CP3-ES-5003 FRev. 4	**TITLE**: Quality Assured Data	Page 1 of 43
DOCUMENT CATEGORY:	Administrative	
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REVISION/CHANGE LOG			
Revision/Change Letter	Description of Changes	Pages Affected	Date of Revision/Change
FR0	Bluesheet	ALL	10/20/2017
FR1	Non-intent to incorporate bluesheet.	ALL	1/8/2018
FR2	Resolution for AI-0004565 associated with CA-002859. General Revision with the addition of step 6.5.8 and re-aligned flow charts in appendices to flow with addition of step 6.5.8. Changes included addition of verbiage “trend charts” under Data Assessment on page 1 of Instructions form CP3-ES-5003-F01. Completion of periodic review.	ALL	4/13/2021
FR2A	Non-intent change to delete acronym FDPD and replace with FRNP and to incorporate 2 additional Data Assessment Comment form pages to CP-ES-5003-F01.	11,13,15, 31-36	5/25/2021

REVISION/CHANGE LOG			
Revision/Change Letter	Description of Changes	Pages Affected	Date of Revision/Change
FR3	Resolution for #AI-0005792 and #AI-0005909 associated with CAPAs CA-003656 and CA-003655 respectively. General Revision of procedure with the addition of NOTEs in Section 6.3 and 6.7 addressing CAPAs. NOTEs include verbiage explaining situations in which data will be given to project before undergoing verification and assessment and that data being used in support of NCS purposes will include uncertainty and will be verified against laboratory data package before loaded into OREIS. Form CP3-ES-5003-F02 *Paducah Data Release to External Agencies* revised (deleted Site DC and Site TIO)	All	8/9/2022
FR3A	Periodic Review has been completed with no changes identified in procedure technical content. Nonintent change to FA, SME, Approver and dates has been incorporated per CP3-NS-2001. Date for review cycle has been reset.	All	10/4/2022
FR3B	Intent change change deleting verbiage " and the final data package" in Note above step 6.7.3. Deleted Environmental Monitoring Manager and revised to Sample Management Office Manager and update Subject Matter Expert and Approved By.	4-6, 8, 12	4/26/2023
FR4	General Revision to address AI-0008141 (CAPA CA-005077) and addition of CP3-ES-5003-F04, *PARRCS PARAMETERS*	All	7/31/2024

TABLE OF CONTENTS

1.0 PURPOSE AND SCOPE

1.1 Purpose

This procedure describes the process, including data collection and data review, to ensure consistent and quality assured data. This process ensures that all data released for decision making and/or external use have received adequate quality assurance reviews.

- Consistency is provided by the use of common resources and services such as the Sample Management Office (SMO), a centralized data system, and common definitions for data quality.
- Quality assured data is obtained through appropriate planning, adequate sampling and laboratory quality controls, and documented data review.

1.2 Scope

The requirements of this procedure apply to work performed by the Paducah Gaseous Diffusion Plant Deactivation and Remediation (PGDP D&R) personnel and subcontractors.

This procedure applies to screening and definitive data that is collected by all PGDP D&R projects at Paducah. The procedure allows for flexibility in implementation for programs and projects based on data collection needs and final use of the data.

Exceptions:

This procedure does **NOT** apply to any of the following:

- Historical data
- Data collected by the Safety and Health program
- Personnel and financial data
- Data generated through external agency operations, such as Kentucky Department for Environmental Protection
- Nondestructive assay (NDA) measurements
- Process technology data
- Environmental dosimetry data

2.0 REFERENCES

2.1 Use References

- CP2-ES-0006, *Environmental Monitoring Plan, Paducah Gaseous Diffusion Plant, Paducah, Kentucky*
- CP2-ES-0063, *Environmental Monitoring Data Management Implementation Plan at the Paducah Gaseous Diffusion Plant, Paducah, Kentucky*
- CP2-QA-1000, *Quality Assurance Program Description for the Paducah Gaseous Diffusion Plant, Paducah, Kentucky*

  CP2-WM-0001, *Four Rivers Nuclear Partnership, LLC, Paducah Deactivation and Remediation Project Waste Management Plan*

- CP3-ES-1034, *Nuclear Criticality Safety Requirements for Sample Labeling, Handling, and Assay Smears*
- CP3-QA-3001, *Issues Management*
- CP4-ES-5007, *Data Management Coordination*
- EPA QA/G-4, *Guidance on Systematic Planning Using the Data Quality Objectives Process*
- Project Specific Quality Assurance Project Plans *(*QAPPs)

2.2 Source References

- *Paducah Gaseous Diffusion Plant Data Management Plan,* DOE/LX/07-2498&D1
- *Paducah Gaseous Diffusion Plant Programmatic Quality Assurance Project Plan*

3.0 COMMITMENTS

- NCSE GEN-01, *General Limits Used At PGDP*
- NCSE 111, *Characterization of Independent Samples in the C-709 and C-710 Laboratory Facilities*
- NCSR-FRNP-17-001, *Addressing Common Mode Failures of Independent Samples Sent Offsite for Analysis*

4.0 RESPONSIBILITIES

4.1 SMO

4.1.1 Populates project-specific laboratory statements of work (SOWs), chains-of-custody (COCs), sample data forms, and labels in Project Environmental Measurements System (PEMS).

4.1.2 Performs loading of Electronic Data Deliverables (EDDs) to PEMS.

4.1.3 Performs electronic verification of data using queries in PEMS.

4.1.4 Tracks data assessment process.

4.1.5 Serves as the primary contact for all matters relating to the analytical laboratories.

4.1.6 Performs contractual screens.

4.1.7 Ensures that data validation deliverables meet the requirements specified in the data validation SOW.

4.1.8 Performs loading of data into Paducah Oak Ridge Environmental Information System (OREIS).

4.2 Sample Management Office Manager

4.2.1 Ensures long-term electronic storage of data.

4.2.2 Ensures compliance with Paducah Data Management Plan.

4.3 Data Reviewer

4.3.1 Performs data assessment.

4.3.2 Determines if quality assured data is generated.

4.3.3 Communicates any observations to Sample Management Office (SMO) Manager allowing manager to make a decision to initiate a Corrective Action Preventative Action (CAPA) report in the Issues Management system according to CP3-QA-3001, *Issues Management*.

4.4 Project Team

Assists team with the data collection planning, review, and decision making. Project Team may include, but is **NOT** limited to the following:

- Data Reviewer
- SMO Manager
- Project Manager
- QA Reviewer
- Quality Representative
- Requestor
- Sampling Personnel

4.5 QA Reviewer

4.5.1 Reviews data to ensure that data quality requirements are met.

4.5.2 Communicates any observations to SMO Manager allowing manager to make a decision to initiate a CAPA report in the Issues Management system according to CP3-QA-3001, *Issues Management*.

4.6 Requestor

Coordinates sample collection, sample analysis, data assessment, and decision making.

4.7 Project Manager

Maintains responsibility and/or designates representatives, as needed:

- Technical lead
- Risk assessor
- Waste management coordinator
- Compliance coordinator
- Individual that needs data to support decision making

5.0 GENERAL INFORMATION

The collection, review, and management of data and information **NOT** addressed under this procedure are maintained according to CP2-QA-1000, *Quality Assurance Program Description for the Paducah Gaseous Diffusion Plant, Paducah, Kentucky.*

6.0 INSTRUCTIONS

NOTE:

Steps are performed sequentially unless otherwise noted.

6.1 Initiation of Data Collection

NOTE:

The Data Quality Objective (DQO) process used for data in support of making Nuclear Criticality Safety (NCS) decisions may deviate from Appendix D, *Options to Implementing and Documenting the DQO Process for Paducah Projects*, depending on NCS requirements.

The Data Quality Objective (DQO) process used for data in support of making ambient air data evaluation decisions may deviate from Appendix D, *Options to Implementing and Documenting the DQO Process for Paducah Projects*, depending on the ambient air data evaluation plan requirements.

Requestor

6.1.1 Determine need for data to support the activity or program/project.

Requestor/Project Team

6.1.2 Choose the DQO process option for the program or project outlined in Appendix D, *Options to Implementing and Documenting the DQO Process for Paducah Projects*.

6.1.3 Follow steps associated with the DQO process.

6.1.4 Select Quality Assurance (QA)/Quality Control (QC) requirements using Appendix E, *Data Quality Reference List* to incorporate into project plans.

6.1.5 Identify the data review steps for the project using Appendix F, *Options for Data Review*.

6.1.6 Ensure the following applicable plans are in place:

- Sampling Analysis Plan (SAP)
- Sampling Analysis and Event Plan (SAEP)
- CP2-QA-1000, *Quality Assurance Program Description for the Paducah Gaseous Diffusion Plant, Paducah, Kentucky*
- CP2-ES-0006, *Environmental Monitoring Plan ,Paducah Gaseous Diffusion Plant, Paducah, Kentucky (EMP)*
- CP2-WM-0001, *Four Rivers Nuclear Partnership LLC Paducah Deactivation and Remediation Project Waste Management Plan (WMP)*
- CP2-ES-0063, *Environmental Monitoring Data Management Implementation Plan at the Paducah Gaseous Diffusion Plant, Paducah, Kentucky*

- Project Specific DMIPs
- Project Specific QAPPs

6.1.7 Notify the SMO of electronic data quality checks that the project would like performed.

6.1.8 Contact the SMO to develop the analytical SOW for new activities **OR** to notify of sample requests that are routine.

