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REVISION LOG		
Revision Number	Description of Changes	Pages Affected
0	Initial Release. Intent Change. Changed numbers and headings to define the beginning point of Paducah Remediation Services, LLC, documentation and to establish Document Control as the control point for tracking document numbers. This document replaces PA-5003, Rev. 0, Quality Assured Data – Paducah, BJC-ES-1004, Rev. 1, Implementing and Documenting the Data Quality Objectives (DQO) Process for Environmental Management (EM) Projects, and ERWM/ER-P2213, Rev. 0, Data Validation Plans for Environmental Restoration Projects.	All

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1.0 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), Data Management, a centralized data system, Quality personnel, and common definitions for data quality.
- Quality assured data is obtained through appropriate planning, adequate sampling and laboratory quality controls, and documented data review.

2.0 SCOPE

The requirements of this procedure apply to work performed by Paducah Remediation Services, LLC, (PRS) for the U. S. Department of Energy (DOE)-owned Paducah Site. This procedure applies to screening and definitive data that is collected by all PRS 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 as defined in Attachment A
- Data collected by the Safety and Health program
- Personnel and financial data
- Data received from external entities

3.0 PROCEDURE

3.1 Initiation of Data Collection

- | | |
|----------------------------|--|
| Requester | 3.1.1 Determine need for data to support the activity or program/project. |
| Requester and Project Team | 3.1.2 Choose the Data Quality Objective (DQO) process option for the program or project outlined in Attachment D, "Options to Implementing and Documenting the DQO Process for Paducah Projects." |
| Requester and Project Team | 3.1.3 Follow steps associated with the DQO process. |
| | 3.1.4 Select Quality Assurance (QA)/Quality Control (QC) requirements using Attachment E, "Data Quality Reference List" to incorporate into project plans. |
| | 3.1.5 Identify the data review steps for the project using Attachment F, "Options for Data Review." |

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3.1.6 Ensure applicable plans, such as the Sampling and Analysis Plan (SAP), the Quality Assurance Plan (QAP), Environmental Monitoring Plan (EMP), Waste Management Plan (WMP), and Data Management Implementation Plan (DMIP) are in place.

3.1.7 Notify the Data Manager or Data Coordinator of electronic data quality checks that the project would like performed.

3.1.8 Contact the Lab Coordinator to develop the analytical Statement of Work (SOW) for new activities or to notify of sample requests that are routine.

NOTE: Routine sampling activities (i.e., groundwater, environmental monitoring, Kentucky Pollutant Discharge Elimination System (KPDES), etc.) are reviewed on a periodic basis.

3.1.9 Ensure the SOW contains the required methods, detection limits, and deliverables.

3.1.10 Collect samples and deliver/ship them to the SMO approved/DOECAP (DOE Consolidated Audit Program) audited laboratory specified by the Lab Coordinator.

3.2 Laboratory Contractual Screening

Lab Coordinator

3.2.1 Upon receipt of data from the laboratory, conduct contractual screening using the Paducah Project Environmental Measurements System (PEMS).

3.2.2 Resolve any issues identified during contractual screening with the laboratory and/or Data Coordinator.

3.2.3 Complete the "Data Assessment Review Checklist" in Attachment G and document any exceptions to the SOW.

3.3 Data Verification

Data Coordinator

3.3.1 Perform electronic review and ensure data is flagged correctly.

3.3.2 Resolve any issues identified during electronic review.

3.3.3 **IF** data has been corrected, **THEN** reevaluate using the electronic data review process **AND** return to step 3.3.1.

Requester and Project Team/Data Coordinator

3.3.4 **IF** deviations in the data cannot be readily resolved with the samplers, laboratory, and requester, **THEN** determine the usability of the data or the need for additional review of the data.

Data Coordinator

3.3.5 Notify the Requester/Project Team that contractual screening and data verification has been completed and that the data is ready for assessment.

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3.4 Data Validation

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

Requester and Project Team

3.4.1 Initiate data validation as defined in Step 3.1.6.

3.4.2 **IF** data validation is **NOT** required for the remaining data set, **THEN** proceed to Section 3.5.

Data Validation Coordinator

3.4.3 Develop a SOW for the validation activity.

3.4.4 Submit the data packages to the validator or validation service selected.

3.4.5 Upon receipt of the validation deliverables, conduct a contractual screening against the validation SOW.

3.4.6 Review the results of the validation process.

3.4.7 **IF** validation or deliverables are **NOT** acceptable, **THEN** resolve discrepancies with validator or validation service until acceptable.

3.4.8 Provide the Data Coordinator with validation qualifiers on the qualified laboratory results and the validation summary report.

Data Coordinator

3.4.9 Enter validation qualifiers into Paducah PEMS **AND** ensure a QC check is performed as required by PRS-ENM-5007, *Data Management Coordination*.

3.4.10 Notify the Requester/Project Team that data validation is complete.

3.4.11 Provide the Requester/Project Team with an electronic and/or hard copy of the data, quality checks, and validation results (if applicable).

Requester and Project Team

3.4.12 Document the performance of data validation on the Data Assessment Review Checklist in Attachment G.

3.5 Data Assessment and Determination of Data Usability

NOTE 1: 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.

NOTE 2: Additional instructions for completing Attachment G, "Data Assessment Review Checklist and Comment Form" are

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provided on page 1 of Attachment G.

NOTE 3: In the Materials and Facilities Disposition groups, the Data Coordinator steps listed below may be performed by the same person performing assessment, such as the Characterization Specialist.

