EPA Field Sampling Personnel will then determine, based on project DQOs, whether an EPA PES that does not contain the specific analyte or concentration will be sufficient to support project DQOs or whether a commercial PES will be utilized. Copies of blank and completed EPA R1 Superfund PES Request Forms are provided in Attachment 4-1.
5. EPA PES and preparation instructions are provided to the requestor and upon receipt the information should be verified against the order submitted by the FSC or EPA Field Sampling Personnel. The R1 CLP COR should be contacted if PESs do not arrive or the shipment was not as requested. The FSC or EPA Field Sampling Personnel must ensure that PESs are handled and stored properly until they are sent to a laboratory for analysis.
6. Sample numbers must be assigned to the EPA PESs by the FSC or EPA Field Sampling Personnel. The EPA PES vial numbers must be documented on the Traffic Report/Chain of Custody Forms.
7. The FSC or the EPA Field Sampling Personnel submit the EPA PESs, the preparation instructions and field samples to the laboratories performing the analyses.
8. The laboratories analyze the EPA PESs and field samples according to the specified methods.

For CLP, the laboratories provide the data packages to EPA. For non-CLP, the laboratories provide the data packages to the FSC.

9. When CLP and non-CLP data packages are received, the FSC or EPA Field Sampling Personnel submits the PES data (Form Is) to the R1 CLP COR. The corresponding EPA PES vial number (ID#) and site name must be written on the Form Is by the FSC or EPA Field Sampling Personnel. The complete analytical method reference (full method name, number, revision date, etc.) must also be written on the Form Is if it is not in the Form I header information.
10. The R1 CLP COR scores the EPA PES data and emails the results back to the FSC or EPA Field Sampling Personnel, usually within 2 business days, or less.
11. The EPA PES score results are evaluated by the FSC or EPA Field Sampling Personnel, and the EPA PES score results are incorporated into the data review process in accordance with the relevant NFG procedures. A summary of the PES score results must be provided with the data review worksheets/checklists and Data Review Report as appropriate.
12. If poor PES results indicate reduced payment or rejection of CLP data, the FSC or EPA Field Sampling Personnel must contact the R1 CLP COR who initiates the reduced payment/data rejection process. When resampling may be necessary, the FSC or EPA Field Sampling Personnel must contact the EPA Site Manager by telephone or email to alert them of the situation, as soon as practical.

Similar procedures should be employed for obtaining and utilizing commercial PESs for Fund-lead projects performed by States or other Federal Agencies that utilize non-CLP methods to obtain analytical services and for Non Fund-lead Superfund projects performed by PRPs or other Federal Agencies.

4.7.2 Non-Superfund Programs

EPA Site Managers and EPA Project Managers should establish procedures for implementing the use of PESs for Non-Superfund data collection activities. Procedures should be similar to the activities described for the Superfund program. Documented procedures establish project QA documentation and project-specific procedures. SOPs or guidance documents could be generated to standardize the procedures critical to producing environmental data that are consistent, comparable, credible and defensible.

4.8 Commercial Vendors of PESs and Standard Reference Materials (SRMs)

Table 4-1 provides a partial list of PES/SRM vendors by name, telephone number and WEB address. The list is not necessarily comprehensive of all potential PES/SRM vendors and does not constitute an endorsement by EPA for these vendors. The list is provided solely for reference when identifying potential commercial PES sources.

