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DOCUMENT CATE	GORY: Adm	inistrative	LEVEL OF USE: Information Leve	;]
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	REVISION/CHANGE LO	G		
Revision/ Change Letter	Description of Changes	Pages Affected	Date of Revision/ Change	Approved By (signature on file)
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	Documentation
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	on File
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	All	8/9/2022	

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	REVISION/CHANGE LO	G		
Revision/ Change Letter	Description of Changes	Pages Affected	Date of Revision/ Change	Approved By (signature on file)
	loaded into OREIS. Form CP3-ES-5003-F02 <i>Paducah</i> <i>Data Release to External Agencies</i> revised (deleted Site DC and Site TIO)			
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 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, <i>PARRCS</i> <i>PARAMETERS</i>	All	7/31/2024	
FR4A	Resolution for #AI-0008524 and #AI-0008627 associated with CAPAs CA-005356 and CA-005369 respectively. Intent change-Deletion of CP3-ES-5003- F03 in CP3-ES-5003. Addition of CP3-ES-5003-F05 with title "Data Verification/Validation Checklist." Revise checklist to capture if all reported analytes in LCS, MS and MSD are spiked. Update CP3-ES-5003 to reflect change of CP3-ES-5003-F03 to CP3-ES-5003- F05.	9,13,38,3 9	3/31/2025	
FR5	General revisions to address AI-0008622 associated with CAPA# CA-005369 and AI-0008660 associated with CAPA# CA-005409.	All	6/25/2025	

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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 data assessment and 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 assessment 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.

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
- Geotechnical data

2.0 REFERENCES

2.1 Use References

- CP2-ER-1000, Data Management Implementation Plan for the Paducah Plumes Operations Paducah Gaseous Diffusion Plant, Paducah, Kentucky
- CP2-ES-0006, Environmental Monitoring Plan, Paducah Gaseous Diffusion Plant, Paducah, Kentucky
- CP2-ES-0026, Wet Chemistry and Miscellaneous Analyses Data Verification and Validation Paducah Gaseous Diffusion Plant, Paducah, Kentucky
- CP2-ES-0063, Environmental Monitoring Data Management Implementation Plan at the Paducah Gaseous Diffusion Plant, Paducah, Kentucky

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- CP2-ES-0811, Pesticide and PCB Analyses Data Verification and Validation Paducah Gaseous Diffusion Plant, Paducah, Kentucky
- CP2-ES-2000, *PFAS Analyses Data Verification and Validation at the Paducah Gaseous Diffusion Plant, Paducah, Kentucky*
- CP2-ES-5102, Radiochemical Analysis Data Verification and Validation Paducah Gaseous Diffusion Plant, Paducah, Kentucky
- CP3-ES-5103, Polychlorinated Dibenzodioxins-Polychlorinated Dibenzofurans Analyses Data Verification and Validation Paducah Gaseous Diffusion Plant, Paducah, Kentucky
- CP2-ES-5105, Volatile and Semivolatile Analyses Data Verification and Validation Paducah Gaseous Diffusion Plant, Paducah, Kentucky
- CP2-ES-5107, Inorganic Analyses Data Verification and Validation 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-ES-5007, Data Management Coordination
- CP3-QA-3001, Issues Management
- DOE/LX/07-2498&D1, Paducah Gaseous Diffusion Plant Data Management Plan
- EPA QA/G-4, Guidance on Systematic Planning Using the Data Quality Objectives Process
- Project-specific Quality Assurance Project Plan (QAPP)

2.2 Source References

• DOE/LX/07-2502&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), chain-of-custody (COC) forms, sample data forms, and sample labels in Paducah Project Environmental Measurements System (PEMS).

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	4.1.2	Performs loading of laboratory Electronic Data Deliverables (EDDs)	to PEMS.
	4.1.3	Performs electronic verification of data using queries in PEMS.	
	4.1.4	Performs data verification steps including contractual screen.	
	4.1.5	Prepares a project data assessment package (DAP).	
	4.1.6	Tracks data assessment review process.	
	4.1.7	Coordinates data validation services when requested by the project te	am.
	4.1.8	Ensures that data validation deliverables meet the requirements specification SOW.	fied in the data
	4.1.9	Performs loading of data into Paducah Oak Ridge Environmental Info (OREIS).	ormation System
4.	2 SMO Ma	anager	
	4.2.1	Serves as the primary contact for all matters relating to analytical labor	oratories.
	4.2.2	Ensures long-term electronic storage of data.	
	4.2.3	Ensures compliance with DOE/LX/07-2498&D1, Paducah Gaseous Management Plan.	Diffusion Plant Data
4.	3 Project 1	Feam	
	4.3.1	Defines project Data Quality Objectives (DQOs).	
	4.3.2	Submits request to SMO for collection of samples.	
	4.3.3	Coordinates sample collection and analysis with the SMO.	
	4.3.4	Assigns Project Reviewer to participate in data assessment review pro	ocess.
4.	4 Data Rev	viewer	
	4.4.1	Reviews project DAP and laboratory data packages.	
	4.4.2	Performs data assessment.	
	4.4.3	Communicates any observations to SMO Manager allowing manager initiate a corrective action in the Issues Management system accordin <i>Issues Management</i> .	
4.	5 Project F	Reviewer	
	4.5.1	Reviews project DAP.	
	4.5.2	Performs data usability assessment.	

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- 4.5.3 Determines if quality assured data is generated **and** determines if data is acceptable for decision making.
- 4.5.4 Communicates any observations to SMO Manager allowing manager to make a decision to initiate a corrective action in the Issues Management system according to CP3-QA-3001.

NOTE:

In this procedure, Quality Assurance (QA) Reviewer does NOT pertain to QA personnel.

4.6 QA Reviewer

- 4.6.1 Reviews project DAP.
- 4.6.2 Performs QA review.
- 4.6.3 Verifies completion of data assessment review process.
- 4.6.4 Communicates any observations to SMO Manager allowing manager to make a decision to initiate a corrective action in the Issues Management system according to CP3-QA-3001.