- Data Coordinator
- 3.5.1** Ensure data verification checks have been completed on Attachment G, “Data Assessment Review Checklist and Comment Form” and print all verification queries such as contractual screening, holding time exceedances, etc.
 - 3.5.2** Print any additional queries or reports generated from Paducah PEMS, field data report (if applicable), lab data report, lab comments, assessment information such as data loading notes, etc.
 - 3.5.3** Make a note of any questions, comments, or follow-up actions in the data assessment package by doing these things:
 - Initialing and dating the comments and notes in black or blue ink
 - Writing legibly
 - Completing the forms in black ink
 - 3.5.4** Provide the Data Reviewer with a data assessment package, which includes the information listed in Steps 3.5.1 and 3.5.2 as well as the required forms.
- Data Reviewer
- 3.5.5** Begin data assessment using Attachment G, “Data Assessment Review Checklist and Comment Form.”
 - 3.5.6** Review the analytical data by looking at the hard copy data printouts, queries, reports, and other documentation provided in the data assessment package.
 - 3.5.7** Complete the applicable shaded areas and the questions on Attachment G, “Data Assessment Review Checklist and Comment Form.”
 - 3.5.8** Document any notes or comments on page 4 of Attachment G, “Data Assessment Review Checklist and Comment Form” and return form to the Data Coordinator or send comments via e-mail to the Data Coordinator.
 - 3.5.9** Return the data assessment package to the Data Coordinator.
- Data Coordinator
- 3.5.10** Resolve any issues noted in the data assessment package by the Data Reviewer and ensure a documented response (either written or e-mail) is included in the data assessment package.

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- 3.5.11** Provide the data assessment package to the Data Reviewer to ensure all comments or issues have been resolved.
- Data Reviewer **3.5.12** Sign the “Data Assessment Review Checklist” in Attachment G **AND** return the data assessment package to the Data Coordinator.
- Data Coordinator **3.5.13** Provide the data assessment package to the QA Reviewer.
- QA Reviewer **3.5.14** Review the data assessment package.
- 3.5.15** Document any notes or comments on page 4 of Attachment G, “Data Assessment Review Checklist and Comment Form” and return form to the Data Coordinator or send comments via e-mail to the Data Coordinator.
- 3.5.16** Return the data assessment package to the Data Coordinator.
- Data Coordinator **3.5.17** Resolve any issues noted in the data assessment package by the QA Reviewer and ensure a documented response (either written or e-mail) is included in the data assessment package.
- Data Coordinator **3.5.18** Provide the data assessment package to the QA Reviewer to ensure all comments or issues have been resolved.
- QA Reviewer **3.5.19** Sign the “Data Assessment Review Checklist” in Attachment G **AND** return the data assessment package to the Data Coordinator.
- Data Coordinator **3.5.20** Generate a “clean” hard copy data printout from Paducah PEMS to include any corrections that may have been made to the data set and place it in the data assessment package.
- 3.5.21** Format data for loading to Paducah Oak Ridge Environmental Information System (OREIS) by creating a Ready-to-Load (RTL) file.
- 3.5.22** Request the Data Manager to load data (RTL file) to Paducah OREIS.
- 3.5.23** Once the data has been loaded to Paducah OREIS, ensure all e-mails and the required forms are included in the data assessment package and in proper order.
- Requester and Project Team **3.5.24** Make project decisions based on data.
- 3.5.25** IF additional data needs to be collected, THEN return to Step 3.1.2.

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3.6 Data Release to External Agencies

Release
Requester/Data
Manager

NOTE 1: 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. A Technical Information Officer (TIO) review is required prior to release of documents and/or information (e.g., data) to any parties outside PRS, its subcontractors, and DOE.

3.6.1 Complete the Attachment H, "Paducah Data Release to External Agencies" form, ensuring that all necessary signatures are present.

NOTE 2: Electronic data formats will contain a "read me" file that will identify the electronic data package and the number of files associated with the package. The "read me" file also will indicate the appropriate data qualifiers, along with their associated definitions and the appropriate data quality level.

NOTE 3: Hard copy data formats will contain a cover letter that will identify the contents of the data package. The cover letter also will indicate the appropriate data qualifiers, along with their associated definitions and the appropriate data quality level.

3.6.2 Transmit data, either hard copy or electronically, as requested.

3.7 Records Management

Requester/Data
Manager

3.7.1 Ensure that all project records associated with the data collection activity, including all forms generated from this procedure, are transmitted to the PRS Document Control Center (DCC) for submittal to the Document Management Center (DMC) for final disposition.

4.0 RECORDS

4.1 Records Requirements

4.1.1 Records generated by this procedure shall be maintained according to PRS-DOC-1009, *Records Management, Administrative Record, and Document Control*.

4.2 Records Generated

4.2.1 Data assessment package, which includes the Data Assessment Review Checklist, Data Assessment Comments, Paducah Data Release to External Agencies form, and the Contractual Screening Verification, hard copy data printouts, applicable queries and reports, e-mails documenting identified deficiencies, and a "clean" hard copy data printout.

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4.2.2 DQOs (e-mails, meeting minutes, SAP, answers to Attachment D questions, if applicable)

4.2.3 Data Validation deliverables consisting of the validation SOW, validation report, and validation-qualified laboratory results (qualified Form I's and e-mails documenting identified deficiencies)

5.0 SOURCE DOCUMENTS

- EPA QA/G-4, *Guidance for the Data Quality Objectives Process*
- EPA QA/G-9, *Guidance for Environmental Data Quality Assessment*
- PRS-ENM-5007, *Data Management Coordination*
- PRS-DOC-1009, *Records Management, Administrative Record, and Document Control*

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Attachment A
DEFINITIONS/ACRONYMS
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DEFINITIONS

Contractual Screening – 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 screening includes, but is not limited to, the chain of custody (COC), 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 (or estimate) 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 printouts from the integrated data system (i.e., Paducah PEMS), laboratory and sample management comments, the “Data Assessment Review Checklist,” the “Data Assessment Comment Form,” routine queries generated to aid in the review of the data, and after the review is completed, any questions or comments by the Data Reviewer, Data Coordinator, Lab Coordinator, or QA Reviewer. This file is submitted as a record to the DMC.