Figure 4-1: Superfund PES Program Process

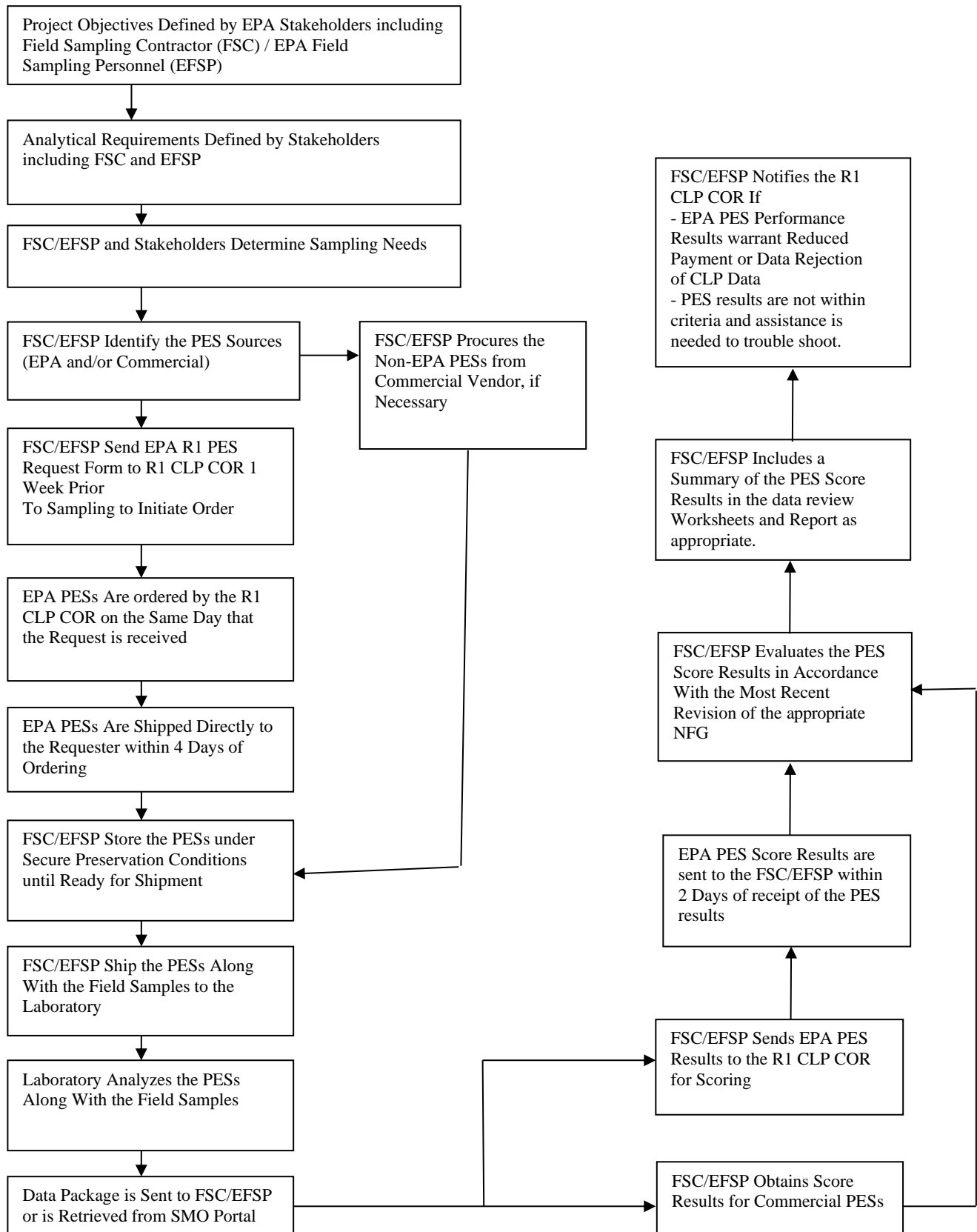


Table 4-1: LIST OF PES/SRM VENDORS

VENDOR	PES or SRM	TELEPHONE/ EMAIL
1. Cambridge Isotope Laboratories, Inc. 3 Highwood Drive, Tewksbury, MA 01876 http://www.isotope.com/	PES	800-322-1174 978-749-8000 cilsales@isotope.com
2. Chem Service, Inc. 660 Tower Lane, PO Box 599. West Chester, PA 19381 http://www.chemservice.com/store.html#	PES	800-452-9994 610-692-3026 (contact web page: https://www.chemservice.com/contact-chem-service)
3. ERA, A Waters Company 16341 Table Mountain Parkway, Golden, Colorado 80403 http://www.eraqc.com/Environmental/catalogid/1-4GR6WY	PES	800-372-0122 303-431-8454 info@eraqc.com
4. Inorganic Ventures 300 Technology Drive, Christiansburg, Virginia 24073 http://inorganicventures.com/catalog/	PES & SRM	800-669-6799 540-585-3030 info@inorganicventures.com
5. Matheson Tri-Gas, Inc. 166 Keystone Drive, Montgomeryville, PA 18936 http://www.mathesongas.com/gases/specialty	PES	800-828-4313 info@mathesongas.com
6. Millipore Sigma Sigma-Aldrich, Customer Support PO Box 14508, St. Louis, MO 63178 http://www.sigmaaldrich.com/analytical-chromatography/analytical-standards/certified-reference.html	CRM	800-325-3010 (contact web page: https://www.sigmaaldrich.com/customer-service/email-for-service.html)
7. National Institute of Standards and Technology (NIST) Office of Reference Materials 100 Bureau Drive, Stop 2300, Gaithersburg, MD 20899 https://www.nist.gov/srm/using-online-catalog	SRM	301-975-2200 srminfo@nist.gov
8. Air Liquide America Specialty Gases LLC (formerly Scott Specialty Gases) https://industry.airliquide.us/products	PES	877-715-8651 solutions.center@airliquide.com
9. ULTRA Scientific 250 Smith Street, N. Kingstown, RI 02852 http://www.ultrasci.com/catalogstart.aspx	PES	800-338-1754 401-294-9400 custserv@ultrasci.com

Chapter 5 Acronyms and Glossary of Terms

For general terms and acronyms, refer to EPA’s Terminology Services Website:

http://iaspub.epa.gov/sor_internet/registry/termreg/searchandretrieve/termsandacronyms/search.do

For QA-related terms EPA R1 adopts the acronyms and definitions provided in the following documents:

- a. **Introduction to the Contract Laboratory Program (Appendix A – List of Acronyms Appendix B – Glossary)** <https://www.epa.gov/sites/production/files/2015-03/documents/clpintro.pdf>