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

NOTES:

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

The DQO process used for data in support of making ambient air data evaluation decisions may deviate from Appendix B depending on the ambient air data evaluation plan requirements.

<u>Project Team</u>

- 6.1.1 Determine need for data to support the activity or program/project.
- 6.1.2 Choose the DQO process option for the program or project outlined in Appendix B.
- 6.1.3 Follow steps associated with the DQO process.
- 6.1.4 Select QA/Quality Control (QC) requirements to incorporate into project plans.
- 6.1.5 Identify if data will be validated **and** determine stage and frequency of the validation.

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- 6.1.6 Ensure the following applicable plans are in place **and** provided to the SMO:
 - Project-specific Sampling Analysis Plan (SAP)
 - Project-specific 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
 - CP2-ER-1000, Data Management Implementation Plan for the Paducah Plumes Operations Paducah Gaseous Diffusion Plant, Paducah, Kentucky
 - Project-specific Data Management Implementation Plan (DMIP)
 - Project-specific QAPP
- 6.1.7 Contact the SMO to develop the laboratory SOW for new activities **OR** notify the SMO when additional sampling is requested for existing laboratory SOWs.

<u>SMO</u>

- 6.1.8 Create project identification code (i.e., ProjectID) in PEMS.
- 6.1.9 Develop project-specific laboratory SOW in PEMS.
- 6.1.10 Ensure the laboratory SOW specifies the analytes requested, analytical methods, reporting limits, and any special deliverable requirements.
- 6.1.11 Populate sample information in PEMS.
- 6.1.12 Generate COC forms, sample data forms, and sample labels in 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).

6.2 Sample Collection & Receipt Review

- 6.2.1 Ensure collection, shipment, and delivery of samples to the laboratory.
- 6.2.2 Complete the required fields and questions in the Sample Collection & Receipt Review section (questions 1-6) on CP3-ES-5003-F01, *Data Assessment Review Checklist and Comment Form.*

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6.3 **Process Laboratory Analytical Data**

- 6.3.1 Import and load laboratory EDDs into PEMS.
- 6.3.2 Resolve any issues identified during loading of data to PEMS.
- 6.3.3 Create a project-specific PEMS loading notes file as described in CP3-ES-5007, *Data Management Coordination*.

6.4 Data Verification

NOTES:

Situations may arise that require preliminary data to be provided to the project team prior to undergoing data verification, data validation (if applicable), data assessment, and data usability 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, data validation (if applicable), data assessment, and data usability assessment due to projects having to make real-time decisions in the field.

- 6.4.1 Using PEMS, run electronic data verification queries to verify project data.
- 6.4.2 Add outputs from electronic data verification queries to Electronic Data Verification section of the PEMS loading notes file.
- 6.4.3 Using PEMS, conduct contractual screen:
 - 1. Review contractual screen verification queries and reports.
 - 2. Resolve any issues identified during contractual screen with the laboratory.
 - **3.** Document any exceptions to the laboratory SOW.
- 6.4.4 Complete the required fields and questions in the Data Verification/Contractual Screen section (questions 7-20) on CP3-ES-5003-F01.

6.5 Data Validation

NOTES:

Data verification steps including contractual screen must be complete before data validation is performed.

CP3-ES-5003-F05, *Data Verification/Validation Checklist* must be completed when Stage 2B, Stage 3, or Stage 4 data validation is required.

- 6.5.1 If data validation is **NOT** required, then proceed to Section 6.6.
- 6.5.2 Initiate data validation as defined in the applicable plans listed in Step 6.1.6.
- 6.5.3 Develop a validation SOW for the data validation activity.
- 6.5.4 Using PEMS, prepare a data validation qualification (DVQ) EDD file.

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6.5.5 Submit the following to the validator selected:

- **1.** laboratory data packages
- 2. DVQ EDD file
- **3.** validation SOW
- 4. CP3-ES-5003-F05
- 5. project-specific QAPP, if applicable
- 6.5.6 Upon receipt of the data validation deliverables, review the data validation report, completed DVQ EDD file, and completed CP3-ES-5003-F05 form.
- 6.5.7 If data validation report, completed DVQ EDD file, or completed CP3-ES-5003-F05 form are **NOT** acceptable, **then** resolve discrepancies with validator until acceptable.
- 6.5.8 Download data validation codes from completed DVQ EDD file into PEMS.
- 6.5.9 If validation codes are entered in PEMS manually, then ensure a QC check is performed as required by CP3-ES-5007.

6.6 Data Assessment & Data Usability Assessment

NOTES:

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

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

- 6.6.1 Using PEMS, create the project DAP by compiling the following documents:
 - 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. PEMS loading notes, laboratory case narratives, CP3-ES-5003-F04 form, etc.)
- 6.6.2 Complete the required fields and questions in the DAP Creation section (questions 21-23) on CP3-ES-5003-F01.
- 6.6.3 Provide the Data Reviewer with the project DAP, laboratory data packages, CP3-ES-5003-F01 form, and project-specific QAPP (if applicable).

Data Reviewer

- 6.6.4 Review the analytical data provided in the project DAP and laboratory data packages.
- 6.6.5 Review the project-specific QAPP (if applicable).