SMO

6.1.9 Develop project-specific laboratory SOW in PEMS.

6.1.10 Ensure the SOW specifies the analytical methods, reporting limits, and deliverable requirements.

6.1.11 Populate sample information in PEMS.

6.1.12 Generate COCs, sample data forms, and labels from PEMS.

NOTE:

Samples requesting polychlorinated biphenyl (PCB) analysis (other than KPDES samples) require the lab to comply with the Toxic Substance Control Act (TSCA) and the Federal Facilities Compliance Act (FFCA). The laboratory basic ordering agreement (BOA) includes the signed agreement that is in place between U.S. Department of Energy (DOE) and the United States Environmental Protection Agency (EPA).

6.1.13 Ensure collection and shipment/delivery of samples to a SMO approved laboratory.

6.2 Process Laboratory Analytical Data

6.2.1 Import and load EDDs into PEMS.

6.2.2 Resolve any issues identified during loading data to PEMS.

6.3 Data Verification

NOTE:

Additional instructions for completing CP3-ES-5003-F01, *Data Assessment Review Checklist and Comment Form,* are provided on instructions page of CP3-ES-5003-F01.

Situations may arise that require assay data to be provided to the project prior to undergoing data verification and data assessment due to projects having to make real-time decisions in the field. This requires approval of the SMO Manager.

UF_6 safety sample data will be provided to operations personnel prior to undergoing data verification and data assessment due to projects having to make real-time decisions in the field.

6.3.1 Using PEMS, run data verification queries.

6.3.2 Conduct contractual screen:

1. Using PEMS, perform contractual screen by reviewing verification queries and reports.

2. Resolve any issues identified during contractual screen with the laboratory.

3. Complete the required fields in the Data Verification section on form CP3-ES-5003-F01.

4. Document any exceptions to the SOW.

Requestor/Project Team/SMO

6.3.3 **If** deviations found during data verification cannot be readily resolved, **then** determine the usability of the data or the need for additional review of the data.

6.4 Data Validation

NOTES:

Contractual screen must be complete before data validation is performed.

CP3-ES-5003-F03, *Data Verification Checklist* must be completed when Level II, Level III, or Level IV data validation is required.

6.4.1 **If** data validation is **NOT** required, **then** proceed to Section **6.5**.

SMO

6.4.2 Initiate data validation as defined in the plans listed in Step **6.1.6**.

6.4.3 Develop a validation SOW for the data validation activity.

6.4.4 Submit the laboratory data packages to the validator selected.

6.4.5 Upon receipt of the data validation deliverables, review the results of the data validation report.

6.4.6 **If** data validation report or deliverables are **NOT** acceptable, **then** resolve discrepancies with validator until acceptable.

6.4.7 Download data validation codes into PEMS.

6.4.8 **If** validation codes are entered manually, **then** ensure a QC check is performed as required by CP4-ES-5007, *Data Management Coordination*.

6.5 Data Assessment and Determination of Data Usability

NOTE:

Data validation must be accompanied by data assessment and is performed concurrent with data assessment.

Data validation can help ensure analyses are correct; however, data assessment must be performed to determine the data quality level (Data of Known Quality or Information Only Data) and to ensure data is useable.

SMO

NOTE:

PARCCS parameter values are recorded on CP3-ES-5003-F04, *PARCCS Parameters* on projects if requested by project team.

6.5.1 Using PEMS, create data assessment package by printing electronically:

- data assessment queries (e.g. verify sampling completeness, verify qualifiers, etc.)
-
- data assessment reports (e.g. laboratory data, laboratory sample analysis comments, etc.)
- additional data assessment information (e.g. data loading notes, laboratory case narratives, PARCCS parmeters, etc.)

6.5.2 Provide the Data Reviewer, assigned by the Requestor/Project Team, with the data assessment package, CP3-ES-5003-F01 and CP3-ES-5003-F02, *Paducah Data Release Form*.

Data Reviewer

6.5.3 Begin data assessment using CP3-ES-5003-F01.

6.5.4 Review the analytical data provided in the data assessment package.

6.5.5 **If** reviewing data for the Environmental Monitoring (EM) program, **then** review for trends by using EM provided trending charts **or** other equivalent means.

6.5.6 Complete the required fields and questions on CP3-ES-5003-F01.

6.5.7 Document any notes or comments on page 2 of CP3-ES-5003-F01 **and** submit to SMO.

SMO

6.5.8 **If** there are issues noted in the data assessment package by the Data Reviewer, **then** resolve issues **and**:

1. Ensure a documented response (either written or e-mail) is included in the data assessment package.

2. Provide the data assessment package to the Data Reviewer to ensure all comments or issues have been resolved.

Data Reviewer

6.5.9 Sign as Data Reviewer on CP3-ES-5003-F01.

6.5.10 Check Data Quality Level and Approval/Not Approved for Release **and** sign as Data Reviewer on CP3-ES-5003-F02.

6.5.11 Notify SMO when data assessment is complete.

NOTE:

The QA Reviewer and the Data Reviewer should be two separate individuals. A member of the SMO may serve as the QA Reviewer.

SMO

6.5.12 Review CP3-ES-5003-F01. **If** data assessment codes were noted to be added to PEMS, **then** add the data assessment codes **and** reprint the reports where data assessment codes are listed.

6.5.13 Provide the data assessment package to the QA Reviewer.

QA Reviewer

6.5.14 Review the data assessment package.

6.5.15 Document any notes or comments on Page 2 of CP3-ES-5003-F01.

6.5.16 Return the data assessment package to the SMO.

SMO

6.5.17 **If** there are issues noted in the data assessment package by the QA Reviewer, **then** resolve issues **and**:

1. Ensure a documented response (either written or e-mail) is included in the data assessment package.

2. Print revised reports and/or queries from PEMS **and** place in data assessment package.

6.5.18 Ensure all emails and the required forms are included in the data assessment package in proper order.

QA Reviewer

6.5.19 Sign as QA Reviewer on CP3-ES-5003-F01.

6.5.20 Notify SMO when QA review is complete.

SMO

6.6 Data Release

NOTE:

A Derivative Classifier (DC) review is requested to ensure that the data or document does **NOT** contain any classified information. This review is required in order to flag data in Paducah OREIS as being approved for release. The DC review is only required for data related to non-environmental matrices.

6.6.1 **If** data is of non-environmental matrices (i.e., waste projects, characterization projects), **then** complete Requestor portion of form PGDP-SS-FO-001, *Paducah Site Derivative Classifier Review Request Form.*

6.6.2 Submit PGDP-SS-FO-001 form and data assessment package for DC review.

6.6.3 Once PGDP-SS-FO-001 has been completed, ensure all necessary signatures are present.

6.6.4 Add PGDP-SS-FO-001 to the data assessment package.

6.7 Loading Data to OREIS

6.7.1 Format data for loading to Paducah OREIS by creating a Ready-to-Load (RTL) file.

NOTE:

Data loaded to Paducah OREIS that is collected in support of making NCS decisions is verified against the laboratory data package to ensure data is loaded correctly.

NCSE GEN-01
NCSE 111
NCSR-FRNP-17-001

Verbal relay of analytical results taken for NCS purposes is prohibited.

6.7.2 Load data (RTL file) to Paducah OREIS.

NOTE:

The Paducah OREIS data report that includes uncertainty will be provided to the project for data collected in support of making NCS decisions. The data will be loaded to PEMS and will undergo data verification and data assessment.

The Paducah OREIS data report will be provided to the Characterization organization **when** sampling is requested by the Characterization organization.

Requestor/Project Team

6.7.3 Make project decisions based on data.

6.7.4 **If** additional data needs to be collected, **then** return to Step **6.1.2**.

6.8 Records Management

NOTE:

SMO submits data assessment package and laboratory data packages to Records Management.

6.8.1 Ensure all project records associated with the data collection activity, including all forms generated from this procedure, are transmitted to Records Management for submittal to Document Control for final disposition.

7.0 RECORDS

7.1 Records Generated

The following records may be generated by this procedure:

- Applicable queries, reports, and e-mails documenting identified deficiencies.
- CP3-ES-5003-F01, *Data Assessment Review Checklist and Comment Form*
- CP3-ES-5003-F02, *Paducah Data Release Form*
- CP3-ES-5003-F03*, Data Verification Checklist*
- CP3-ES-5003-F04, *PARRCS Parameters*
- DQOs (e-mails, meeting minutes, SAP, SAEP, answers to Appendix D questions, if applicable).
- Data Assessment Packages
- Laboratory Data Packages
- PGDP-SS-FO-001, *Paducah Site Derivative Classifer Review Request Form*

Forms are to be completed according to CP3-OP-0024, *Forms Control*.

7.2 Records Disposition

The records are to be maintained according to CP3-RD-0010, *Records Management Process*.