Data Coordinator – The Data Coordinator assists the project in populating Paducah PEMS. The Data Coordinator is responsible for loading electronic data deliverables, electronic verification of data, and tracking the data assessment process. The Data Coordinator interfaces with the project for activities relating to data and works closely with the Data Manager and Lab Coordinator.

Data Manager – The Data Manager is responsible for the long-term electronic storage of data, loading data to Paducah OREIS, and ensuring compliance to the Paducah Data Management Policy.

Data of Known Quality – Data, along with appropriate laboratory, verification, validation, and assessment qualifiers, 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.

Data Quality Level – A description that indicates whether the data was generated according to this procedure. The two levels are Data of Known Quality and Information Only Data.

Data Quality Objectives – 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 Environmental Protection Agency (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.

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Attachment A
DEFINITIONS/ACRONYMS
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Data Reviewer – The Data Reviewer is responsible for performing data assessment and determining if the data was generated according to this procedure.

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 Validation Coordinator – The Data Validation Coordinator is responsible for procuring data validation services for the project. The Data Validation Coordinator ensures data validation deliverables meet the requirements specified in the SOW.

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 screening 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, chain of custody, logbooks, standards information, etc.

Electronic Data Deliverables (EDD) – Data that is received in electronic format from a laboratory, either through transfer on physical media or direct communication between computerized data management systems. EDD contents must meet defined completeness, consistency, and format requirements. These criteria are defined in the analytical SOW for each project.

External Agency – Any organization external to PRS, its subcontractors, and DOE.

Historical Data – Data which was collected and managed prior to implementation of this procedure.

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 can be used for decision making with relevant documentation.

Lab Coordinator – The Lab Coordinator is responsible for procurement of laboratory services and performing contractual screening. The Lab Coordinator is the primary contact for all matters relating to analytical laboratories, ensuring proper interface and compliance.

PARCCS Parameters - Precision, Accuracy, Representativeness, Completeness, Comparability, Sensitivity, as explained in Attachment E.

Project Team - Personnel involved in the data collection planning, review, and decision making, and include, but are not limited to, the Project Manager, Requester, Data Coordinator, Data

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Attachment A
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Reviewer, QA Reviewer, Quality Representative, Lab Coordinator, Data Manager, and sampling personnel.

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

QA Reviewer – The Project Team member involved in the planning and review of data to ensure that data quality requirements are met.

Release Requester – Person who requests release of data to an external agency.

Requester – A project manager (or his designated representative), such as a technical lead, risk assessor, waste management coordinator, compliance coordinator, or other individual who determines the need for data to support decision making. The requester is responsible for coordinating sample collection, sample analysis, data assessment, and decision making. If the requestor is a designated representative, the project manager has ultimate responsibility.

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 (estimated) result. Field measurement and other screening quality data include, but are not limited to, Draeger tube; organic vapor analysis (OVA); 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.

ACRONYMS

ASTM - American Society for Testing Materials
COC - Chain of Custody
DC - Derivative Classifier
DCC – Document Control Center
DMC - Document Management Center
DMIP – Data Management Implementation Plan
DOE - United States Department of Energy
DOECAP – United States Department of Energy Consolidated Audit Program
DQOs - Data Quality Objectives
EDD - Electronic Data Deliverables
EMP - Environmental Monitoring Plan
EPA - United States Environmental Protection Agency
ISMS – Integrated Safety Management System

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Attachment A
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KPDES - Kentucky Pollutant Discharge Elimination System
MS - Matrix Spike
MSD - Matrix Spike Duplicate
OREIS – Paducah Oak Ridge Environmental Information System
OVA - Organic Vapor Analysis
PARCCS - Precision, Accuracy, Representativeness, Completeness, Comparability, Sensitivity
PCB - polychlorinated biphenyl
PEMS – Project Environmental Measurements System
PGDP - Paducah Gaseous Diffusion Plant
pH – Hydrogen ion potential
PRS – Paducah Remediation Services, LLC
QAP - Quality Assurance Plan
QA - Quality Assurance
QC - Quality Control
RI/FS - Remedial Investigation/Feasibility Study
RTL – Ready-to-Load
SAP - Sampling and Analysis Plan
SOW - Statement of Work
TIO - Technical Information Officer
TSD - Treatment Storage Disposal
VOA - Volatile Organic Analysis
WAC - Waste Acceptance Criteria
WM - Waste Management
WMP - Waste Management Plan

NOTE: The above includes all acronyms used in the text of this procedure and in the other attachments.