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- 6.6.6 Complete the required fields and questions in the Data Validation & Data Assessment section (questions 24-30) on CP3-ES-5003-F01.
- 6.6.7 **If** questions for the laboratory arise during data assessment review, **then** notify SMO to contact laboratory for resolution.
- 6.6.8 Evaluate data quality using the following data validation plans as guidance:
 - CP2-ES-0026, Wet Chemistry and Miscellaneous Analyses Data Verification and Validation Paducah Gaseous Diffusion Plant, Paducah, Kentucky
 - CP2-ES-0811, Pesticide and PCB Analyses Data Verification and Validation Paducah Gaseous Diffusion Plant, Paducah, Kentucky
 - CP2-ES-2000, PFAS Analyses Data Verification and Validation at the Paducah Gaseous Diffusion Plant, Paducah, Kentucky
 - CP2-ES-5102, Radiochemical Analysis Data Verification and Validation Paducah Gaseous Diffusion Plant, Paducah, Kentucky
 - CP2-ES-5103, Polychlorinated Dibenzodioxins-Polychlorinated Dibenzofurans Analyses Data Verification and Validation Paducah Gaseous Diffusion Plant, Paducah, Kentucky
 - CP2-ES-5105, Volatile and Semivolatile Analyses Data Verification and Validation Paducah Gaseous Diffusion Plant, Paducah, Kentucky
 - CP2-ES-5107, Inorganic Analyses Data Verification and Validation Paducah Gaseous Diffusion Plant, Paducah, Kentucky
- 6.6.9 **If** data has quality deficiencies and requires qualification, **then** note issues in the comments field and add notes to the action field on page 3 of CP3-ES-5003-F01.
- 6.6.10 Sign the CP3-ES-5003-F01 form as Data Reviewer **and** submit completed form to the SMO.

<u>SMO</u>

- 6.6.11 If Data Reviewer added data assessment codes to the data, then add data assessment codes in PEMS and:
 - 1. Record entry of data assessment codes to PEMS in the resolution field of CP3-ES-5003-F01.
 - 2. Reprint project data reports from PEMS and replace reports in project DAP so that data assessment codes are displayed.
- 6.6.12 Provide the Project Reviewer with the project DAP, CP3-ES-5003-F01, and CP3-ES-5003-F02, *Paducah Data Release Form*.

Project Reviewer

- 6.6.13 Review project DAP and CP3-ES-5003-F01 form provided by the SMO.
- 6.6.14 Review project-specific QAPP (if applicable).

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6.6.15		g data for the Environmental Monitoring (EM) program ata trending charts located within the following director ing Charts.	
6.6.16		ne required fields and questions in the Data Usability A 31-40) on CP3-ES-5003-F01.	ssessment section
6.6.17		ires additional qualification, then note issues in the connected on page 3 of CP3-ES-5003-F01.	nments field and add no
6.6.18	Sign the CP	3-ES-5003-F01 form as Project Reviewer.	
6.6.19	Complete th	ne CP3-ES-5003-F02 form:	
	• Add	Project Reviewer name in designated field.	
		ek appropriate Data Quality Level (i.e., Data of Known Data).	Quality or Information
	• Choo etc.)	ose appropriate Data Release options from dropdown lis	st (i.e., OREIS, PEGAS)
	• Sign	the CP3-ES-5003-F02 form as Project Reviewer.	
6.6.20		0 when data usability assessment is complete and subm 03-F01 and CP3-ES-5003-F02 forms to the SMO.	it completed
MO			
6.6.21	If Project R in PEMS ar	eviewer added data assessment codes to the data, then nd:	add data assessment cod
	1.	Record entry of data assessment codes to PEMS in th ES-5003-F01.	ne resolution field of CP
	2.	Reprint project data reports from PEMS and replace that data assessment codes are displayed.	reports in project DAP
6.6.22	Provide the Reviewer.	project DAP, CP3-ES-5003-F01 form, and CP3-ES-50	03-F02 form to the QA
7 QA Revi	ew		
A Reviewer			
6.7.1	Review the	project DAP, CP3-ES-5003-F01 form, and CP3-ES-50	03-F02 form.
(7)	Communitate di	· · · · · · · · · · · · · · · · · · ·	(

- 6.7.2 Complete the required fields and questions in the QA Review section (questions 41-44) on CP3-ES-5003-F01.
- 6.7.3 Document any notes or comments on page 3 of CP3-ES-5003-F01.
- 6.7.4 Ensure all applicable emails have been added to the project DAP.
- 6.7.5 Verify completion of data assessment review process.

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6.7.6 Sign the CP3-ES-5003-F01 form as QA Reviewer.

- 6.7.7 Review CP3-ES-5003-F02 form to verify completion.
- 6.7.8 Notify SMO when QA review is complete.

<u>SMO</u>

6.8 Data Classification Review

NOTE:

A Derivative Classifier (DC) review is requested to ensure that the data or document does **NOT** contain any classified information. The DC review is only required for data related to non-environmental matrices.

- 6.8.1 If data is of environmental matrices (i.e., sediment, soil, groundwater, surface water), then proceed to Section 6.9.
- 6.8.2 **If** data is of non-environmental matrices (i.e., waste projects, characterization projects), **then** complete Requester portion of form PGDP-SS-FO-001, *Paducah Site Derivative Classifier Review Request Form.*
- 6.8.3 Submit PGDP-SS-FO-001 form and project DAP for DC review.
- 6.8.4 Once PGDP-SS-FO-001 has been completed, ensure all necessary signatures are present.
- 6.8.5 Add PGDP-SS-FO-001 to the project DAP.

6.9 Loading Data to OREIS

- 6.9.1 Format data for loading to OREIS by creating a Ready-to-Load (RTL) file.
- 6.9.2 Ensure data that is approved for release to PEGASIS on CP3-ES-5003-F02 form is appropriately flagged in OREIS.

NOTES:

NCSE GEN-01

NCSE 111 NCSR-FRNP 17-001 Data loaded to OREIS that is collected in support of making NCS decisions is verified against the laboratory data package to ensure data is loaded correctly.

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

6.9.3 Load data (RTL file) to OREIS.

NOTES:

The OREIS data report which includes uncertainty will be provided to the project for data collected in support of making NCS decisions.

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

- 6.9.4 Send OREIS report and Excel file of analytical data to Project Team.
- 6.9.5 If project data contains component identification numbers assigned by Characterization and Criticality Incredible Database (CCID), then send OREIS report, Excel file of analytical data, and a completed project DAP to the CCID group.

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Project Team

- 6.9.6 Make project decisions based on data.
- 6.9.7 If additional data needs to be collected, then return to Step 6.1.2.