Appendix A – Acronyms/Definitions

ACRONYMS

ASTM – American Society for Testing Materials

BOA –Basic Ordering Agreement

CAPA -Corrective Action Preventative Action

COC – Chain of Custody

DC – Derivative Classifier

DMIP – Data Management Implementation Plan

DOE – United States Department of Energy

DQO – Data Quality Objectives

EDD – Electronic Data Deliverables

EMP – Environmental Monitoring Plan

EPA – United States Environmental Protection Agency

FFCA – Federal Facilities Compliance Act

FRNP – Four Rivers Nuclear Partnership

KPDES– Kentucky Pollutant Discharge Elimination System

MS – Matrix Spike

MSD – Matrix Spike Duplicate

NCS – Nuclear Criticality Safety

NCSA – Nuclear Criticality Safety Approval

OREIS – Paducah Oak Ridge Environmental Information System

PARCCS – Precision, Accuracy, Representativeness, Completeness, Comparability, Sensitivity

PEMS – Project Environmental Measurements System

PGDP D&R – Paducah Gaseous Diffusion Plant Deactivation and Remediation

QA – Quality Assurance

Appendix A – Acronyms/Definitions (Continued)

QC – Quality Control

RMDC – Records Management and Document Control

RI/FS – Remedial Investigation/Feasibility Study

RTL – Ready-to-Load

SAEP – Sampling Analysis and Event Plan

SAP – Sampling and Analysis Plan

SMO – Sample Management Office

SOW – Statement of Work

TSCA – Toxic Substance Control Act

VOA – Volatile Organic Analysis

WMP – Waste Management Plan

DEFINITIONS

Contractual Screen – A process of evaluating a set of data against the requirements specified in the SOW to ensure that all requested information is received. The contractual screen includes, but is **NOT** limited to, the review of COC information, analytes requested, method used, electronic data deliverables, units, holding times, and reporting limits achieved.

Data Assessment – A process for assuring that the type, quality, and quantity of data are appropriate for their intended use. It allows for the determination that the decision can be made with the desired level of confidence, given the quality of the data set. Data Assessment follows Data Verification and can be performed in parallel with Data Validation. Data Assessment must be performed to ensure data is useable.

Data Assessment Package – A package that includes data reports from the integrated data system (i.e., PEMS), CP3-ES-5003-F04, *PARCCS Parameters* (if applicable), laboratory and sample management comments, CP3-ES-5003-F01, *Data Assessment Review Checklist and Comment Form*, CP3-ES-5003-F02, *Paducah Data Release Form*, routine queries generated to aid in the review of the data. After the review is complete, any questions or comments by the Data Reviewer, SMO, or QA Reviewer are added to the package. This package is submitted as a record to RMDC.

Data of Known Quality – Data, along with appropriate laboratory qualifiers, verification codes, validation codes, and data assessment codes, that can be used for decision making purposes and was collected and managed according to this procedure.

Data Quality Checks – A list of quality control elements associated with a data collection activity, which are evaluated during data verification, data validation, and/or data assessment.

Appendix A – Acronyms/Definitions (Continued)

Data Quality Objectives (DQO) – A set of criteria established for the collection of data. The DQO process is a planning tool based on the scientific method that clearly identifies an environmental problem; the remedial decisions to address the problem; and the type, quantity, and quality of data needed to support the decision. This process is based on the DQO process developed by the EPA. The DQO process may be applied in modified form to any data collection activity. The DQO process balances risk with cost in selecting the most appropriate data collection plan.

Data Reviewer – Performs independent review of data assessment package. Reviewer can be personnel from SMO, Waste or Characterization organizations, project team, etc. Individual performing data assessment review cannot be the same individual performing the QA review.

Data Validation – A process performed for a data set by a qualified individual independent from sampling, laboratory, project management, or other decision making personnel for the project. Data validation evaluates the laboratory adherence to analytical method requirements.

Data Verification – A process for comparing a data set against a set standard or contractual requirement. Verification may be performed electronically, manually, or by a combination of both. Data verification includes contractual screen and can include other data quality checks established by the project team.

Definitive Data – Analytical measurements for which the presence, and corresponding concentration, of the target analyte(s) can be determined with a known degree of certainty. The measurements are supported with appropriate physical evidence documenting the acquisition and analysis. Definitive data in electronic form must be supported with retrievable, but **NOT** necessarily retrieved, physical evidence in the laboratory. This evidence can include analytical results, QA/QC results, COC, analytical logbooks, standards information, etc.

Electronic Data Deliverables (EDD) – Data that is received in electronic format from a laboratory through a direct communication between computerized data management systems. EDD contents must meet defined completeness, consistency, and format requirements. These criteria are defined in the laboratory BOA.

External Agency – Any organization external to PGDP D&R personnel, its subcontractors, and DOE.

Information Only Data – Data for which quality is **NOT** assured and may or may **NOT** contain the appropriate qualifiers; however, data can be used for informational purposes or may be used for decision making with relevant documentation.

PARCCS Parameters – Precision, Accuracy, Representativeness, Completeness, Comparability, Sensitivity, as explained in Appendix E and recorded on CP3-ES-5003-F04, *PARPCCS Parameters*.

Quality Assured Data – Data that has undergone a documented review, as specified by this procedure, to provide confidence that the data conforms to established technical requirements and is sufficient for the intended use.

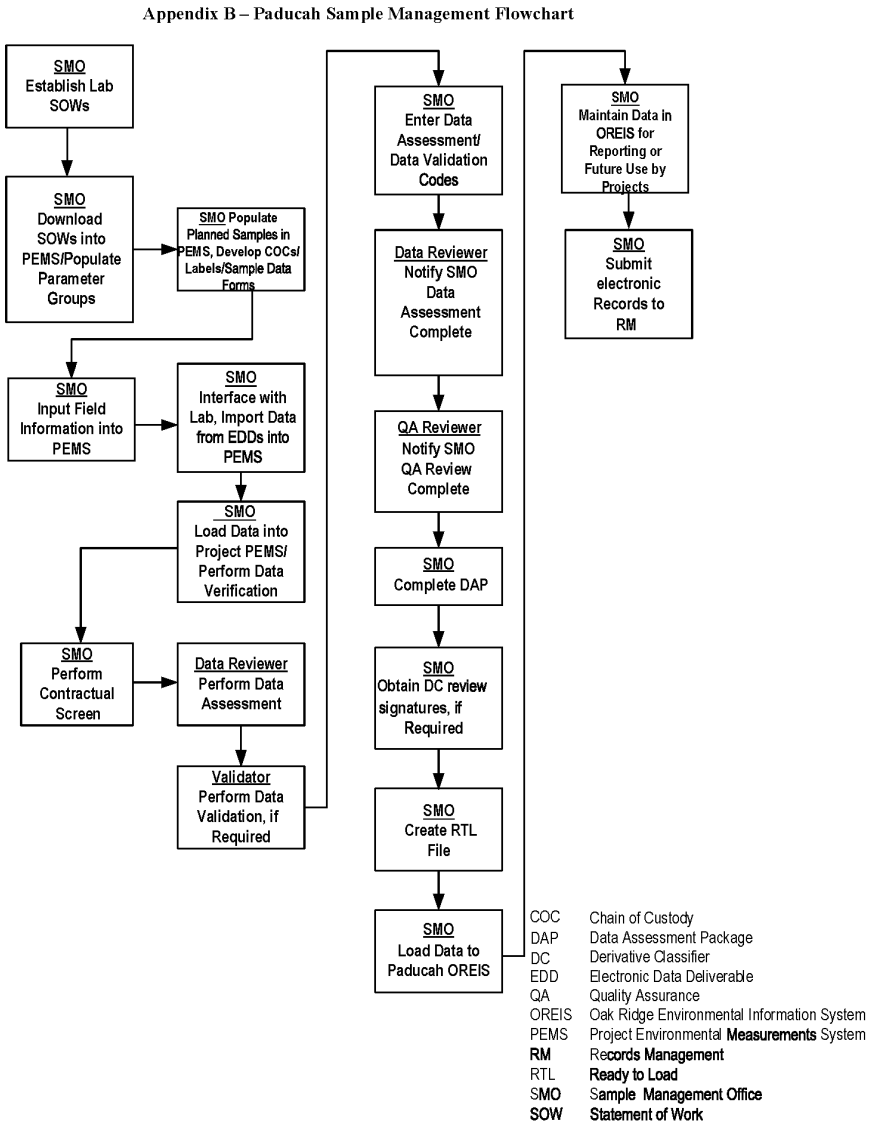
Appendix A – Acronyms/Definitions (Continued)

QA Reviewer –Performs independent review of data assessment package and verifies completion of data assessment. Reviewer can be personnel from SMO, Waste or Characterization organizations, project team, etc. Individual performing QA review cannot be the same individual performing the data assessment review.

Screening Data – Measurements generated through the use of field or fixed laboratory methods in which the level of certainty in the data cannot be determined given physical evidence documenting the acquisition and analysis of the sample. Analytical methods producing field measurements or screening quality data include those that indicate the presence or absence of an analyte or class of analytes, or provide a semi-quantitative result. Field measurement and other screening quality data include, but are **NOT** limited to, Draeger tube; soil gas surveys; radiation and contamination monitoring; and measurements for pH, conductivity, temperature, dissolved oxygen, and turbidity. Screening data results may be confirmed by collecting a specified percentage of definitive data.