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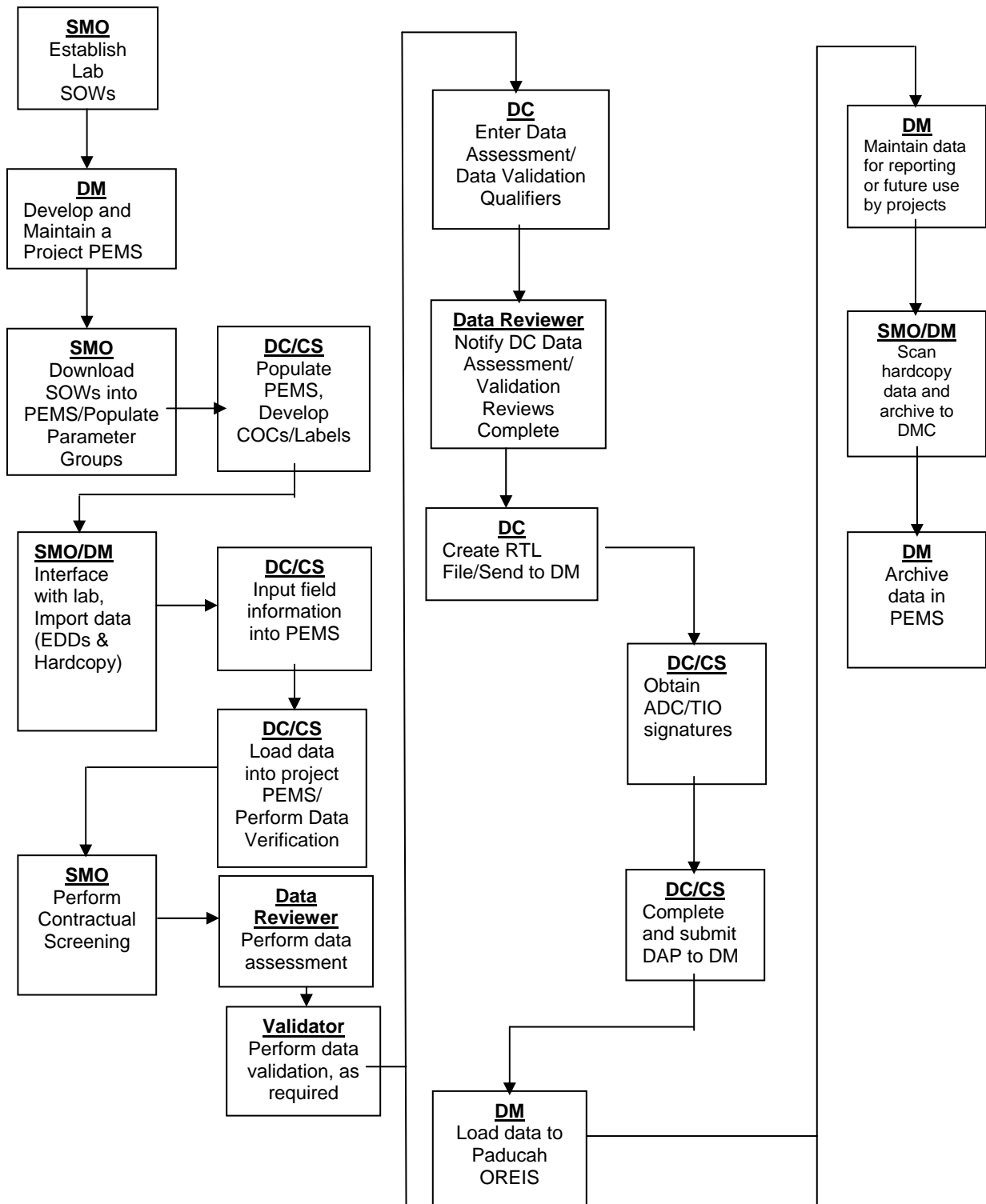
Attachment B
PADUCAH SAMPLING AND DATA MANAGEMENT FLOWCHART
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The following acronyms are used in the flowchart on the next page:

ADC	Authorized Derivative Classifier
COC	Chain of Custody
CS	Characterization Specialist
DAP	Data Assessment Package
DC	Data Coordinator
DM	Data Management
DMC	Document Management Center
EDD	Electronic Data Deliverable
OREIS	Oak Ridge Environmental Information System
PEMS	Project Environmental Measurements System
RTL	Ready to Load
SMO	Sample Management Office
SOW	Statement of Work
TIO	Technical Information Officer