6.10 Records Management

NOTE:

SMO submits project DAP and laboratory data packages to Records Management.

6.10.1 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:

- CP3-ES-5003-F01, Data Assessment Review Checklist and Comment Form
- CP3-ES-5003-F02, Paducah Data Release Form
- CP3-ES-5003-F04, *PARCCS PARAMETERS*
- CP3-ES-5003-F05, Data Verification/Validation Checklist
- Project DAP
- Laboratory Data Packages
- DQOs (e-mails, meeting minutes, SAP, SAEP, answers to Appendix D questions, if applicable).

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.

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Appendix A – Acronyms/Definitions

ACRONYMS

- **BOA**-Basic Ordering Agreement
- COC Chain of Custody
- DAP Data Assessment Package
- **DC** Derivative Classifier
- **DMIP** Data Management Implementation Plan
- **DOE** U.S. Department of Energy
- **DQO** Data Quality Objective
- **DUP** Laboratory Duplicate
- **DVQ** Data Validation Qualification
- **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
- LCS Laboratory Control Sample
- LCSD Laboratory Control Sample Duplicate
- MS Matrix Spike
- MSD Matrix Spike Duplicate
- NCS Nuclear Criticality Safety
- **OREIS** Paducah Oak Ridge Environmental Information System
- PARCCS Precision, Accuracy, Representativeness, Completeness, Comparability, Sensitivity
- PCB polychlorinated biphenyl
- PEGASIS PPPO Environmental Geographic Analytical Spatial Information System
- PEMS Paducah Project Environmental Measurements System

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Appendix A – Acronyms/Definitions (Continued)

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

- **QA** Quality Assurance
- QAPP Quality Assurance Project Plan
- **QC** Quality Control
- 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
- WMP Waste Management Plan

DEFINITIONS

Basic Ordering Agreement (BOA) – The contractual agreement between PDGP D&R contractor and the laboratory. The BOA covers programmatic contractual elements such as QA/QC requirements and laboratory deliverable requirements.

Contractual Screen – A process of evaluating a set of data against the requirements specified in the laboratory 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, units, holding times, and reporting limits achieved.

Data Assessment – A process of evaluating a set of data and its associated laboratory QC data to determine if any quality deficiencies are present. Data Assessment is performed by the Data Reviewer. Data assessment follows Data Verification. It can be performed in parallel with Data Validation, however data assessment cannot be completed until data validation report is reviewed.

Data Assessment Package (DAP) – A package that includes data reports from the integrated data system (i.e., PEMS), CP3-ES-5003-F04, (if applicable), laboratory and sample management comments, CP3-ES-5003-F01, CP3-ES-5003-F02, and routine queries generated to aid in the review of the data. After the review is complete, any questions or comments by the Data Reviewer, Project Reviewer, SMO, or QA Reviewer are added to the project DAP. The project DAP is submitted as a record to Records Management.

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.

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Appendix A – Acronyms/Definitions (Continued)

Data Quality Objectives (DQOs) – 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 presented in project DAP. Data Reviewer can be personnel from SMO or Characterization organizations who are appropriately trained. Data Reviewer and QA Reviewer cannot be the same individual.

Data Usability 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 Usability Assessment follows Data Verification and Data Validation & Data Assessment in the data assessment review process. Data Usability Assessment is performed by the Project Reviewer. Data Usability Assessment must be performed to ensure data is useable.

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. Data 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 – <u>Precision, A</u>ccuracy, <u>R</u>epresentativeness, <u>C</u>ompleteness, <u>C</u>omparability, <u>S</u>ensitivity, as explained in Appendix E and recorded on CP3-ES-5003-F04.

Project Reviewer – Performs independent review of data presented in project DAP. Project Reviewer is assigned by the project team and can be personnel from project team who are appropriately trained. The Project Reviewer bears the ultimate responsibility for determining the usability of a data set for decision making purposes. Project Reviewer and QA Reviewer cannot be the same individual.

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Appendix A – Acronyms/Definitions (Continued)

Project Team – The project team consists of project personnel responsible for initiating a data collection activity (i.e., sampling event). The project team defines the project DQOs and submits request to the SMO for collection of samples. The project team coordinates sample collection and analysis with the SMO to ensure project requirements are met. The project team assigns a representative of the project to serve as the Project Reviewer.

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.

QA Reviewer –Performs independent review of project DAP and verifies completion of data assessment. QA Reviewer is a member of the SMO who is appropriately trained. QA Reviewer and Data Reviewer cannot be the same individual.

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 (SOW) – The contractual agreement between the requesting organization and the service provider. The SOW defines the scope of work including analytes requested, reporting limits to be achieved, sample quantities, and sampling schedules. Any project-specific QA/QC requirements that are not standard to laboratory BOA requirements should be defined in laboratory SOW.

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Appendix B – 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 B.1 – ENVIRONMENTAL MONITORING PROJECTS – DQO PROCESS

- Model B.2 ENVIRONMENTAL RESTORATION PROJECTS DQO PROCESS
- Model B.3 SITE CHARACTERIZATION PROJECTS DQO PROCESS

Model B.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.

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.

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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, QAPPs, 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.

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Model B.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?
 - What reporting limits are needed?
- 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.

- 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?
 - What additional QA/QC is requested?

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Model B.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.

- 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?
 - What additional QA/QC is requested?

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Model B.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?
 - \circ 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.

- 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?
 - What additional QA/QC is requested?

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Model B.4 – WASTE CHARACTERIZATION PROJECTS – DQO PROCESS

- 1. 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 TSDF 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?
 - o 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.

- 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?
 - What additional QA/QC is requested?

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Appendix C – DATA TYPES AND STAGES OF VALIDATION

INTRODUCTION

The following information is an aid to the project team or requester to understand the types of data and choose appropriate stage of validation (if required).

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. 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.