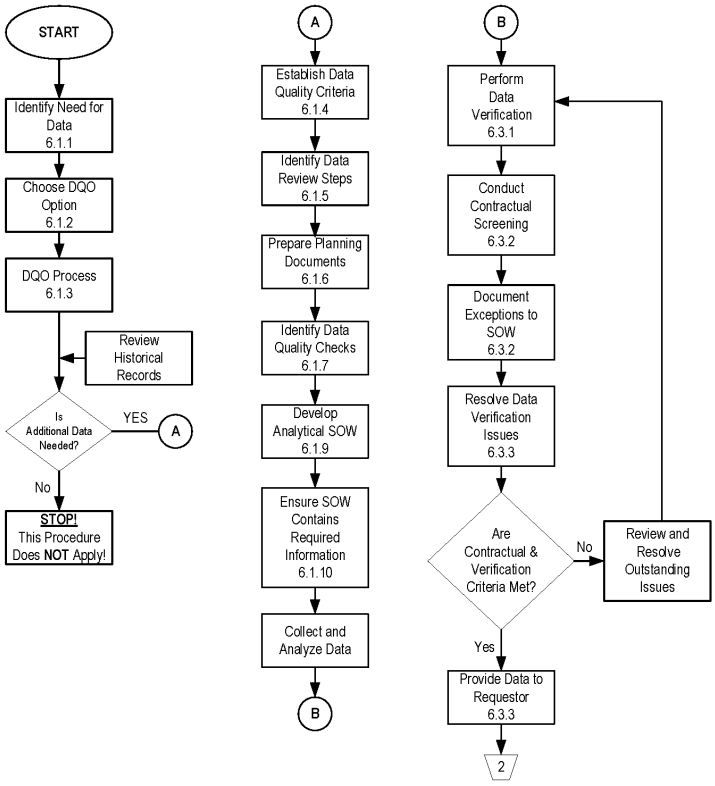
Statement of Work - The contractual agreement between the requesting organization and the service provider. The SOW defines the scope of work including associated QA/QC, schedules, and deliverables.

Appendix B – Sample Management Flowchart



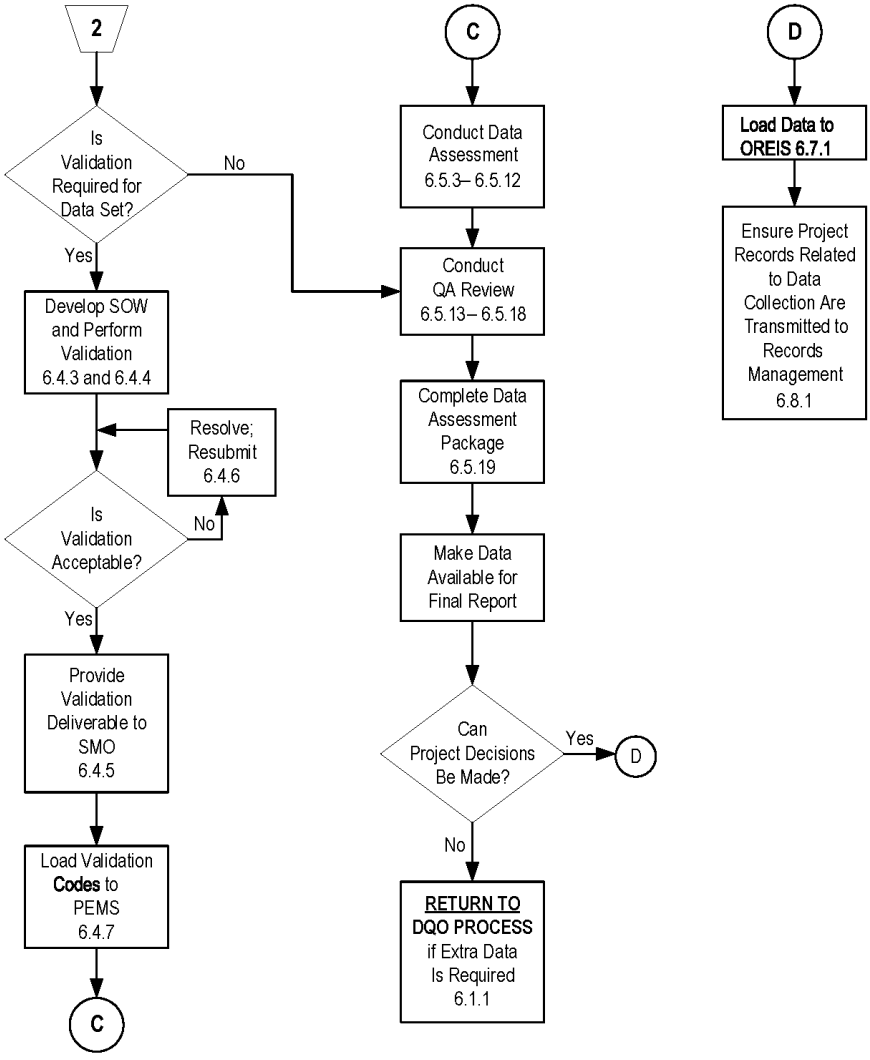
Appendix C – Data Cycle Flowchart

Appendix C – DATA CYCLE FLOWCHART



Appendix C – DATA CYCLE FLOWCHART (Continued)

Appendix C – DATA CYCLE FLOWCHART



Appendix D – OPTIONS TO IMPLEMENTING AND DOCUMENTING THE DQO PROCESS FOR PADUCAH PROJECTS INTRODUCTION

INTRODUCTION

The DQO process is a scientific and legally-defensible data collection and planning process to help users decide what type, quality, and quantity of data will be sufficient for decision making. This attachment is based on a series of planning steps designed to assure that data collected is adequate for the intended purpose.

PURPOSE

The purpose of this appendix is to provide options for implementing and documenting the DQO process.

DQO OPTIONS AND APPLICABILITY

Option 1

For Environmental Remediation projects, the detailed approach as found in the EPA *Guidance on Systematic Planning Using the Data Quality Objectives Process* (EPA QA/G-4) is appropriate. For long-term environmental monitoring sampling programs and extensive waste sampling activities, this detailed and structured approach can be useful. However, full implementation of the process may not always be appropriate.

Option 2 (Minimum Requirements)

The following models are provided for guidance in documenting a simplified version of the DQO process. Use the applicable model for your project.

Model D.1 – ENVIRONMENTAL MONITORING PROJECTS – DQO PROCESS
Model D.2 – ENVIRONMENTAL RESTORATION PROJECTS – DQO PROCESS
Model D.3 – SITE CHARACTERIZATION PROJECTS – DQO PROCESS
Model D.4 – WASTE CHARACTERIZATION PROJECTS – DQO PROCESS

Option 3

A user-defined DQO process that includes the minimum requirements from Option 2 and any additional actions needed.

Appendix D – OPTIONS TO IMPLEMENTING AND DOCUMENTING THE DQO PROCESS FOR PADUCAH PROJECTS (Continued)

APPLICABILITY EXCLUSIONS

This attachment is **NOT** applicable to PCB spills, asbestos events, and environmental spills due to the quick response time and the well-defined actions to be taken in the event of the occurrence.

DOCUMENTATION

Documentation of the DQO process is required and will do the following:

- Provide a source of historic data and process knowledge for related sampling,
- Provide a tool for conducting data assessment,
- Facilitate efficient project management transfers, or
- Allow decisions to be recalled and defended.

The documentation may be presented in various ways and will include:

- An outline or text form following the format shown in this attachment. Include responses to the questions as separate, brief accounts of the information gathered, its sources, and the rationale for decisions made.
- References to various other documents, such as SAPs, SAEPs, QAPs, EMPs, WMPs, DMIPs, etc., as necessary.
- An e-mail and CP3-ES-1034-F01, *Sample Request Form,* are routinely provided for special sampling requests and serve as the DQO documentation.

Appendix D – OPTIONS TO IMPLEMENTING AND DOCUMENTING THE DQO PROCESS FOR PADUCAH PROJECTS (Continued)

Model D.1 – ENVIRONMENTAL MONITORING PROJECTS – DQO PROCESS

1. **The Problem and the Decision**--(The drivers for data collection activities.)
   - What is the description of the area of concern? (Where is the current location?)
   - What are the contaminants or analytes of interest? (What is the media of concern? What are the suspected contaminants? How were they selected? What are the known or potential routes of migration? What are the known or potential human and environmental receptors? What are the exposure pathways?)
   - What decision needs to be made regarding the area (i.e., disposition of waste, etc.)?

2. **Inputs to the Decision**--(The sources of data and information used to make the decision.)
   - What historical data exists? Is it adequate for use?
   - What process knowledge exists? Is it adequate for use?
   - What additional data must be collected? (What are the analytes and analytical methods?)

3. **Physical Boundaries to be Considered**--(Physical characteristics that affect the sampling design.)
   - What is the location of the potential contamination? (What are the depth and boundaries/geometry of the potential contamination area?)
   - What considerations affect the sample location choices? (Is the intention to characterize the average of the environmental media? What are the site conditions that affect sampling [power lines, trees, concrete pad, etc.]? Is it homogenous? Is the contamination level expected to be a continuous range?)
   - Are there other sampling constraints, such as temporal, schedule, seasonal concerns, regulatory requirements, etc.?

4. **Decision Statement and Uncertainty**
   - What are the steps to be taken after the analytical results are received? (Is this preliminary sampling? What results will trigger further testing, verification, or action? What additional steps will be taken? If I find ...., then what will I do? Consider the potential impact for making an incorrect decision based on the data.)

5. **Develop the Data Sampling Design**
   - State the type of data to be obtained. (Will it be screening, definitive, or a combination?)
   - State the approach to sample selection. (Will it be grab or composite, judgmental [selective] or random? Will it be a statistically-based selection?)
   - Optimize the design and approach for efficiency and effectiveness. (What confidence intervals are needed? What QA/QC will be required by sample method or this procedure? For minimum quality criteria, see Appendix E. For data validation requirements, see Appendix F. What additional QA/QC is requested?)