- b. **National Functional Guidelines for Organic Superfund Methods Data Review (Appendix A – Glossary)** https://www.epa.gov/sites/production/files/2017-01/documents/national_functional_guidelines_for_organic_superfund_methods_data_review_013072017.pdf
- c. **National Functional Guidelines for Inorganic Superfund Methods Data Review (Appendix A – Glossary)** https://www.epa.gov/sites/production/files/2017-01/documents/national_functional_guidelines_for_inorganic_superfund_methods_data_review_01302017.pdf
- d. **National Functional Guidelines for High Resolution Superfund Methods Data Review (Appendix A – Glossary)** https://www.epa.gov/sites/production/files/2016-05/documents/hrsm_nfg.pdf
- e. **Uniform Federal Policy for Quality Assurance Project Plans – Evaluating, Assessing, and Documenting Environmental Data Collection and Use Programs Part 1: UFP-QAPP Manual (Glossary of Quality Assurance and Related Terms)** https://www.epa.gov/sites/production/files/2015-07/documents/ufp_qapp_v1_0305.pdf

In addition, the following terms are defined by EPA R1.

Action High/Action Low - Analytes in PESs are scored as “action high” or “action low” if the concentration of the analyte is above or below, respectively, the acceptance limit for that particular analyte. The action high and action low acceptance limits are set by the Quality Assurance Technical Support (QATS) team based on statistical analysis of multiple analytical results. The PES scores are used to qualify the field sample results based on the procedures described in the relevant NFG.

Complete SDG File Inventory Sheet (DC-2 Form) - The “DC-2 Form” lists all the deliverable components in the Complete SDG File. Each laboratory record is listed by page number. The form can be found in the CLP Statements of Work.

Data Qualifier Flags – A code applied to sample results by a data reviewer to indicate a verifiable or potential data deficiency or bias with the data being reviewed. Acceptable qualifiers for use in EPA R1 are listed in Section 1.3.2.

Data Review Report –Is a one page report produced by the data reviewer to document for EPA R1 the results of the data review. The report follows the specific format outlined in Section 2.3.2.