STAGES OF VALIDATION

- Stage 1 Validation: A verification and validation based only on completeness and compliance of sample receipt condition checks. Client sample IDs and target analytes are verified against the COCs for completeness; sample conditions upon arrival at laboratory noted; sample preservation was appropriate and verified by the laboratory; holding times were met; concentrations and units were appropriate; trip blanks, field blanks, and equipment rinsate blanks, and field duplicates met project requirements for frequency and field quality control.
- Stage 2A Validation: A verification and validation based on completeness and compliance checks of sample receipt conditions and ONLY sample-related QC results. Method blanks, laboratory control samples (LCS), matrix spikes (MS), laboratory duplicates (LCSD, MSD, DUP), surrogates (organics), serial dilutions, post-digestion spikes (as appropriate to the method) and any preparatory batch cleanup QC to assure project requirements for analyte spike list, frequency, and quality control limits are met.
- **Stage 2B Validation**: A verification and validation based on completeness and compliance checks of sample receipt conditions and **BOTH** sample-related and instrument-related QC results.
- **Stage 3 Validation**: A verification and validation based on completeness and compliance checks of sample receipt conditions, both sample-related and instrument-related QC results, **AND** recalculation checks.
- Stage 4 Validation: A verification and validation based on completeness and compliance of sample receipt conditions, both sample–related and instrument-related QC, recalculation checks AND the review of actual instrument outputs.

The stage of validation required is generally defined at the program/project level. Validation parameters to be reviewed depending on stage of validation can include instrument calibrations, calibration verification checks, quality control sample results, analytical yields, holding times, and sample preservation. It is not the role of data validation to determine if project goals are met or to provide the decisions to be made. Data validation provides the overall appraisal of a data set and the project team should use this appraisal along with their own judgment to make their own decisions.

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Appendix D – DATA ASSESSMENT REVIEW PROCESS

INTRODUCTION

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

PURPOSE

The purpose of this appendix is to provide overview of the data assessment review process. 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 the data assessment review process. The preferred method for performing verification is electronic. Verification criteria are documented using CP2-ES-5003-F01 and CP3-ES-5003-F05 (if Stage 2B, Stage 3, or Stage 4 data validation is required). Data verification is performed on 100 percent of data.

DATA VALIDATION

Data validation follows data verification in the data assessment review process when requested by the project team. Stage 3 and Stage 4 validations must be performed by a third party. Third party data validation is defined as validation performed by persons independent from sampling, laboratory, and decision making for the project (i.e., not the Project Reviewer, etc.). Data validation is documented in a formal deliverable from the data validator. The stage and frequency chosen for validation is based on project requirements 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)

Project team determines if data set requires validation. Project team also determines stage and frequency of data validation. See Appendix C, *Data Types and Stages of Validation* for more information.

DATA ASSESSMENT

Data assessment follows data verification and data validation (if requested) in the data assessment review process. Data assessment is performed by data reviewers who have been trained to evaluate laboratory QA/QC requirements. Data assessment is performed on 100 percent of data.

DATA USABILITY ASSESSMENT

Data usability assessment is the last review step of the data assessment review process 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 usability 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 usability assessment must be performed for all data collection activities and documented using CP3-ES-5003-F01. Data usability assessment is required prior to use of the data, or data release into the final data repository (i.e., OREIS). Data usability assessment is performed on 100 percent of data.

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Appendix E – PARCCS PARAMETERS

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. The calculations performed in PEMS for PARCCS parameters should be recorded on CP3-ES-5003-F04, during the creation of the project DAP when requested by the project team.

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 evaluation of results from duplicate/replicate analyses on laboratory control samples, spiked samples and/or field samples. The most commonly used estimate of precision is relative percent difference (RPD). In PEMS, the analytical precision result is evaluated in the laboratory case narratives when laboratory duplicates, laboratory control sample duplicates, matrix spike duplicates, and/or post-digestion spike duplicates are discussed. Data not meeting laboratory acceptance criteria are qualified by the laboratory using PGDP D&R laboratory qualifiers (*, L1, N1, W1, and Y2).

<u>Accuracy</u> – Accuracy is a quantitative measurement of the bias of the data. It represents the closeness of a measured result to an accepted reference value (true value). Sampling accuracy can be assessed by evaluating results from field blanks, equipment rinsate blanks, and trip blanks (if applicable). Analytical accuracy is measured by evaluating percent recoveries associated with internal standards, laboratory control samples, surrogates, tracers, matrix spikes, and post-digestion spikes. It also includes evaluating results from analysis of preparation blanks and method blanks. In PEMS, the accuracy result is evaluated in the laboratory case narratives when blanks, tracers, surrogates, lab control samples, matrix spikes, and/or post-digestion spikes are discussed. Data not meeting laboratory acceptance criteria are qualified by the laboratory using PGDP D&R laboratory qualifiers (B, L, M, N, S, T, W, and Y1).

<u>**Representativeness**</u> – Representativeness is a qualitative term that expresses the degree to which the sample data accurately and precisely represent the characteristics of a population, parameter variations at a sampling point, a process condition, or an environmental condition. Representativeness is dependent on the proper design of the sampling program and will be satisfied by ensuring the approved procedures and plans were followed during sampling and analysis. Sampling strategy (location, method, and frequency) is critical to assure that the samples statistically represent the population. Precision, accuracy, and completeness all affect representativeness. Analytical precision and accuracy reflect how representative the data is of the sample as a qualitative measurement.

<u>Completeness</u> – Completeness is a quantitative measurement of the percentage of acceptable data as compared to the number planned. Measurements are considered to be valid if they are not qualified as rejected or unusable during data assessment and/or data validation. Both sampling (field) and analytical (laboratory) completeness can be measured. Field completeness is a measure of the number of valid analytical results from samples collected versus the number of analytical results expected from samples planned. Analytical completeness is a measure of the number of valid analytical results received versus the number of valid analytical results received versus the number of analytical results received versus the number of valid analytical results received versus the number of analytical results received versus the numb

<u>Comparability</u> – Comparability is a qualitative term that expresses the confidence with which a data set can be compared with another. Strict adherence to standard sample collection procedures, analytical detection limits, and analytical methods assures that data from like samples and sample conditions are comparable. Utilizing such procedures and methods enables the current data to be comparable with previous data sets generated with similar methods. This comparability is independent of laboratory personnel, data reviewers, or sampling personnel.