Appendix D – OPTIONS TO IMPLEMENTING AND DOCUMENTING THE DQO PROCESS FOR PADUCAH PROJECTS (Continued)

Model D.2 – ENVIRONMENTAL RESTORATION PROJECTS – DQO PROCESS

1. **The Problem and the Decision**--(The drivers for data collection activities.)
   - What is the description of the area of concern? (Where is the current location?)
   - What are the contaminants or analytes of interest? (What is the media of concern? What are the suspected contaminants? How were they selected? What are the known or potential routes of migration? What are the known or potential human and environmental receptors? What are the exposure pathways?)
   - What are potential corrective actions for this problem?
   - What decision needs to be made regarding the area (e.g., disposition of waste, etc.)?

2. **Inputs to the Decision**--(The sources of data and information used to make the decision.)
   - What historical data exists? Is it adequate for use?
   - What process knowledge exists? Is it adequate for use?
   - What additional data must be collected? (What are the analytes and analytical methods?)

3. **Physical Boundaries to be Considered**--(Physical characteristics that affect the sampling design.)
   - What is the location of the potential contamination? (What are the depth and boundaries/geometry of the potential contamination area?)
   - What considerations affect the sample location choices? (Is the intention to characterize the average of the environmental media or do you need to know the "hot spots"? What are the site conditions that affect sampling [power lines, trees, concrete pad, etc.]? Is it homogenous? Is the contamination level expected to be a continuous range?)
   - Are there other sampling constraints, such as temporal, schedule, seasonal concerns, NCS controls, regulatory requirements, etc.?

4. **Decision Statement and Uncertainty**
   - What are the steps to be taken after the analytical results are received? (Is this preliminary sampling? What results will trigger further testing, verification, or action? What additional steps will be taken? If I find ...., then what will I do? Consider the potential impact for making an incorrect decision based on the data.)

5. **Develop the Data Sampling Design**
   - State the type of data to be obtained. (Will it be screening, definitive, or a combination?)
   - State the approach to sample selection. (Will it be grab or composite, judgmental [selective] or random? Will it be a statistically-based selection?)
   - Optimize the design and approach for efficiency and effectiveness. (What confidence intervals are needed? What QA/QC will be required by sample method or this procedure? For minimum quality criteria, see Appendix E. For data validation requirements, see Appendix F. What additional QA/QC is requested?

Appendix D – OPTIONS TO IMPLEMENTING AND DOCUMENTING THE DQO PROCESS FOR PADUCAH PROJECTS (Continued)

Table D.3 – SITE CHARACTERIZATION PROJECTS – DQO PROCESS

1. **The Problem and the Decision**--(The drivers for data collection activities.)
   - What is the description of the area of concern? (Where is the location?)
   - What are the boundaries of the area that will be characterized?
   - What are the contaminants or analytes of interest? (What is the media of concern? What are the suspected contaminants? How were they selected?)

2. **Inputs to the Decision**--(The sources of data and information used to make the decision.)
   - What historical data exists? Is it adequate for use?
   - What process knowledge exists? Is it adequate for use? Are there any NCS hazards?
   - What additional data must be collected? (What are the analytes and analytical methods?)

3. **Physical Boundaries to be Considered**--(Physical characteristics that affect the sampling design.)
   - What is the location of the potential contamination? (What are the depth and boundaries/geometry of the potential contamination area?)
   - What considerations affect the sample location choices? (Is the intention to characterize the average of the environmental media? What are the site conditions that affect sampling [power lines, trees, concrete pad, etc.]? Is it homogenous? Is the contamination level expected to be a continuous range?)
   - Are there other sampling constraints, such as temporal, schedule, seasonal concerns, NCS concerns, regulatory requirements, etc.?

4. **Decision Statement and Uncertainty**
   - What are the steps to be taken after the analytical results are received? (Is this preliminary sampling? For what event? What results will trigger further testing, verification, or action? What additional steps will be taken? If I find ...., then what will I do? Consider the potential impact for making an incorrect decision based on the data.)

5. **Develop the Data Sampling Design**
   - State the type of data to be obtained. (Will it be screening, definitive, or a combination?)
   - State the approach to sample selection. (Will it be grab or composite, judgmental [selective] or random? Will it be a statistically-based selection?)
   - Optimize the design and approach for efficiency and effectiveness. (What confidence intervals are needed? What QA/QC will be required by sample method or this procedure? For minimum quality criteria, see Attachment E. For data validation requirements, see Appendix F. What additional QA/QC is requested?)

Appendix D – OPTIONS TO IMPLEMENTING AND DOCUMENTING THE DQO PROCESS FOR PADUCAH PROJECTS (Continued)

Model D.4 – WASTE CHARACTERIZATION PROJECTS – DQO PROCESS

The Problem and the Decision--(The drivers for data collection activities.)

- What is the description of the waste? (Where and when was it generated? What is the media and the volume? Where is it now?)
- Who needs information about the waste? Why do they need the information? (Waste Management for characterization purposes? Waste Management to determine TSD options? Waste Management to meet a specific vendor's WAC?)
- What are the contaminants or analytes of interest? (What are the suspected contaminants? How were they selected?)
- What decision needs to be made regarding the area (e.g., disposition of waste, NCS hazards,etc.)?

2. **Inputs to the Decision**--(The sources of data and information used to make the decision.)
   - What historical data exists? Is it adequate for use?
   - What process knowledge exists? Is it adequate for use?
   - What additional data must be collected? (What are the analytes and analytical methods?)

3. **Physical Boundaries to be Considered**--(Physical characteristics of waste that affect sampling design.)
   - What is the location of the potential contamination? (Surface contamination or volumetric?)
   - What considerations affect the sample location choices? (Is the intention to characterize the average of the waste stream or do you need to know the "hot spots"?)
   - How is the waste containerized?
   - Are there sampling problems? (What is the geometry of the waste? Is it homogenous? Is the contamination level expected to be a continuous range?)
   - Are there other sampling constraints, such as temporal, schedule, seasonal concerns, NCS concerns, regulatory requirements, etc.?

4. **Decision Statement and Uncertainty**
   - What are the steps to be taken after the analytical results are received? (Is this preliminary sampling? What results will trigger further testing, verification, or action? What additional steps will be taken? If I find ...., then what will I do? Consider the potential impact for making an incorrect decision based on the data.)

5. **Develop the Data Sampling Design**
   - State the type of data to be obtained. (Will it be screening, definitive, or a combination?)
   - State the approach to sample selection. (Will it be grab or composite, judgmental [selective] or random? Will it be a statistically-based selection?)
   - Optimize the design and approach for efficiency and effectiveness. (What confidence intervals are needed? What QA/QC will be required by sample method or this procedure? For minimum quality criteria, see Appendix E. For data validation requirements, see Appendix F. What additional QA/QC is requested?)

Appendix E – DATA QUALITY REFERENCE LIST

INTRODUCTION

The following information is an aid to the project manager, project scoping team members, and/or DQO facilitators to select the project data quality elements. This information should be obtained during the sampling design optimization step in Appendix D, Step **5**, or Step **7** of the Data Quality Objectives Process in EPA QA/G-4, *Guidance on Systematic Planning Using the Data Quality Objectives Process*. The minimum requirements are listed for screening and/or definitive data. A program/project manager may choose to implement quality control above the minimum requirements; however, certain data quality elements are not applicable to screening data.

PURPOSE

The purpose of this appendix is to provide a reference list of data quality elements and data quality requirements for a data collection activity. The selected elements should be incorporated into applicable project plans.

SCREENING AND DEFINITIVE DATA

There are two types of data generated using this procedure. Screening Data is defined in Appendix A and generally refers to qualitative data. Screening data has been previously termed EPA Levels I and II. In order to increase confidence, screening data results should be confirmed by collecting a specified percentage of definitive data. The recommended percentage of definitive data for confirming screening data is 10 percent. This, in turn, makes the data more usable for decision making. Definitive Data also is defined in Appendix A and describes data usually generated from a fixed-based laboratory following appropriate quality control requirements for various analytical methods.

Definitive data has been previously termed EPA Levels III, IV and V. In this appendix and in appendix F, screening data is categorized by S, S1, or S2, depending on the level of detail needed for the data collection activity. Definitive data is categorized by D, D3A, D3B, D4, and D5. Appendix F provides additional explanation and examples for the categories.

Appendix E – DATA QUALITY REFERENCE LIST (Continued)

PARCCS PARAMETERS

Data are only useable if the precision and accuracy is known. Data is only useable for decision making if it is also precise, accurate, representative of the whole, comparable to expectations, complete as planned, and sensitive as needed. These requirements are known as the PARCCS parameters and are explained in detail below. Data quality criteria should be chosen to address all six parameters. The PARCCS parameters should be recorded on CP3-ES-5003-F04, *PARCCS Parameters* during the data assessment when requested by the project team.

Precision--a quantitative measurement of the variability of a group of measurements as compared to their average. Usually expressed as a percentage or a standard deviation, it evaluates the reproducibility of the system. Sample duplicates measure the reproducibility of the sampling event, while lab replicates measure the precision of the analytical process. The acceptable precision may be defined by the laboratory method used.

Accuracy--a quantitative measurement of the bias of the data. It represents how close the measurement data is to the true value. Sampling accuracy can be assessed by evaluating field, equipment rinseate, and trip blanks. Analytical accuracy is measured by percent recoveries associated with the laboratory analytical control spikes (blank spikes), surrogate spikes, or matrix spikes. The acceptable accuracy may be defined by the laboratory method used.

Representativeness--a qualitative measurement of the ability of a sample or group of data to adequately describe or define the conditions being measured. Precision, accuracy, and completeness all affect representativeness. Sampling strategy (location, method, and frequency) is critical to assure that the samples statistically represent the population. Laboratory precision and accuracy reflect how representative the data is of the sample.