Data Summary Tables - Are spreadsheets attached to the Data Review Report which list the analytical results and their qualifiers (flags) for the field samples.

Data Usability - The process of determining and ensuring that the quality of the data produced meets the intended use of the data. A data usability assessment may be reported in conjunction with the Data Review Report and included as part the final project report; alternatively, a separate Data Usability Assessment Report may be issued. However reported, all limitations and restrictions on the use of the data are documented.

Electronic Data Exchange and Evaluation System (EXES) - The web-based Electronic Data Exchange and Evaluation System (EXES) is used by CLP customers and laboratories to perform automated data assessment and contract compliance screening. EXES provides CLP customers with electronic data assessment reports and spreadsheets customized to their data review needs. EXES provides contract compliance screening to CLP laboratories. Laboratories use EXES to upload their Electronic Data Deliverable (EDD) and receive an emailed report outlining any compliance issues found in the EDD. This allows CLP laboratories to inspect the contractual completeness and compliance of their EDD prior to delivery to EPA, resulting in a more compliant deliverable for CLP customers. EXES is one of the online tools provided by EPA’s Analytical Services Branch and found at: <https://epasmoweb.fedcsc.com>

EPA Field Sampling Personnel (EFSP) - EPA R1 staff members who perform field sampling operations.

False Negative - The situation where a laboratory fails to detect and identify an analyte which is present in the PES or in an environmental sample. This is a serious problem which could lead to failure to implement necessary remedial actions.

False Positive - The situation where a laboratory reports the presence of a target or non-target analyte which was not present in a PES or in the environmental sample. This is a serious problem which could lead to unnecessary site actions.

Field Sampling Contractor (FSC) - Environmental firms which are under contract to EPA to perform field sampling operations at Superfund sites in the Region.

PES Scoring Evaluation Report (PES Score Report) - Is the report generated by the SPSWEB program from QATS. The report shows the results of the comparison between the PES’s analytical results and the statistically defined acceptance windows. Each analyte in the PES is scored as either Acceptable or Warning High/Low or Action High/Low. The data reviewer qualifies/flags the field sample results based on the information in the PES score report.

Potentially Responsible Party (PRP) - A PRP is an individual or company (such as owners, operators, transporters, or generators of hazardous waste) that is potentially responsible for, or contributing to, the contamination problems at a Superfund site. Whenever possible, EPA R1 requires PRPs, through administrative and legal actions, to clean up hazardous waste sites they have contaminated.

Sample Log-In Sheet (CLP DC-1 Form) - The DC-1 Form is completed by the analytical laboratory upon sample receipt and documents critical information concerning the samples including log-in date and sample condition.

Staged Electronic Data Deliverable (SEDD) - The Staged Electronic Data Deliverable (SEDD) is a uniform format for electronic delivery of analytical data for environmental programs. The data deliverable generated by SEDD is an industry-standard Extensible Markup Language (XML) file. For more details see: <https://www.epa.gov/clp/staged-electronic-data-deliverable-sedd>.

Standard Reference Materials (SRM) - The reference materials distributed and certified by an appropriate national institute for standardization, including the National Institute of Standards and Technology (NIST) found at <http://www.nist.gov/srm/>. The National Research Council Canada also supplies certified reference materials at https://www.nrc-cnrc.gc.ca/eng/solutions/advisory/crm_index.html.

Tiered Approach - EPA R1 adopts a tiered approach for reviewing data which allows EPA R1 Project Managers to apply data review procedures commensurate with project objectives.

Warning High/Warning Low - PES results for a particular analyte will be scored as Warning High or Warning Low if the result is outside the range set by plus and minus two sigma units away from the mean but within the range set by three sigma units. The warning high and warning low limits are set by the Quality Assurance Technical Support (QATS) team based on statistical analysis of multiple analytical results. The PES scores are used to qualify the field samples based on the procedures described in relevant NFG.