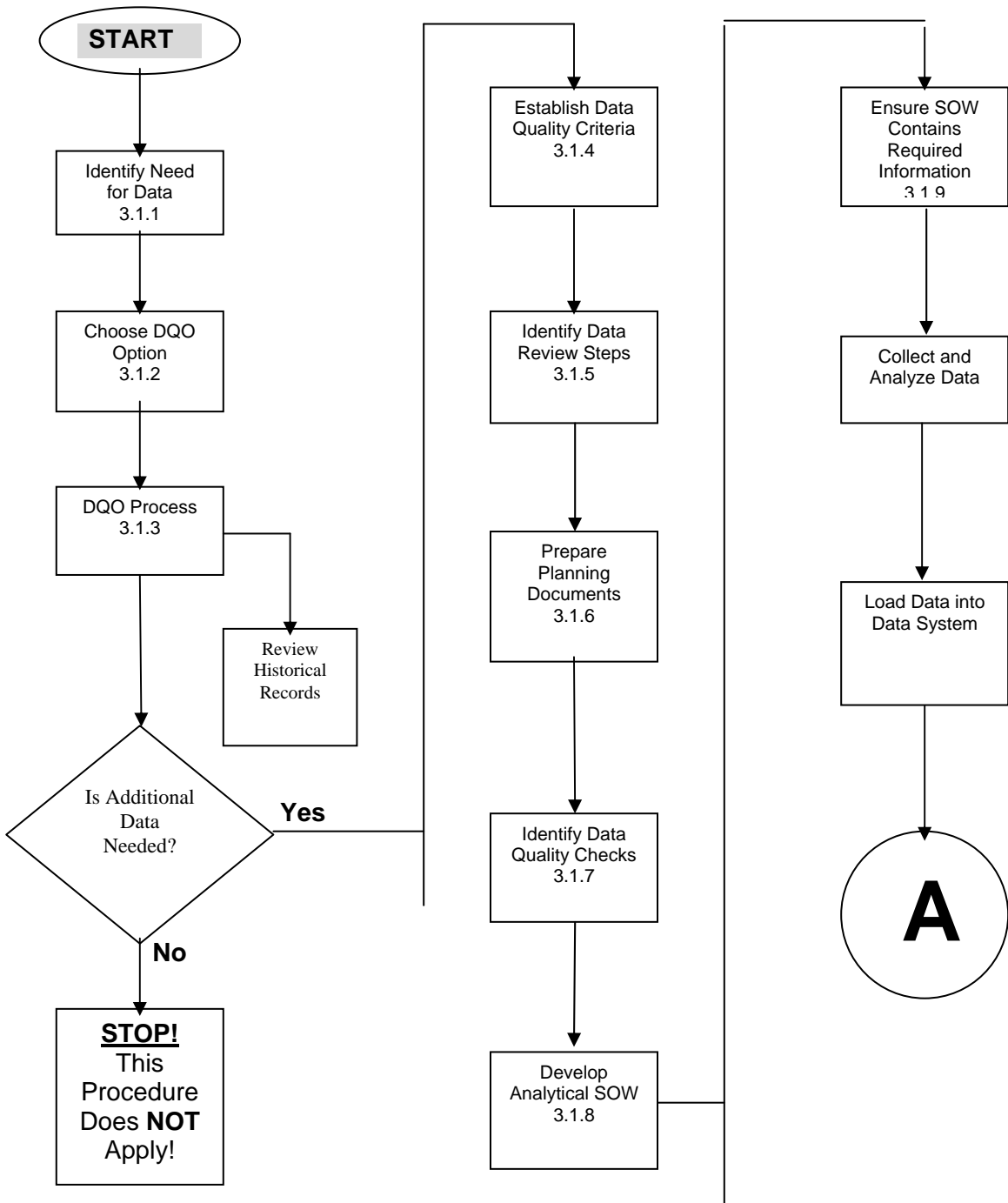
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Attachment B - Paducah Sampling and Data Management Flowchart – Page 2 of 2