Completeness--a quantitative measurement of the percentage of acceptable data as compared to the number planned. Both sampling (field) and analytical (laboratory) completeness can be measured.

Comparability - a qualitative measurement of the confidence with which one data set can be compared with another. Comparability is achieved by using standard techniques for sample collection and analysis.

Sensitivity – the sensitivity of analysis (or the detection limit) is determined by the analytical method and the laboratory analyst and instrumentation.

Appendix E – DATA QUALITY REFERENCE LIST (Continued)

DATA QUALITY REFERENCE LIST		
Data Quality Element	**Minimum For: Screening (S) Definitive (D)**	**PARCCS**
Field Sampling Quality Control		
Sample Data Forms	S, D	Representativeness, Completeness
Sample Chain of Custody (COC)	S, D	Representativeness, Completeness
Transcription - Sample Data Form vs. COC	S, D	Representativeness, Completeness
Containers		
Preservation	S, D	Representativeness
Field Duplicates	S, D	Representativeness
Trip Blanks (VOA Only)	S, D (5% Min for S, D)	Precision
Field Blanks	S, D (5% Min for S, D)	Accuracy
Equipment Rinseate Blanks	S, D (5% Min for S, D)	Accuracy
Sampling Completeness Requirement	S, D (5% Min for S, D)	Accuracy Representativeness, Completeness
Field/Laboratory Methods[a]	**Screening:** Analyte or instrument specific **Definitive:** SW-846, EPA, ASTM	
Analytical/Measurement Quality Control[b]		
Initial Calibration of Instrument	S, D	Accuracy
Calibration Check of Instrument	S, D	Accuracy
Calibration Range	S, D	Accuracy
Reporting Detection Limits (Method)	S, D	Comparability, Sensitivity
Analytical Error Determination	D	Precision, Accuracy
Laboratory COC	S, D	Representativeness, Completeness
Transcription COC vs Samples	S, D	Representativeness, Completeness
Holding Times	S, D	Representativeness, Comparability
Analytical Method	S, D	Comparability
Method Units	S, D	Accuracy, Comparability
Calculation Verifications	S, D	Representativeness, Completeness
Transcription-Lab data vs. EDD/Report	D	Representativeness, Completeness
Analytical Completeness Requirement	S, D	Precision
Lab Duplicates	S[b], D[b]	Accuracy, Precision
Blank Duplicates	D	Accuracy
Reagent Blanks	D[b]	Accuracy
Method Blanks	D[b]	Accuracy
Spikes/Laboratory Control Samples	D[b]	Accuracy
Matrix Spikes	D[b]	Precision
Matrix Spike Duplicates	D[b]	Accuracy
Post Digestion Spikes	D[b]	Precision, Accuracy
Performance Samples	S[b], D[b]	Accuracy
Interference Check Samples	D[b]	Accuracy

Appendix E – DATA QUALITY REFERENCE LIST (Continued)

DATA QUALITY REFERENCE LIST		
Data Quality Element	**Minimum for: Screening (S) Definitive (D)**	**PARCCS**
Analytical Deliverables	Electronic Data Deliverables (EDD) and hard copy results	
Identification number (sample number or location name)	S, D	
Date/time sampled	S, D	
Lab sample number	D	
Date analyzed	S, D	
Date completed	S2, D	
Parameter/analyte	S, D	
Qualifier	S, D	
Results	S, D	
Units	S, D	
Comments	S2, D	
Method (lab and field)	S2, D	
Blanks	S2, D	
Spikes (MS*, MSD*, blank [DI water spiked-provides feedback on the matrix effect])	D	
Surrogates, if applicable		
Lab duplicates*	D	
Reporting Detection Limits	D	
Former Level III Data Package	D	
Former Level IV Data Package Former Level V Data Package	These data packages include minimum definitive data elements plus additional information.	
Data Verification Percentages	S, D 100% for both	
Data Validation Percentages	D 5% Min**	
Data Assessment[c]	100%	

[a] If ER, waste characterization, or compliance monitoring activities are planned, SW-846 methods must be considered. If SW-846 methods are **NOT** available, use EPA-approved methods. If a remedial design is planned, ASTM methods must be considered. If environmental monitoring data is collected, EPA methods must be considered.

[b] Analytical quality control is dependent on the method specified.

[c] NOTE: 100% of the data should be assessed. However, individual project records, such as sample data forms, COCs, etc., should be reviewed on a project designated frequency.

* Lab duplicates are optional and can be performed at lab or customer request. If doing a field duplicate, a lab duplicate is not value added.

** A greater percentage of validation may be required for some projects (i.e., risk assessments and remedial investigations). The project teams can increase as needed to ensure valid data.

S = S1 or S2 as defined in Appendix F.

D = D3A, D3B, D4, or D5 as defined in Appendix F

Appendix F – OPTIONS FOR DATA REVIEW

INTRODUCTION

To ensure the process for data quality continues, data review must be performed for results received from a data collection activity. The three elements of data review outlined in this procedure are verification, validation, and assessment.

PURPOSE

The purpose of this appendix is to provide guidelines for data review. The documentation checklist to be used for assessment of a data collection activity is also provided in this appendix.

DATA VERIFICATION

Data verification is the first step of data review. The preferred method for performing verification is electronic. Verification criteria are documented using the Data Assessment Review Checklist or the Data Verification Checklist (if Level II, Level III, or Level IV data validation is required). The extent of verification is based on the data category as demonstrated in the table below.

DATA VALIDATION

Data validation follows verification in the data review process. The data validation options in this appendix are similar to the format specified by the former EPA data quality levels with the exception of diverging from the former EPA Level III data validation. Grade 3A, as listed in the following Review Options and Applicability table, is a less rigorous form of validation based on the minimum data deliverable requirements. Grade 3B, Grade 4, and Grade 5 are the same as the former EPA Level III, Level IV, and Level V data validation, respectively. All grades of validation must be performed by a third party. Third party validation is defined as validation performed by persons independent from sampling, laboratory, and decision making for the project (i.e., not the project manager). Data validation is documented in a formal deliverable from the data validator. The option chosen (level and frequency) for validation is based on data category and the following considerations:

- Regulatory drivers/requirements
- End-user of data
- Future applicability of the data (other users such as regulatory agencies, risk assessment personnel, internal users, etc.)
- Legal ramifications and defensibility of data
- Confidence in laboratory (DOECAP approved laboratory)

The data set to be validated may be determined programmatically or by the individual project. The option chosen for data validation should be made by the project team.

DATA ASSESSMENT

Data assessment is the last review step prior to release of the data from the project team. It is an integration of all information collected about a result. Data verification and validation can ensure analyses are correct; however, data assessment must be performed to evaluate data usability. This includes a review of the data itself, the results of all previous reviews of the data, checking data for trends, and evaluation against the intended purpose for data collected. Data assessment must be performed for all data collection activities and documented using the Data Assessment Review Checklist. Data assessment is required prior to use of the data, or data release into the final data repository (i.e., Paducah OREIS). Data assessment frequency is determined based on decision making and releasability requirements. This decision is made by the project team.

Appendix F – OPTIONS FOR DATA REVIEW (Continued)

REVIEW OPTIONS AND APPLICABILITY

Data Category	Examples for Generation of Category	Former Level of Data	Data Verification	Data Validation	Data Assessment
Screening Data S1	Soil gas surveys Qualitative	Level I or A	100% Grade 1 or None Review only the sample results presented.	N/A	100%
Screening Data S2	Portable field GC Hydrolab pH, Conductivity Qualitative Semiquantitative	Level II or B	100% Grade 2 Electronic review of data. Review of quality control samples as defined in the Data Assessment Review Checklist	N/A	100% Comparison to definitive data results, if applicable.
Definitive Data D3A	Routine laboratory Quantitative	Level III or C	100% Grade 3A	5% Validation would consist of looking at the criteria in the minimum lab deliverable in Attachment E, plus any additional information required for the program/project.	100%
Definitive Data D3B	Routine laboratory RI/FS Quantitative	Level III or C	100% Grade 3B	5% Traditional Level III data validation on a data package.	100%
Definitive Data D4	Routine laboratory Quantitative, RI/FS More rigorous QC	Level IV or D	100% Grade 4	5% Same as Grade 3B plus raw data.	100%
Definitive Data D5	Not standard methods Unusual parameters	Level V or E	100% Grade 5	5% Same as Grade 3B on the user-defined lab.	100%