Chapter 6 References

1. *Region 1 - EPA New England Environmental Data Review Program Guidance*, <https://www.epa.gov/quality/managing-quality-environmental-data-epa-region-1>
2. *USEPA Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use*, OSWER Directive 9200.1-85, <https://www.epa.gov/clp/superfund-clp-analytical-services-guidance-documents>
3. *USEPA CLP National Functional Guidelines for Superfund Organic Methods Data Review* https://www.epa.gov/sites/production/files/2017-01/documents/national_functional_guidelines_for_organic_superfund_methods_data_review_013072017.pdf
4. *USEPA CLP National Functional Guidelines for Inorganic Superfund Data Review* https://www.epa.gov/sites/production/files/2017-01/documents/national_functional_guidelines_for_inorganic_superfund_methods_data_review_01302017.pdf
5. *USEPA National Functional Guidelines for High Resolution Superfund Methods Data Review* https://www.epa.gov/sites/production/files/2016-05/documents/hrsm_nfg.pdf
6. Office of Water Regulations and Standards Industrial Technology Division (Method 1620 Section 14.16, DRAFT September 1989) <http://nepis.epa.gov/Exe/ZyNET.exe/20002GLA.txt?ZyActionD=ZyDocument&Client=EPA&Index=1986%20Thru%201990&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&UseQField=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5CZYFIL ES%5CINDEX%20DATA%5C86THRU90%5CTXT%5C00000003%5C20002GLA.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=p%7Cf&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=10&ZyEntry=33>
7. FINAL QUALITY ASSURANCE and QUALITY CONTROL DATA STANDARD, Standard No.: EX000012.2, February 4, 2010, https://www.epa.gov/sites/production/files/2015-06/documents/qa-qc_10-03-2014_final.pdf
8. Quality Standard for Environmental Data Collection, Production, and Use by EPA Organizations, CIO Standard 2106-S-01
9. *Quality Systems for Environmental Data and Technology Programs - Requirements with Guidance for Use*, American National Standard, (ANSI/ASQ E4 -2004), February 2004
10. *USEPA Guidance on Data Verification and Data Validation* (EPA QA/G-8), November 2002, EPA/240/R-02/004, <https://www.epa.gov/sites/production/files/2015-06/documents/g8-final.pdf>
11. *EPA NE England Quality Management Plan*, May 2016 <https://www.epa.gov/sites/production/files/2017-11/documents/qaqmp-2016qmp0.pdf>
12. *EPA NE Quality Assurance Project Plan Program Guidance*, 2010 <https://www.epa.gov/sites/production/files/2015-06/documents/QAPPProgram.pdf>
13. *USEPA Science Policy Council Peer Review Handbook*, 2000 <https://www.epa.gov/sites/production/files/2014-05/documents/prhandbk.pdf>

14. *USEPA Science Policy Council Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*, 2003
<https://www.epa.gov/sites/production/files/2015-01/documents/assess2.pdf>
15. *USEPA Guidance on the Development, Evaluation, and Application of Environmental Models*, 2009 https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf
16. *Quality Assurance Handbook for Air Pollution Measurement Systems*, EPA-454/R-98-004
<https://nepis.epa.gov/Exe/ZyNET.exe/2000QNC4.TXT?ZyActionD=ZyDocument&Client=EPA&Index=1995+Thru+1999&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C95thru99%5CTxt%5C00000017%5C2000QNC4.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=hpfr&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL>
17. EPA Records Management Schedules <https://www.epa.gov/records/epa-records-schedules-detailed-information>
18. *Data Usability in Risk Assessment* Publication 9285.7-09A PB92-963356 April 1992
<https://nepis.epa.gov/Exe/ZyNET.exe/2000FH7U.TXT?ZyActionD=ZyDocument&Client=EPA&Index=1986+Thru+1990&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C86thru90%5CTxt%5C00000007%5C2000FH7U.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=hpfr&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL>

Attachment 2-1: EPA Region 1 QA Data Review Personnel and Contact Information

Title	Name	Phone Number	e-mail Address
R1 CLP Contract Officer Representative (COR)	Vicki Maynard	617.918.8614	Maynard.Vicki@epa.gov
	Backup: Steve DiMattei	617.918.8369	DiMattei.Steve@epa.gov