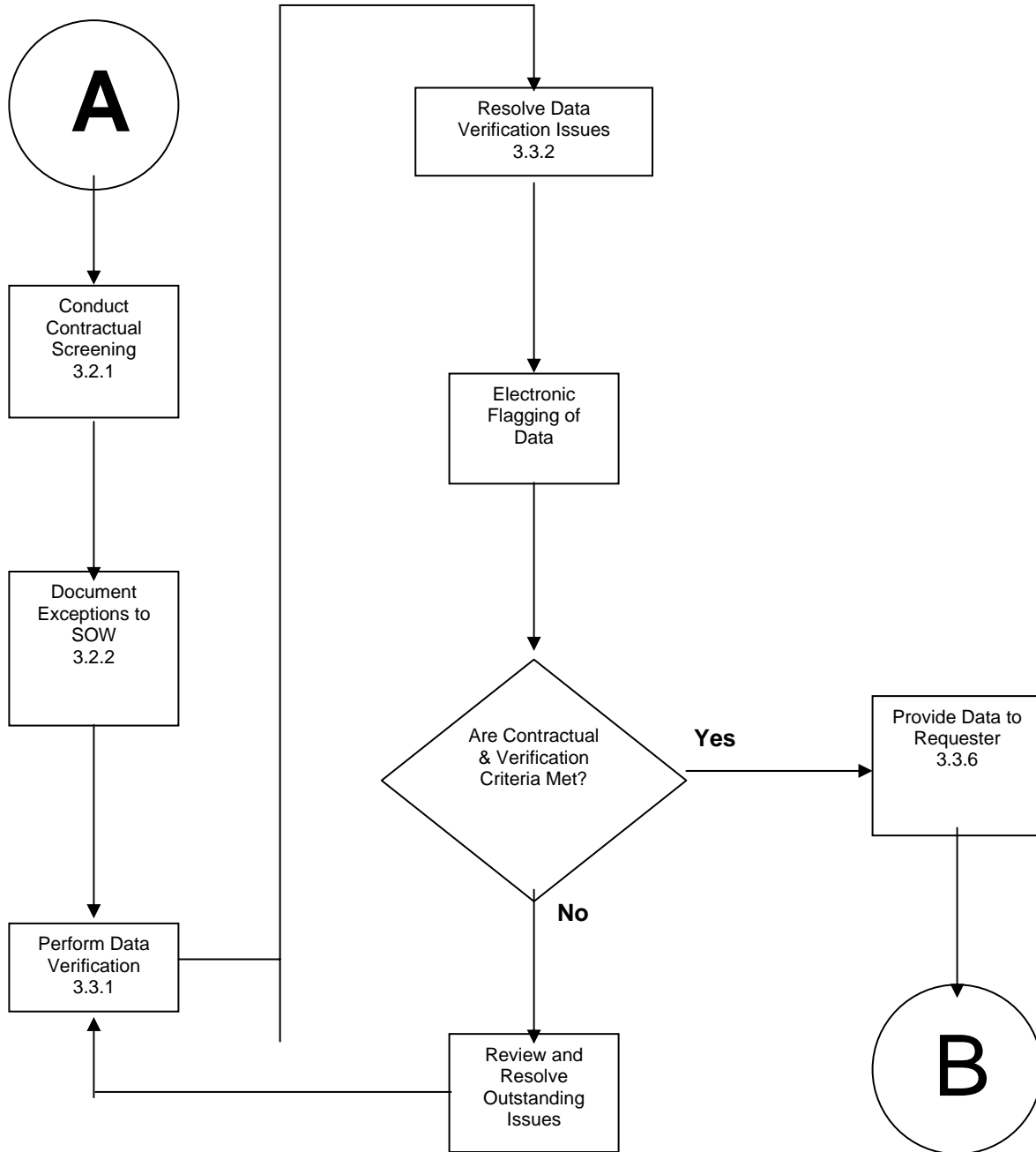
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**Attachment C
DATA CYCLE FLOWCHART
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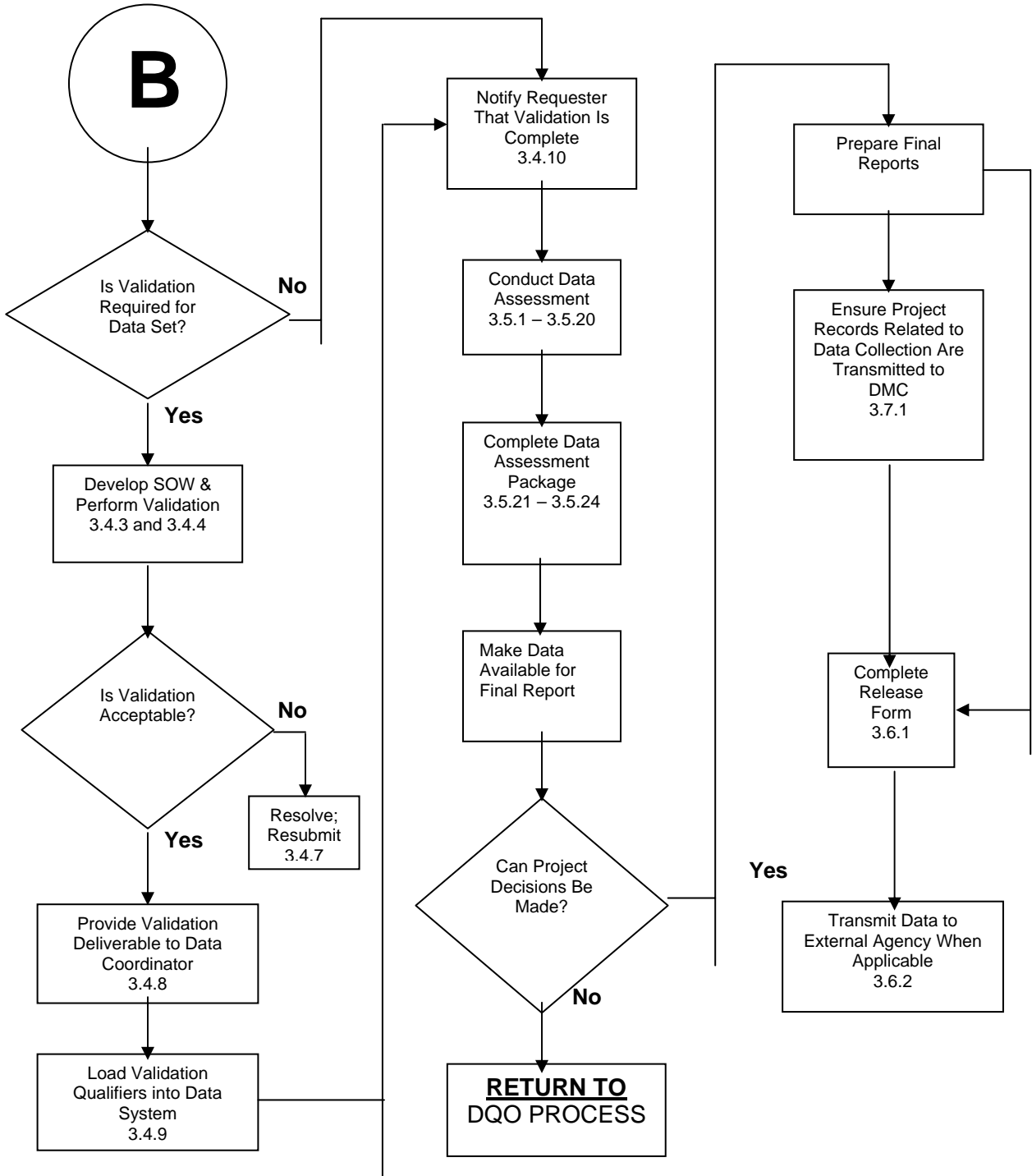
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**Attachment C
DATA CYCLE FLOWCHART
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**Attachment C
DATA CYCLE FLOWCHART
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Attachment D
OPTIONS TO IMPLEMENTING AND DOCUMENTING THE DQO PROCESS FOR PADUCAH
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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 attachment is to provide options for implementing and documenting the DQO process.

DQO OPTIONS AND APPLICABILITY

Option 1

For ER projects, the detailed approach as found in the EPA Guidance for 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 tables are provided for guidance in documenting a simplified version of the DQO process. Use the applicable table for your project.

- Table D.1 – ENVIRONMENTAL MONITORING PROJECTS – DQO PROCESS**
- Table D.2 – ENVIRONMENTAL RESTORATION PROJECTS – DQO PROCESS**
- Table D.3 – SITE CHARACTERIZATION PROJECTS – DQO PROCESS**
- Table 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.

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Attachment D
OPTIONS TO IMPLEMENTING AND DOCUMENTING THE DQO PROCESS FOR PADUCAH
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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, QAPs, EMPs, WMPs, DMIPs, etc., as necessary.
- An e-mail is routinely provided for special sampling requests. When special sampling is requested, the e-mail will be printed and will serve as the DQO documentation.