Appendix G – CP3-ES-5003-F01 - Data Assessment Review Checklist and Comment Form

CP3-ES-5003-F01 Data Assessment Review Checklist and Comment Form

Project ID:			Project Title:				
ITEM			YES	NO	N/A	COMMENTS	*
DATA VERIFICATION 1. Are analytical methods, units, and reporting/detection limits correct as specified according to the laboratory SOW and regulatory limits?			☐	☐	☐		☐
Data Quality Checks	Analytical Method	SMO:	Date:				
	Method Units	SMO:	Date:				
	Reporting/Detection Limits	SMO:	Date:				
2. Have the impacts of holding time violations been evaluated?			☐	☐	☐		☐
Data Quality Checks	Holding Times	SMO:	Date:				
	Extraction Holding Times	SMO:	Date:				
3. Is data complete as planned?			☐	☐	☐		☐
Data Quality Checks	Analytical Completeness	SMO:	Date:				
	Sampling Completeness	Data Reviewer:	Date:				
DATA VALIDATION 4. Does data validation indicate the data is usable?			☐	☐	☐		
Data Quality Checks	Miscellaneous Laboratory Quality Control Samples	Data Reviewer:	Date:				☐
DATA ASSESSMENT 5. Are quality control sample results acceptable?			☐	☐	☐		☐
Data Quality Checks	Field Duplicates	Data Reviewer:	Date:				
	Trip Blanks (VOAs only)	Data Reviewer:	Date:				
	Field Blanks	Data Reviewer:	Date:				
	Equipment Rinsate Blanks	Data Reviewer:	Date:				
6. Does the sampling design and data provide enough information to support Data Quality Objectives (DQOs) and the current decision?			☐	☐	☐		☐
7. Have the impacts of data qualifiers and laboratory comments from lab and field sampling notes been considered?			☐	☐	☐		☐
Data Quality Checks	Sample Chains of Custody	Data Reviewer:	Date:				
	Containers/Preservatives	Data Reviewer:	Date:				
	Sample Data Forms	Data Reviewer:	Date:				
	Laboratory Case Narrative(s)	Data Reviewer:	Date:				
8. Is data reasonable when compared to known or expected levels?			☐	☐	☐		☐
9. Have outliers been evaluated to determine possible cause?			☐	☐	☐		☐
10. Is data of adequate quality to be used?			☐	☐	☐		☐
DECISION DETERMINATION 11. Was this data generated according to *Quality Assured Data* procedure and is data deemed *Data of Known Quality* ?			☐	☐	☐		
12. Can current decision be made from this data based on this review?			☐	☐	☐		

SIGNATURES

Data Reviewer: _____
(Data Reviewer peformed data assessment and confirms data can be made available for final reporting.)

QA Reviewer: _____
(QA Reviewer reviewed and verified completion of data assessment.)

* Place a mark in this column if data assessment codes are applied to the data.

Appendix G –CP3-ES-5003-F01 - Data Assessment Review Checklist and Comment Form (Continued)

CP3-ES-5003-F01 Data Assessment Review Checklist and Comment Form (continued)

Project ID:	Project Title:	
Comment	Action	Resolution

Appendix G – CP3-ES-5003-F01 - Data Assessment Review Checklist and Comment Form

(Instructions page 1 of 2)

Data Assessment Review Checklist and Comment Form

(Instructions page 1 of 2)

INTRODUCTION

The Data Assessment Review Checklist and Comment Form will be used by SMO, Data Reviewer, and QA Reviewer to perform data verification, data validation, and data assessment on a data set. The purpose of this attachment is to document Data Quality Checks performed and provide instructions to aid in completion of CP3-ES-5003-F01 form.

DATA QUALITY CHECKS

Data Quality Checks are a list of field sampling and analytical/measurement quality control elements associated with a data collection activity which are evaluated during data verification, data validation and/or data assessment. The table below identifies the Data Quality Checks that are routinely reviewed and the data review section where they are evaluated.

Data Quality Checks		
Data Verification	**Data Validation**	**Data Assessment**
Analytical method	Initial and continuing calibration	Sampling completeness
Method units	Analytical error determination	Field duplicates
Reporting/detection limits	Laboratory COCs	Trip blanks
Holding times	Calculations	Field blanks
Extraction holding times (if applicable)	Laboratory duplicates	Equipment rinseate blanks
Analytical completeness	Blank duplicates	Sample COCs
	Reagent blanks	Containers/preservatives
	Method blanks	Sample data forms
	Spikes/laboratory control samples	Laboratory comments
	Matrix spikes/matrix spike duplicates	
	Post digestion spikes	
	Performance samples	
	Interference check samples	

INSTRUCTIONS FOR COMPLETING THE ATTACHMENT

Project ID and Project Title are to be documented by the SMO at the top of the attached form for the data set.

The item column on the checklist provides the major questions to be answered to perform data verification, data validation, and data assessment. There are twelve questions to be answered on the checklist to verify data, validate data, assess data, and determine usability of the data. The appropriate answer to each question will result in checking one of the following response boxes: Yes, No, or N/A. Several questions have Data Quality Checks beneath them to guide the user to review certain elements of the data set. These Data Quality Checks are indicated on the checklist by shaded rows and are completed by either the SMO or the Data Reviewer. Upon completion of Data Quality Checks, the SMO or Data Reviewer will add initials to denote completion and fill in date completed. If necessary for explanation purposes, additional information can be recorded in the Comments column of the checklist.

Any significant information, comments, or questions must be documented either by email included in the data assessment package or on the Data Assessment Comment Form on page 2 of CP3-ES-5003-F01. If any data assessment codes are applied during the review of the data, a checkmark will be placed in the last column denoted by the "*" to aid the SMO in ensuring applicable data assessment codes are added to PEMS.

Appendix G – CP3-ES-5003-F01 - Data Assessment Review Checklist and Comment Form

Data Assessment Review Checklist and Comment Form

(Instructions page 2 of 2)

The SMO assembles a data assessment package (DAP) for each data set. The information contained in the DAP is to be reviewed by the Data Reviewer to aid in answering of following items on the checklist. DAP includes contractual screen queries/reports, PEMS data reports, laboratory comments, PEMS data assessment queries/reports, data assessment comments, result qualifier and PEMS/OREIS code definitions, COC and sample data forms, SMO correspondence section, and data validation report (if applicable).

DATA VERIFICATION

Items 1-3 cover Data Quality Checks concerning Analytical Method, Method Units, Reporting/Detection Limits, Holding Times, Extraction Holding Times, and Analytical Completeness. The SMO completes most questions related to Data Verification by completing the contractual screen for the project. SMO will include contractual screen queries/reports in the data assessment package for review and will note any issues on the form. Data Reviewer will complete the Sampling Completeness check.

DATA VALIDATION

Item 4 covers review of the data validation report (if applicable) and Data Quality Checks to review miscellaneous laboratory quality control samples. If data validation was performed on the data set, the data validation report will be included in the DAP. Data Reviewer will review data validation report if applicable. If data validation was not performed, the Data Reviewer will place checkmark in the "N/A" box. Data Reviewer will review laboratory comments (laboratory case narratives are included in the laboratory comments section of the DAP) and may request full lab data package from SMO for review. See Data Quality Checks table for listing of items reviewed for Data Validation.

DATA ASSESSMENT

Items 5-10 cover questions and Data Quality Checks related to Data Assessment. The Data Reviewer will review the field quality control sample results in the DAP. If specific field quality control samples were not performed for the data set, the Data Reviewer will place checkmark in the "N/A" box. Data Reviewer will review sample COCs (containers/preservative noted on COCs), sample data forms, and laboratory comments (including case narratives).

DECISION DETERMINATION

Items 11 and 12 cover questions concerning usability of the data set. Data Reviewer will answer questions regarding data quality and make decision determination.

SIGNATURES

Once all questions are answered and any comments are added to form, the Data Reviewer will sign the form to complete the data review and assessment process. The Data Reviewer should then notify the SMO that data assessment is complete.

The QA Reviewer is responsible for performing a final review of the data set and verifying that all issues and questions are resolved. QA Reviewer also verifies that form has been correctly completed. The QA Reviewer will sign form upon completion.

Appendix H – CP3-ES-5003-F02 - Paducah Data Release Form

CP3-ES-5003-F02 - Paducah Data Release Form

Project ID:

Project Title:

Data Reviewer:

Data Quality Level:

☐ **Data of Known Quality**

Data, along with appropriate laboratory, verification, validation, and assessment qualifiers, can be used for decision making purposes and was collected and managed per procedure CP3-ES-5003.

☐ **Information Only Data**

Data quality is not assured and may or may not contain the appropriate qualifiers; however, data can be used for informational purposes or can be used for decision making with relevant documentation.

Data Release:

☐ **Approval for release to following organizations/entities:**

1. _____
2. _____
3. _____

☐ **Not Approved for Release**

Explanation: _____

Attach necessary documentation for additional release criteria.

Data Reviewer: _____
(Signature Required)

Appendix I – CP3-ES-5003-F03 - Data Verification Checklist

CP3-ES-5003-F03 - Data Verification Checklist

Project ID:	**Laboratory:**	**SDG(s):**

Data Package Review	Yes	No	N/A
1. What data package level was requested from the laboratory? (circle one) Level 1 Level 2 Level 3 Level 4 Other			
2. Has all data been received from the laboratory in the correct deliverable format?			
3. Has any missing information been requested and received from the laboratory?			
4. Is a laboratory case narrative and/or cover letter present?			
5. Are chain of custody (COC) forms present for all samples?			
6. Are samples traceable through inspection of signature records on field and laboratory COCs?			
7. Do the COCs or case narrative indicate any problems with the sample receipt, condition of the samples, analytical problems, or special circumstances that would affect the quality of the data?			
Action: For any samples not traceable upon inspection of COCs, indicate the identities below and where the break in traceability occurred. For any other issue noted with the data package review, please provide a brief description of what occurred and what effect, if any, on data quality it may have.			

Holding Times and Sample Preservation	Yes	No	N/A
8. Has a holding time violation occurred in which the acceptable hold time from sample collection to extraction or preparation been exceeded?			
9. Has a holding time violation occurred in which the acceptable hold time from sample extraction (or preparation) to analysis been exceeded?			
10. For samples submitted to the laboratory on the same day as sample collection, is there evidence that ice (if required) was present in coolers and sample cooling had begun?			
11. For samples shipped to the laboratory, were temperatures of samples upon receipt within acceptance criteria when temperature preservation is required?			
12. Has the laboratory indicated that any samples were received with improper chemical preservation?			
Action: Identify all samples that are outside of hold time or do not meet sample preservation and provide a description of the problem. For any other issue noted with the data package review, please provide a brief description of what occurred and what effect, if any, on data quality it may have.			