Attachment 2-2: Example Data Review Reports

US EPA Approval Signature

Date

Ms. XXXXXXXXXXXX
Remedial Project Manager
EPA New England
5 Post Office Square, Suite 100
Boston, MA 02109

June 7, XXXX

Re: TO No. 5, Task No. 1, TDF No. 1718
Case No. 48103, SDG No. MA41D5
(LABORATORY), Mountainside, NJ
Precision Plating, Vernon, CT
Tier 2/Stage_3_Validation_Electronic_and_Manual (T2/S3VEM)

ICP-MS Metals / Hg:

3/Potable Water/	MA41D5, MA41E6, MA41F7
8/Ground Water/	MA41G5, MA41H4, MA41H6, MA41H7, MA41H8, MA41H9, MA41J1, MA41K7
2/Equipment Blanks/	MA4196, MA41E2

Dear Ms. XXXXXXXXXXXX:

A Tier 2/Stage 3 electronic and manual validation was performed on the metals and mercury analytical data for three potable water samples, eight ground water samples and two equipment blank samples collected by XXXXXXXXXXXX for the U.S. EPA at the Precision Plating Site in Vernon, CT. The samples were analyzed according to USEPA SOW ISM02.4, October 2016. The samples were validated according to the Region 1 - EPA New England Environmental Data Review Program Guidance, June 2018, using first the criteria in the Quality Assurance Project Plan (QAPP) for Remedial Investigation/ Feasibility Study, Precision Plating Superfund Site, Vernon, Tolland County, CT, March 2017, Rev. 5; then the criteria in the Region 1 - EPA New England Environmental Data Review Supplement, June 2018, and the National Functional Guidelines for Inorganic Superfund Methods Data Review, January 2017; and finally to EPA Region I's Environmental Services Assistance Team Inorganic Data Review, SOP ESAT-01-0081 (9/30/13).

The data were evaluated based on the following parameters:

- * ● Data Completeness
- * ● Preservation and Technical Holding Times
- * ● ICP-MS Tune
- * ● Calibrations
- Blanks
- NA ● ICP-AES Interference Check Sample
- * ● ICP-MS Interference Check Sample
- * ● ICP-MS Internal Standards
- Matrix Spikes
- * ● Laboratory Control Sample

Ms. XXXXXXXXX
Case: 48103, SDG No. MA41D5

June 7, XXXX
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- * ● Laboratory Duplicate Samples
- NA ● Field Duplicates
- * ● ICP Serial Dilutions
- NA ● Performance Evaluation Samples/Accuracy Check
- * ● Analyte Quantitation and Reported Quantitation Limits

* - All criteria were met for this parameter.

NA - Not Applicable

Stage 3 Electronic Data Review Reports were available for this SDG.

Overall Evaluation of Data and Potential Usability Issues

The following is a summary of the site investigation/assessment objectives:

- Complete the RI and Feasibility Study (RI/FS) that results in a well-supported Record of Decision (ROD) for the Site;
- Refine the understanding of Site hydrogeology and the sources, nature, vertical extent, and fate of contaminants released at the Site to soil, groundwater, residential well water, and sediment;
- Identify an appropriate remedy for the Site to mitigate residual risk;
- Complete a Baseline Human Health Risk Assessment (BHHRA) and a Screening Level Ecological Risk Assessment (SLERA); and
- Develop a technical document to assess Technical Impracticability (TI) viability.

Data validation indicated the following data quality issues:

ICP-MS: Results were qualified due to calibration blank contamination, equipment blank contamination, negative preparation blank results and high matrix spike recovery.

Mercury: None.

See the attached worksheets and Data Summary Table for details. The results reported on the Data Summary Table are usable for the site objectives.