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Attachment D
OPTIONS TO IMPLEMENTING AND DOCUMENTING THE DQO PROCESS FOR PADUCAH
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Table 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 [i.e., 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 Attachment E. For data validation requirements, see Attachment F. What additional QA/QC is requested?)

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Table 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 analyte 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 (i.e., disposition of waste, etc.)?

- 2. Inputs to the Decision--**(The sources of the 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 [i.e., 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 Attachment E. For data validation requirements, see Attachment F. What additional QA/QC is requested?)

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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 the 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 [i.e., 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? 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 Attachment F. What additional QA/QC is requested?)

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Table D.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? (WM for characterization purposes? WM to determine TSD options? WM 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 (i.e., disposition of waste, etc.)?

- 2. Inputs to the Decision--**(The sources of the data and information used to make the decision.)
 - What historical data 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, 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 liability for making an incorrect characterization 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 Attachment F. What additional QA/QC is requested?)

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Attachment E
DATA QUALITY REFERENCE LIST
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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 Attachment D, Step 5, or the DQO Process, Step 7. 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 attachment 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 Attachment 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 Attachment 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 attachment and in Attachment 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. Attachment F provides additional explanation and examples for the categories.

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 reviewed during data assessment.

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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 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 and analytical 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 collection and analysis.

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

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DATA QUALITY REFERENCE LIST
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DATA QUALITY REFERENCE LIST		
Data Quality Element	Minimum For: Screening (S) Definitive (D)	PARCCS
Field Sampling Quality Control Sample Logbooks Sample Chain of Custody (COC) Transcription - Logbook vs. COC Containers Preservation Field Duplicates Trip Blanks (VOA Only) Field Blanks Equipment Rinseates Sampling Completeness Requirement	S, D S, D S, D S, D S, D S, D (5% Min for S, D) S, D (5% Min for S, D) S, D (5% Min for S, D) S, D (5% Min for S, D)	Representativeness, Completeness Representativeness, Completeness Representativeness, Completeness Representativeness Representativeness Precision Accuracy Accuracy 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 Calibration Check of Instrument Calibration Range Reporting Detection Limits (Method) Analytical Error Determination Laboratory COC Transcription COC vs Samples Holding Times Analytical Method Method Units Calculation Verifications Transcription-Lab data vs. EDD/Report Analytical Completeness Requirement Lab Duplicates Blank Duplicates Reagent Blanks Method Blanks Spikes/Laboratory Control Samples Matrix Spikes Matrix Spike Duplicates Post Digestion Spikes Performance Samples Interference Check Samples	S, D S, D S, D S, D D S, D S, D S, D S, D S, D S, D D S, D S ^b , D ^b D D ^b D ^b D ^b D ^b D ^b D ^b D ^b D ^b S ^b , D ^b D ^b	Accuracy Accuracy Accuracy Comparability, Sensitivity Precision, Accuracy Representativeness, Completeness Representativeness, Completeness Representativeness, Comparability Comparability Accuracy, Comparability Representativeness, Completeness Representativeness, Completeness Precision Accuracy, Precision Accuracy Accuracy Accuracy Accuracy Precision Accuracy Precision, Accuracy Accuracy Accuracy

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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	D	
Lab duplicates*	D	
Reporting Detection Limits	D	
Former Level III Data Package	These data packages include minimum definitive data elements plus additional information.	
Former Level IV Data Package		
Former Level V Data Package		
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 logbooks, chain of custody forms, 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 Attachment F.

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

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Attachment F
OPTIONS FOR DATA REVIEW
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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 attachment 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 attachment.

DATA VERIFICATION

Data verification is the first step of data review. The preferred method for performing verification is electronic. Verification criteria are documented using Attachment G. 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 attachment 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

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.

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**Attachment F
OPTIONS FOR DATA REVIEW
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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, 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 in Attachment G. 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.

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REVIEW OPTIONS AND APPLICABILITY

Data Category	Examples for Generation of Category	Former Level of Data	Data Verification	Data Validation	Data Assessment
Screening Data S1	OVA Qualitative	Level I or A	100% Grade 1 or None Review only the sample results presented.	NA	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 Attachment G.	NA	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%

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Attachment G
DATA ASSESSMENT REVIEW CHECKLIST AND COMMENT FORM
Page 1 of 4

(Pages 3 and 4 of the attachment contain a full size copy of the form and may be used directly. It has no headers.)

INTRODUCTION

The Data Assessment Review Checklist will be used by applicable data review personnel (i.e., the Data Reviewer, Lab Coordinator, and QA Reviewer) to perform data assessment on a particular set of data. The purpose of this attachment is to document the **Data Quality Checks** and results of the review performed during **Data Assessment**.

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 step where the Data Quality Check is evaluated. The Data Quality Checks are divided on the Data Assessment Review Checklist under the appropriate question to which it applies.

Data Quality Checks in the Data Review Process		
Data Verification	Data Validation	Data Assessment
<ul style="list-style-type: none"> • analytical method • method units • detection limits • holding times • analytical completeness 	<ul style="list-style-type: none"> • initial and continuing calibration and the associated calibration range • analytical error determination • laboratory COC • calculations • laboratory duplicates • blank duplicates • reagent blanks • method blanks • spikes/laboratory control samples • matrix spikes/matrix spike duplicates • postdigestion spikes • performance samples • interference check samples 	<ul style="list-style-type: none"> • sample logbooks • chain of custody records • containers • preservatives • field duplicates • trip blanks • refrigerator blanks • field blanks • equipment rinseates • sampling completeness • data quality objectives

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Attachment G
DATA ASSESSMENT REVIEW CHECKLIST AND COMMENT FORM
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INSTRUCTIONS FOR COMPLETING THE ATTACHMENT

The **Project ID** and **Project Title** are to be documented by the **Data Coordinator** at the top of the attached form, “Data Assessment Review Checklist.”