Sample Methodology	Yes	No	N/A
13. Have all analytical methods been verified to match the requested analytical method?			
14. Are any requested analytes missing from the reported data?			
15. Are all samples reported with the correct units?			
16. Were the target analytes identified correctly and confirmation acceptance criteria met?			
17. Were all required reporting limits achieve?			
Action: Please provide a brief description of any issues with methods, missing data, units, or reporting limits. Follow the guidelines in the appropriate Data Verification and Validation Plan for qualification requirements, or provide this information to the data validator for further qualification.			

Appendix I – CP3-ES-5003-F03 - Data Verification Checklist (Continued)

CP3-ES-5003-F03 - Data Verification Checklist (continued)

Surrogates, Tracers and Carriers	Yes	No	N/A
18. Does a review of reported data indicate that a sample surrogate (if required) is outside acceptable criteria? (Note: This could be identified by the laboratory in the case narrative, or on footnotes and/or data qualifiers reported on Form 1s or equivalent.)			
19. Does a review of reported data indicate that a sample tracer and/or carrier (if required) is outside acceptable criteria? (Note: This could be identified by the laboratory in the case narrative, or on footnotes and/or data qualifiers reported on Form 1s or equivalent.)			
Action: Identify the sample(s) affected and the surrogate, tracer or carrier recovery. Follow the guidelines in the appropriate Data Verification and Validation Plan for qualification requirements, or provide this information to the data validator for further qualification.			
Isotope Dilution and Internal Standard	Yes	No	N/A
20. Are internal standard and/or isotope dilution results included in the data package?			
21. Were internal standard responses within the acceptance criteria? (Note: This could be identified by the laboratory in the case narrative, or on footnotes and/or data qualifiers reported on Form 1s or equivalent).			
22. Does a review of reported data indicate that the isotope dilution recovery related to a sample is outside acceptance criteria? (Note: This could be identified by the laboratory in the case narrative, or on footnotes and/or data qualifiers reported on Form 1s or equivalent)			
23. Were internal standard(s) detected within the retention time window?			
Action: Identify the sample(s) affected. Follow the guidelines in the appropriate Data Verification and Validation Plan for qualification requirements, or provide this information to the data validator for further qualification.			
Calibration	Yes	No	N/A
24. Does the calibration meet the specified acceptance criteria?			
25. Were the instrument performance and/or interference checks analyzed at the appropriate frequency?			
26. Does the instrument performance and/or interference checks meet the specified acceptance criteria?			
27. Does a review of reported data indicate that the CCV and/or ICV recovery related to a sample is outside acceptance criteria? (Note: This could be identified by the laboratory in the case narrative, or on footnotes and/or data qualifiers reported on Form 1s or equivalent)			
Action: Identify the sample(s) affected. Follow the guidelines in the appropriate Data Verification and Validation Plan for qualification requirements, or provide this information to the data validator for further qualification.			
Laboratory Control Samples	Yes	No	N/A
28. Are LCS results included in the data package and analyzed at the appropriate frequency?			
29. Does a review of reported data indicate that the LCS recovery related to a sample is outside acceptance criteria? (Note: This could be identified by the laboratory in the case narrative, or on footnotes and/or data qualifiers reported on Form 1s or equivalent).			

Appendix I – CP3-ES-5003-F03 - Data Verification Checklist (Continued)

CP3-ES-5003-F03 - Data Verification Checklist (continued)

Action: Identify the sample(s) affected. Follow the guidelines in the appropriate Data Verification and Validation Plan for qualification requirements, or provide this information to the data validator for further qualification.

Blank Results	Yes	No	N/A
30. Are results for method and/or prep blanks included in the data package and analyzed at the appropriate frequency?			
31. Were there any positive and/or negative detections identified in the method or prep blank?			
32. Have any field QC blanks been included in the data package? This may include field blanks, rinseate blanks, trip blanks, etc.			
33. Were there any positive and/or negative detections identified in the field QC blanks?			

Action: If associated sample results are nondetect for the analyte(s) detected in the blank, then no further action is required. For samples with positive results, identify the samples that are affected by a positive blank detection. In the case of a method or prep blank, the laboratory will typically place a "B" qualifier on affected data. For the field QC blanks, identify the samples that are associated with the blank. Follow the guidelines in the appropriate Data Verification and Validation Plan for qualification requirements, or provide this information to the data validator for further qualification.

Matrix Spike/Matrix Spike Duplicates	Yes	No	N/A
34. Are MS/MSD results included in the data package and analyzed at the appropriate frequency?			
35. Are the recovery limits for the MS/MSD within acceptable limits?			
36. Are RPD results reported for MS/MSD analysis within acceptance limits?			

Action: Identify the sample(s) affected. Never qualify data based on the MS/MSD alone. Follow the guidelines in the appropriate Data Verification and Validation Plan for qualification requirements, or provide this information to the data validator for further qualification.

Appendix I – CP3-ES-5003-F03 - Data Verification Checklist (Continued)

CP3-ES-5003-F03 - Data Verification Checklist (continued)

Duplicates	Yes	No	N/A
37. Does the data package include serial dilutions, field duplicates and/or lab duplicates?			
38. Does the calculated RPD and/or the mean difference meet acceptance criteria?			
Action: Identify the parent and field duplicate samples below. Calculate the RPD and/or mean difference between the two samples. Follow the guidelines in the appropriate Data Verification and Validation Plan for qualification requirements, or provide this information to the data validator for further qualification.			

By signing below, the person performing the Data Verification Checklist is verifying that all data received has been generated in accordance with the procedure CP3-ES-5003, *Quality Assured Data* and is data of known quality.

Data Verification
Performed by:_____Date: _____

QA Review:_____Date: _____

Appendix J – CP3-ES-5003-F04 – PARCCS Parameters

CP3-ES-5003-F04 PARCCS PARAMETERS

Project ID: _____

PRECISION	Precision measures the agreement among a set of replicate measurements. Field precision is assessed through the collection and analysis of field duplicates. Analytical precision is estimated by duplicate/replicate analyses, usually on laboratory control samples, spiked samples and/or field samples. The most commonly used estimates of precision are the relative standard deviation (RSD) and the relative percent difference (RPD). In PEMS, precision result below is evaluated in the laboratory comments when laboratory duplicates, matrix spike duplicates, and/or post-digestion spike duplicates are discussed. Data not meeting acceptance criteria, as specified by the analytical method, are qualified by the laboratory. Standard laboratory qualifiers counted for precision include *, L1, N1, W1, and Y2. _____ % of data records received have been qualified in this data set.
ACCURACY	Accuracy is the closeness of a measured result to an accepted reference value. Accuracy is usually measured as a percent recovery. QC analyses used to measure accuracy include standard recoveries, laboratory control samples, spiked samples, surrogates, and tracers. In PEMS, accuracy result below is evaluated in the laboratory comments when blanks, tracers, surrogates, lab control samples, matrix spikes, and/or post-digestion spikes are discussed. Data not meeting acceptance criteria, as specified by the analytical method, are qualified by the laboratory. Standard laboratory qualifiers counted for accuracy include B, L, N, S, T, W, and Y1. _____ % of data records received have been qualified in this data set.
REPRESENTATIVENESS	Sample representativeness expresses the degree to which data accurately and precisely represents a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition. It is dependent on the proper design of the sampling program and will be satisfied by ensuring the approved procedures or plans were followed during sampling and analysis. Laboratory precision and accuracy reflect representativeness as a qualitative measurement.
COMPARABILITY	Comparability expresses the degree of confidence with which one data set can be compared to another. It is dependent upon the proper design of the sampling program and will be satisfied by ensuring that the approved plans are followed and that proper sampling and analysis techniques are applied. Further, when assessing comparability, data sets should be of known and documented quality. In PEMS, comparability is evaluated by comparing analytical results of samples and associated field duplicates. Please see the Duplicate Comparison report for more detail.

Appendix J – CP3-ES-5003-F04 – PARCCS Parameters (Continued)

CP3-ES-5003-F04 PARCCS PARAMETERS

COMPLETENESS	Completeness is a measure of the amount of valid data collected compared to the amount planned. Measurements are considered to be valid if they are unqualified or qualified as estimated during validation. Field completeness is a measure of the number of samples collected versus the number of samples planned. Laboratory completeness is a measure of the number of valid measurements compared to the total number of measurements planned. In PEMS, completeness is calculated by two methods: (1) Field Completeness: The number of valid analytical results reported divided by the number of analytical results planned, multiplied by 100 to obtain a percentage. (2) Laboratory Completeness: The number of valid analytical results divided by the number of analytical results requested, multiplied by 100 to obtain a percentage. _____ % Field Completeness [Field Completeness as described above in (1)] _____ % Laboratory Completeness [Laboratory Completeness as described above in (2)]
SENSITIVITY	Sensitivity is an instrument's or method's minimum concentration that can be reliably measured or reported. In PEMS, sensitivity is evaluated by reviewing the detection limit received compared to what was requested in the laboratory statement of work (SOW). _____ % of data records received that have met specified detection limits requested in this data set.

PARCCS Entry

Initials: _____ Date: _____