Sincerely,
XXXXXXXXXXXX

XXXXXX
Senior Consultant

XXXXXX
ESAT Program Manager

Attachments: Data Summary Table
Data Validation Report - Analytical Sample Listing

Data Validation Worksheets
Support Documentation:
Field Notes

Site: Precision Plating, Vernon, CT **Lab:** XXXXXXXXXXXXXXX **Case:** 48103 **SDG:** MA41D5 **SOW:** ISM02.4 **Analysis:** ICP-MS/Hg

	MA4196		MA41D5		MA41E2		MA41F7		MA41G5		
Sample No.:	MA4196		MA41D5		MA41E2		MA41F7		MA41G5		
Sample Location:	EB		Bamforth Rd		EB		Maxwell Dr		MW-19		
Sample Identifier:	GW-EB-05		BMF0042		GW-EB-25		MXD0040		MW-19-00D		
Sample Type:	Equipment Blank		Field Sample		Equipment Blank		Field Sample		Field Sample		
Matrix:	Water		Potable Water		Water		Potable Water		Groundwater		
% Solids:	N/A		N/A		N/A		N/A		N/A		
Dilution Factor:	1		1		1		1		1		
Units:	ug/L		ug/L		ug/L		ug/L		ug/L		
Compound	Result	Flag	Result	Flag	Result	Flag	Result	Flag	Result	Flag	Method
Aluminum	5.9	J	20.0	U ¹	20.0	U ¹	20.0	U ¹	20.7		ICP-MS
Antimony	2.0	U ¹	2.0	U ¹	2.0	U ¹	2.0	U ¹	2.0	U ¹	ICP-MS
Arsenic	1.0	U	1.0	U	1.0	U	0.52	J	0.53	J	ICP-MS
Barium	10.0	U	141		10.0	U	37.7		11.5		ICP-MS
Beryllium	1.0	U	1.0	U ¹	1.0	U	1.0	U ¹	1.0	U	ICP-MS
Cadmium	1.0	U	1.0	U ¹	1.0	U ¹	1.0	U ¹	1.0	U ¹	ICP-MS
Calcium	26.6	J	34900		500	U ¹	71900		47400		ICP-MS
Chromium	2.0	U	2.0	U ¹	2.0	U	2.0	U ¹	258		ICP-MS
Cobalt	1.0	UJ ⁴	1.0	UJ ⁴	1.0	UJ ⁴	1.0	UJ ⁴	1.0	UJ ⁴	ICP-MS
Copper	0.23	J	169		2.0	U ¹	86.3		2.0	U ²	ICP-MS
Iron	200	U	200	U ¹	200	U	275		200		ICP-MS
Lead	1.0	U ¹	35.9		1.0	U ¹	2.4		1.0	U ¹	ICP-MS
Magnesium	500	U ¹	11100		500	U ¹	9090		7060		ICP-MS
Manganese	1.0	UJ ⁴	8.5		1.0	UJ ⁴	10.4		41.3		ICP-MS

Nickel	0.080	J	2.2		0.070	J	2.4		1.0	U ²	ICP-MS
Potassium	500	U ¹	6920		500	U ¹	4750		2200		ICP-MS
Selenium	5.0	U	5.0	U	5.0	U	5.0	U	5.0	U	ICP-MS
Silver	1.0	U	1.0	U ¹	1.0	U ¹	1.0	U ¹	1.0	U ¹	ICP-MS
Sodium	590		59400		590		145000		21500		ICP-MS
Thallium	1.0	U	1.0	U ¹	1.0	U	1.0	U ¹	1.0	U ¹	ICP-MS
Vanadium	0.060	J	0.33	J	5.0	U	0.14	J	5.0	U ²	ICP-MS
Zinc	3.5		133		6.3		394		24.2	J+ ³	ICP-MS
Mercury	0.20	U	0.20	U	0.20	U	0.20	U	0.20	U	CVAA

TIER 2/S3VEM DATA VALIDATION QUALIFIER COMMENTS:

J - Sample concentrations reported by the laboratory below the lowest standard are flagged (J) on the Data Summary Table as estimated values with no superscripts.

- 1 Calibration blank contamination; positive sample results that are less than the CRQL are reported as non-detects (U) at the CRQL.
- 2 Equipment blank contamination; positive sample results that are less than the CRQL are reported as non-detects (U) at the CRQL.
- 3 Equipment blank contamination; positive sample results for Zn that are less than 10x EB concentration are reported as estimated with high bias (J+).
- 4 Negative preparation blank contamination; positive sample results for Co and Mn less than 10x the blank concentration are estimated with low bias (J-) and non-detects are estimated (UJ).