The **Data Quality Checks** are indicated on the form by the shaded rows and are completed by either the **Lab Coordinator** or the **Data Reviewer**. The first items to be completed on the form are the Data Quality Checks related to Data Verification. The Lab Coordinator completes the checks related to Contractual Screening. These checks include **Analytical Method, Method Units, Detection Limits, Holding Times, and Analytical Completeness**. The **Sampling Completeness** check is completed by the Data Reviewer. Upon completion of performing the data verification steps, the Lab Coordinator and Data Reviewer will initial and date the appropriate row, make any clarifying comments in the **Comments** column, document any significant information, comments, or questions by e-mail or with the “Data Assessment Comment Form” on page 4 of Attachment G.

The Data Validation Coordinator will check the analytical/measurement quality control elements during Data Validation (see table on page 1 of Attachment G for a listing). If data validation was not performed for the data set, the Data Validation Coordinator will indicate “N/A.”

The Data Reviewer will check the field sampling quality control elements during Data Assessment (see table on page 1 of Attachment G for a listing) based upon information received from the Sampling group. If specific field sampling quality control elements were not performed for the data set, the Data Reviewer will indicate “N/A.”

The Item column provides the major questions needed to perform data assessment. The Data Reviewer will proceed to review the information provided by the Lab Coordinator and Data Validation Coordinator, will review the data set, and answer Question 1 through Question 12 on the “Data Assessment Review Checklist.” The appropriate answer to the question will result in one of the **YES, NO, or N/A** columns being checked, and if necessary for explanation purposes, additional information written in the **Comments** column. Any significant information, comments, or questions must be documented either by e-mail or with the “Data Assessment Comment Form.” If any data assessment qualifiers are applied during the review of the data, a “check mark” will be placed in the last column, denoted by the “*” to aid the Data Coordinator in ensuring the placement of the assessment qualifiers in the database. Once all questions are answered, the Data Reviewer will complete the form by signing on the “Data Assessment Performed By” signature.

The **QA Reviewer** is responsible for performing a final review of the data set and verifying that all issues and questions are resolved and that the checklist is complete. The QA Reviewer will complete the “Data Assessment Review Checklist” by signing on the “QA Reviewer” signature.

DATA ASSESSMENT REVIEW CHECKLIST

Data Project Number:			Data Project Title:				
ITEM			YES	NO	NA	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	Lab Coordinator:	Date:				
	Method Units	Lab Coordinator:	Date:				
	Detection Limits	Lab Coordinator:	Date:				
2. Have the impacts of holding time violations been evaluated?							
Data Quality Checks	Holding Times	Lab Coordinator:	Date:				
3. Is data complete as planned?							
Data Quality Checks	Analytical Completeness	Lab Coordinator:	Date:				
	Sampling Completeness	Data Reviewer:	Date:				
DATA VALIDATION							
4. Does data validation indicate that data is useable?							
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/Refrigerator Blanks (VOAs Only)	Data Reviewer:	Date:				
	Field Blanks	Data Reviewer:	Date:				
	Equipment Rinseates	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 impacts of data qualifiers and laboratory comments from field samplers and laboratory technicians been considered?							
Data Quality Checks	Sample Logbooks	Data Reviewer:	Date:				
	Sample Chain of Custody	Data Reviewer:	Date:				
	Containers/Preservatives	Data Reviewer:	Date:				
8. Is data reasonable when compared to known/expected levels?							
9. Have outliers been evaluated to determine the possible cause?							
10. Is data of adequate quality to be used?							
DECISION DETERMINATION							
11. Was this data generated according to Procedure "Quality Assured Data" and is data "Data of Known Quality?"							
12. Can current decision be made from this data based on this review?							
Data Assessment Performed By:							
Data Reviewer: _____			Date: _____				
(Performed assessment and data can be made available for final reporting.)							
QA Reviewer: _____			Date: _____				
(Reviewed and verified completion of assessment)							
* Place a "check mark" in this column if assessment qualifiers are applied to the data.							

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Attachment H
PADUCAH DATA RELEASE TO EXTERNAL AGENCIES
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(Page 2 of the attachment contains a full size copy of the form and may be used directly. It has no headers.)

PADUCAH DATA RELEASE TO EXTERNAL AGENCIES

Data Reviewer:	Project ID:
Project Title:	
<p>Data Quality Level:</p> <p><input type="checkbox"/> 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 PRS-ENM-5003.</p> <p><input type="checkbox"/> 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.</p>	
<p><input type="checkbox"/> Approval for Release to:</p> <p style="margin-left: 150px;">1. _____</p> <p style="margin-left: 150px;">2. _____</p> <p style="margin-left: 150px;">3. _____</p> <p>(List specific organizations to release to.)</p> <p><input type="checkbox"/> Not Approved for Release: _____</p> <p style="margin-left: 150px;">(Explanation)</p> <p>(Attach necessary documentation for additional release criteria.):</p>	
<p>Data Reviewer (or Designated Alternate): _____ Date: _____</p> <p>(Signature Required)</p> <p>Site DC: _____ Date: _____</p> <p>Site TIO: _____ Date: _____</p>	
<p>The original form is to be included in the data assessment package and provided to the Data Manager. If this dataset is not being released to any External Agencies, single-line through the DC/TIO signatures and initial this form.</p>	