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Appendix E – PARCCS PARAMETERS (Continued)

<u>Sensitivity</u> – Sensitivity is related to the ability to compare analytical results with project-specific levels of interest, such as project action levels. The sensitivity of an analysis (or the detection limit) is determined by the analytical method and the laboratory analyst and instrumentation. In PEMS, sensitivity is evaluated by reviewing the detection limit received compared to what was requested in the laboratory SOW.

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

Project Title:		Pro	ject ID:		
SDG(s):			-		
ו(ו) בערב					
Instructions: Complete the checklist by answering questions presented below. A member of the SMO completes questions 1-23. Data Reviewer completes questions 24-30. Project Reviewer completes questions 31-40. QA Reviewer completes question 41-44. Refer to guidelines in the appropriate Data Verification and Validation Plan for data qualification requirements. All personnel completing this checklist must be appropriately trained.					
Sample Collection & Receipt Review	YES	NO	N/A	COMMENTS	
(This section to be completed by Sample Management Office (SMO) personnel)				Contractory	
 Are all chain-of-custody (COC) forms for samples shipped to the laboratory present in the laboratory data package(s)? 					
Are there any missing signatures/dates or breaks in custody for samples?					
Does a review of the laboratory sample receipt checklist(s) indicate a problem with sample preservation or temperature upon receipt?					
Are all COC forms present in the project data assessment package (DAP)?					
 Are all sample data forms (if applicable) present in the project DAP? 	╞	╞	╞		
 Are the quality control (QC) reviews of COC form and sample data form (if applicable) entries into 	<u> </u>	屵	<u> </u>		
PEMS included in the project DAP?					
Sample Collection & Receipt Review Completed by:	Date:				
Data Verification / Contractual Screen	YES	NO	N/A	COMMENTS	
(This section to be completed by SMO personnel) 7. Does a review of the PEMS Loading Notes indicate any potential issues with how the data was					
electronically loaded to PEMS?					
8 Has the data been electronically verified in PEMS (e.g., verification codes added as needed, analysis types assigned, etc.)?					
9. Were all samples collected as planned? (see Data Package Tracking-Verify report)					
10. Is there any missing data not received from the lab? (see Missing Analytes by Project ID query)					
11. Do the analytical methods reported match what was requested on the laboratory SOW(s)?					
(see Verify AnaMethod querγ)		<u> </u>	<u> </u>		
12. Is the data reported in the correct units? (see Verify Units Sample Data query)					
13. Did the lab meet all requested reporting limits? (see Reporting Limits report)					
14. Has the lab reported data in the appropriate basis (e.g., "as received" or "dry weight" basis) as requested on the laboratory SOW?					
15. Were any samples extracted out of holding time requirements, if applicable?					
(see Holding Time Violations - Extraction Exceedance report) 16. Were any samples analyzed outside of holding time requirements?	<u> </u>	<u> </u>	<u> </u>		
(see Holding Time Violations - Analysis Exceedance report)					
17. Were T verification codes properly applied to affected data in PEMS?					
(see Check T Verification Codes Applied query) 18. Is there more than one result reported by the laboratory for any sample and parameter?	믐	믐	믐		
(see Check for Duplicate Records query)					
19. Has third party data validation service been requested for any SDG in this project?					
20. Have all laboratory case narratives been reviewed by the SMO?					
Data Verification / Contractual Screen Completed by:	Date:				
DAP Creation	YES	NO	N/A	COMMENTS	
(This section to be completed by SMO personnel)					
21. Have all laboratory case narratives been added to the project DAP?	╞	⊢⊢	╞		
22. Have PARCCS parameters been calculated and added to appropriate form (if applicable)?	井	<u> </u>	<u> </u>		
23. Has data validation report been added to the project DAP (if applicable)?					
DAP Creation Completed by:	Date:				
Data Validation & Data Assessment	YES	NO	N/A	COMMENTS	
(This section to be completed by Data Reviewer) 24. Does project have project-specific requirements defined in a Quality Assurance Project Plan (QAPP)?					
(Contact SMO if there is a question if data has a project-specific QAPP)					
25. Were sample COCs and sample data forms (if applicable) reviewed?					
26. Were samples collected in acceptable containers and preserved correctly?					
27. Does data validation report indicate data is usable (if applicable)?					