Attachment 2-3a: Example Inorganic Data Review Worksheets

See separate file.

Attachment 2-3b: Example Organic Data Review Worksheets

See separate file.

**Attachment 2-4a: Example Region 1 DAS/Tier 4 Projected Sampling Event - Part
1 Form**

Tier 4 PROJECTED Sampling Event – Part 1

Date:	Program:	Field Sampling Contractor:	Contact Name & Phone No.:
Site Name:		Site Location:	
Lab Name:		Lab Location:	
Estimated Sampling Date(s):		Data Turnaround Time:	
Parameter	Matrix	Estimated No. of Samples	Attach a list of compounds-of-interest and the required quantitation limits for each parameter.

Subcontracted Services Rationale:

Projected Tier 4 Analyses Accepted: Yes No Comments:

Program Approval Signature and Date _____ Comments:

**Attachment 2-4b: Example Region 1 DAS/Tier 4 Actual Sampling Event - Part 2
Form**

Tier 4 ACTUAL Sampling Event – Part 2

Field Sampling Contractor/Contract:		Ship to Lab Date:		Data Package Receipt Date:	
DAS Case No.:		SDG:		Data Turnaround Time:	
Site Name:		Site Location:		CERCLIS #:	
Site ID:	Action Code:	Operable Unit:		Purpose Code:	
Lab Name:		Lab Location:		Lab Code:	
No. of Samples: (Total-Including PES & Blanks)		Sample IDs:		Case Complete: Yes or No	Total Cost:

Parameter	Cost per Parameter, Matrix & Sample	Matrix	No. of Samples	Associated PE Sample Numbers	Associated Field Duplicates	Associated Spike/Duplicates	Associated MS/MSD Samples	Associated Blanks & Type

Note: The Chain of Custody and Data Validation Memo must be attached.
 List the Parameter and Matrix from the NEST Look-Up Table. If the parameter does not exist in the look-up table, send a copy of the Method or a definition along with this form to the RSCC for entry into NESTS.

**Attachment 4-1: Superfund Performance Evaluation Sample (PES) Request
Form**



SUPERFUND PERFORMANCE EVALUATION SAMPLE REQUEST FORM

Complete this form and send it to:

QATS Laboratory
 2700 Chandler Avenue, Bldg. C
 Las Vegas, NV 89120

PHONE: (702) 895-8722
 FAX: (702) 795-8210
 EMAIL: QATSPESORDER@aptim.com

**QATS SHIPS ALL MATERIALS WITHIN 72 HOURS
 OF RECEIPT OF REQUEST**

FOR QATS USE ONLY	
Packed By/Shipped By:	
Ship Date:	
Airbill # :	
COC #:	
Order #:	

Ship materials, request and chain of custody with sample numbers to:

Date of Request: _____ / _____ / _____

SDG Number: _____

Date Materials Needed: _____ / _____ / _____

For Use With SOW: _____

Site-specific Superfund Acct. #: _____ Superfund Site Name: _____ CERCLIS #: _____

Ship materials, request and chain of custody with sample numbers to:

Name:		
Company:		
Address:		
City:	State:	Zip Code:
Telephone No.:	Fax No.:	E-Mail:

Send copies of this request and chain of custody with sample numbers to:

Name:		
Company:		
Address:		
City:	State:	Zip Code:
Telephone No.:	Fax No.:	E-Mail:

Sample Catalog Number	Required Analyte & Concentration (If Known)	Sigma # (Optional)	# Requested	FOR QATS USE ONLY	
				Sample #	Remarks

I acknowledge that, by law, PESs from the Superfund PES Repository cannot be used to support other U.S. EPA programs and/or other federal/state/local agencies for non-Superfund activities. As an Authorized PES Requestor, I certify that the above Performance Evaluation Samples are to be used in support of Superfund activities only.

Print Name

Authorized Signature