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

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

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

Data Validation & Data Assessment (continued)	YES		NO		N/A	COMMENTS
28. Does a review of the laboratory result qualifiers, laboratory case narratives, and/or QC summary						
forms from laboratory data package indicate any issues with reported sample data? A. Are there any issues with instrument calibration?						
B. Did the lab analyze a laboratory control sample (LCS) for each batch?	늼		H		=	
C. Were all reported analytes spiked in the LCS?	╞		H		=	
D. Were there any detections in method blank (MB) or preparation blank (PB) above the	늼		片	_	=	
practical quantitation limit (PQL)/limit of quantitation (LOQ)? E. Did the lab analyze a matrix spike/matrix spike duplicate (MS/MSD) or post spike/post	ᆜ					
spike duplicate (PS/PSD) as applicable for each batch?						
F. Were all reported analytes spiked in the MS/MSD and/or PS/PSD?						
G. Were internal standard, tracer, and/or surrogate recoveries reported and acceptable (if applicable)?						
H. Was a laboratory duplicate analyzed and acceptable (if applicable)?						
I. Other QC issues present?						
29. Are the following field QC sample results acceptable?						
A. Field duplicates						
B. Field blanks						
C. Equipment rinsate blanks						
D. Trip blanks (VOAs only)						
30. Have data assessment codes been added to sample results?						
Data Validation & Data Assessment Completed by:	Date	e:				
Data Usablity Assessment		Т		Т		
(This section to be completed by Project Reviewer)	YES		NO		N/A	COMMENTS
31. Have impacts of comments from SMO and Data Reviewer noted on this checklist been evaluated?						
32. Were sample COCs and sample data forms (if applicable) reviewed?						
33. Were all samples collected as planned?						
34. Is data reasonable when compared to known or expected levels?						
35. Are there any outliers observed in this data? (Please note evaluation of possible cause for any outliers on page 3 of this form)						
36. Are there any issues in terms of compliance with project-specific QAPP (if applicable) that affect usability of the data?						
37. Does the sampling design and data provide enough information to support the Data Quality Objectives (DQOs) and the current decision?						
38. Is data of adequate quality to be used and is data deemed Data of Known Quality?	$\overline{\neg}$					
39. Was this data generated according to <i>Quality Assured Data</i> procedure?	H		H			
40. Have any additional data assessment codes been added to sample results based on the project's	⊢⊢		片			
review?						
Data Usability Assessment Completed by:	Date	e:	_	_	_	
Quality Assurance (QA) Review (This section to be completed by SMO personnel)	YES		NO		N/A	COMMENTS
41. Have all data validation codes and/or data assessment codes been added to PEMS?						
42. Have all data reports been updated to display data validation and data assessment codes in the						
project DAP? 43. Have all applicable emails been added to the DAP?	믐			-	╡	
44. Has project DAP been reviewed and verified for completion?	╞					
QA Review Completed by:	Date	e:				
SIGNATURES By signing below, Data Reviewer and Project Reviewer confirm that the data has been reviewed, necessary qualification	ns have t	been i	nade	(if ap	plicab	e), and the data can be made available for final
reporting. QA Reviewer confirms review of data and verifies completion of data assessment review process.						
Data Reviewer:						
Project Reviewer:						
· · · · · · · · · · · · · · · · · · ·						
QA Reviewer:						

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

Comment	Action	Resolution

CP3-ES-5003-F01 Data Assessment Review Ch	necklist and Comment Form (continued)
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Appendix G – CP3-ES-5003-F02 – Paducah Data Release Form

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

Project ID:							
Projec	Project Title:						
Projec	Project Reviewer:						
Data Q	Quality Level:						
	Data of Known Quality						
	Data, along with appropriate laboratory qualifiers, verification codes, assessment codes, and validation codes, 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 or codes; however, data can be used for informational purposes or can be used for decision making w relevant documentation.	/ith					
Data R	telease:						
	opproval for release to following organizations/entities:						
	1						
2							
	3						
	4						
	5						
י	Not Approved for Release						
	Explanation:						
Attach	Attach any necessary documentation for additional release criteria.						
Projec	Project Reviewer: (Signature Required)						

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Appendix H – 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 evaluation of results from duplicate/replicate analyses on laboratory control samples, spiked samples and/or field samples. The most commonly used estimate of precision is relative percent difference (RPD).							
	In PEMS, the analytical precision result below is evaluated in the laboratory case narratives when laboratory duplicates, laboratory control sample duplicates, matrix spike duplicates, and/or post- digestion spike duplicates are discussed. Data not meeting laboratory acceptance criteria are qualified by the laboratory. PGDP D&R contractor standard laboratory qualifiers counted for precision include *, L1, N1, W1, and Y2.							
	% of data records received have been qualified in this data set.							
	Field precision is evaluated by comparing analytical results of samples and associated field duplicates. Please see the Duplicate Comparison report for more detail.							
ACCURACY	Accuracy is a quantitative measurement of the bias of the data. It represents the closeness of a measured result to an accepted reference value (true value). Sampling accuracy can be assessed by evaluating results from field blanks, equipment rinsate blanks, and trip blanks (if applicable). Analytical accuracy is measured by evaluating percent recoveries associated with internal standards, laboratory control samples, surrogates, tracers, matrix spikes, and post-digestion spikes. It also includes evaluating results from analysis of preparation blanks and method blanks. In PEMS, the accuracy result is evaluated in the laboratory case narratives when blanks, tracers, surrogates, lab control samples, matrix spikes, and/or post-digestion spikes are discussed. Data not meeting acceptance criteria are qualified by the laboratory. Standard laboratory qualifiers counted for accuracy include B, L, M, 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. Sampling strategy (location, method, and frequency) is critical to assure that the samples							
	statistically represent the population. Precision, accuracy, and completeness all affect representativeness. Analytical precision and accuracy reflect how representative the data is of the sample as a qualitative measurement.							
COMPARABILITY	Comparability is a qualitative term that expresses the confidence with which a data set can be compared with another. Strict adherence to standard sample collection procedures, analytical detection limits, and analytical methods assures that data from like samples and sample conditions are comparable. Utilizing such procedures and methods enables the current data to be comparable with previous data sets generated with similar methods. This comparability is independent of laboratory personnel, data reviewers, or sampling personnel.							

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Appendix H – CP3-ES-5003-F04 – PARCCS PARAMETERS (Continued)

CP3-ES-5003-F04 PARCCS PARAMETERS

COMPLETENESS	Completeness is a quantitative measurement of the percentage of acceptable data as compared to the number planned. Measurements are considered to be valid if they are not qualified as rejected or unusable during data assessment and/or data validation. Both sampling (field) and analytical (laboratory) completeness can be measured. Field completeness is a measure of the number of valid analytical results from samples collected versus the number of analytical results expected from samples planned. Analytical completeness is a measure of the number of valid analytical results received versus the number of analytical results requested from samples submitted to the laboratory.						
	In PEMS, completeness is calculated by two methods:						
	 Field Completeness: The number of valid analytical results reported divided by the number of analytical results planned, multiplied by 100 to obtain a percentage. Analytical 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)]						
	% Analytical Completeness [Analytical Completeness as described above in (2)]						
SENSITIVITY	Sensitivity is related to the ability to compare analytical results with project-specific levels of interest, such as project action levels. The sensitivity of an analysis (or the detection limit) is determined by the analytical method and the laboratory analyst and instrumentation. 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: _____

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Appendix I – CP3-ES-5003-F05 - Data Verification/Validation Checklist

CP3-ES-5003-F05 Data Verification/Validation Checklist

Project ID:	Laboratory		tory:				
SDG(s):							
Instructions:							
Complete the checklist by answering questions presented below. Please follow the guidelines in the appropriate Data Verification and Validation Plan for data validation qualification requirements. For lab QC issues not covered in this checklist, please note the items reviewed in the data validation report/case narrative (i.e., serial dilutions, TPU evaluations, etc.).							
Data Package F	Review	YES		NO		N/A	COMMENTS
1. What data	package level was requested from the laboratory? (circle one)						
Level 1	Level 2 Level 3 Level 4 Other						
2. Hasalldata	a been received from the laboratory in the correct deliverable format?				[
3. Hasanymi	ssing information been requested and received from the laboratory?				[
4. Is a laborat	ory case narrative and/or cover letter present in the data package?				[
5. Are chain c	of custody (COC) forms present for all samples?				[
	Cs or case narrative indicate any problems with the sample receipt, condition of ss, or special circumstances that would affect data quality?				[
	Sample Preservation	YES		NO		N/A	COMMENTS
	ing time violation occurred in which the acceptable hold time from sample			Π]		
	o extraction has been exceeded? ing time violation occurred in which the acceptable hold time from sample		1	믐			
collection of	or extraction to analysis has been exceeded?						
	is submitted to laboratory on same day as sample collection, is there evidence required) was present in coolers and cooling had begun?				[
	s shipped to laboratory, were temperatures of samples on receipt within		1		[
	e criteria for samples where temperature preservation is required? poratory indicated that any samples were received with improper chemical			=		=	
preservatio					l		
Sample Metho		YES		NO		N/A	COMMENTS
12. Have all an method on	alytical methods reported been verified to match the requested analytical				[
	quested analytes missing from the reported data?				[
14. Were the t	arget analytes identified correctly and confirmation acceptance criteria met?				[
Surrogates and	Tracers/Carriers	YES		NO		N/A	COMMENTS
15. Were surro	ogates added to all samples in the applicable methods?				[
16. Does a revi acceptance	iew of the reported data indicate that a sample surrogate (if required) is outside e criteria?				[
17. Were trace	ers/carriers added to all samples in the applicable methods?				[
	iew of the reported data indicate that a sample tracer and/or carrier (if required)			Π	Ī		
	acceptance criteria? n and Internal Standards	YES				N/A	COMMENTS
	al standards and/or isotope dilution results included in the data package?				ſ		
20. Were inter	nal standard responses within the acceptance criteria?			Ħ	ī	=	
21 Were inter	nal standard(s) detected within the retention time window?			Ħ	ī	=	
	iew of reported data indicate that the isotope dilution recovery related to a			一	Ī		
sample is c Calibration	outside acceptance criteria?	YES				N/A	COMMENTS
	alibration meet the specified acceptance criteria?				1		
24. Were the i	nstrument performance and/or interference checks analyzed at the appropriate			片			
	strument performance and/or interference checks meet the specified		•	一		╡	
	iew of reported data indicate that the CCV and/or ICV recovery related to a			=	י ו	╡	
	outside acceptance criteria?						COMPARINTS
	i (MB) and Preparation Blanks (PB) for MB and/or PB included in the data package and analyzed at the appropriate	YES			1	N/A	COMMENTS
frequency?			1	븜		=	
28. Were there	e any positive and/or negative detections identified in the MB or PB?			1			

Appendix I – CP3-ES-5003-F05 - Data Verification/Validation Checklist (Continued)

Laboratory Control Sample/Laboratory Control Sample Duplicate (LCS/LCSD)	YES	NO	N/A	COMMENTS	
29. Are LCS results included in the data package and analyzed at the appropriate frequency?					
30. Was LCS spiked with all reported analytes as required per the current QSM?					
31. Does a review of the reported data indicate that the LCS recovery related to a sample is outside acceptance criteria?					
32. Did the lab report an LCSD due to limited sample volume?					
33. Are Relative Percent Difference (RPD) results between LCS and LCSD analysis within acceptance limits?					
Matrix Spike/Matrix Spike Duplicate (MS/MSD)	YES	NO	N/A	COMMENTS	
34. Are results for MS/MSD included in the data package and analyzed at the appropriate frequency?					
35. Were MS/MSD spiked with all reported analytes as required per the current QSM?					
36. Does a review of the reported data indicate that the MS/MSD recovery related to a sample is outside acceptance criteria?					
37. Are RPD results between MS and MSD analysis within acceptance limits?					
Laboratory Duplicates	YES	NO	N/A	COMMENTS	
38. Does the data package include results for laboratory duplicates?					
39. Do the calculated RPDs for the laboratory duplicate(s) and/or mean difference meet acceptance criteria?					
Field Quality Control (QC) Samples	YES	NO	N/A	COMMENTS	
40. Does the data package include results for field duplicate samples?					
 Do the calculated RPDs for the field duplicate(s) and/or mean difference meet acceptance criteria? 					
42. Does the data package include results for field blank samples? (Station = QC and Sample IDs usually include "FB" or "BF")			Π		
43. Does the data package include results for equipment rinsate blank samples?					
(Station = QC and Sample IDs usually include "RI", "BE" or "BEP")	<u> </u>	<u> </u>	<u> </u>		
45. Does the data package include results for trip blank samples for volatiles? (Station = QC and Sample IDs usually include "TB" or "BT")					
46. Were there any positive detections identified in the field QC blanks (i.e., field blanks, equipment rinsate blanks, and/or trip blanks)?					
Additional Comments/Notes					
By signing below, the person performing the Data Verification/Validation Checklist is verifying that all data received has been reviewed and data appropriately qualified according to applicable FRNP Data Verification and Validation Plans.					
SIGNATURES Data Validator:		_			
Data Validator:		_			

CP3-ES-5003-F05 Data Verification/Validation Checklist