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Energy Systems Environmental Restoration Program
ORNL Environmental Restoration Program

**Technical Management Plan for Sample Generation, Analysis, and
Data Review for Phase 2 of the Clinch River
Environmental Restoration Program**

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Date Issued—March 1994

Prepared by
Environmental Sciences Division
Oak Ridge National Laboratory
ESD Publication 4226

Prepared for
U.S. Department of Energy
Office of Environmental Restoration and Waste Management
under budget and reporting code EW 20

OAK RIDGE NATIONAL LABORATORY
Oak Ridge, Tennessee 37831-6285
managed by
MARTIN MARIETTA ENERGY SYSTEMS, INC.
for the
U.S. DEPARTMENT OF ENERGY
under contract DE-AC05-84OR21400

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ABBREVIATIONS

APO	Analytical Projects Office
ASC	Analytical Services Coordinator
CAVEAT	Computer Assisted Validation Evaluation Technique
CCS	contract compliance screening
CLP	Contract Laboratory Program
CR-ERP	Clinch River Environmental Restoration Program
CRRI	Clinch River Remedial Investigation
DC	Data Coordinator
DMC	Document Management Center
DOE	U.S. Department of Energy
DQO	data quality objective
EDS	Electronic Data Specialist
Energy Systems	Martin Marietta Energy Systems
ER	Environmental Restoration
FCOC	field chain-of-custody
FCTM	field collection task map
FVC	Field Validation Coordinator
GPS	Global Positioning System
ID	identifier
IMC	Information Management Coordinator
IMG	Information Management Group
IV	Inorganic Validator
IVC	Inorganic Validation Coordinator
LCOC	laboratory chain-of-custody
LPTM	laboratory processing task map
LQAP	laboratory quality assurance plan
MPR	monthly progress report
ORNL	Oak Ridge National Laboratory
ORR	Oak Ridge Reservation
OV	Organic Validator
OVC	Organic Validation Coordinator
PCB	polychlorinated biphenyl
PE	performance evaluation
PEC	Programmatic Exception Coordinator
PER	programmatic exception report
QA	quality assurance
QAC	Quality Assurance Coordinator
QAS	Quality Assurance Specialist
QC	quality control
RV	Radiological Validator
RVC	Radiological Validation Coordinator
SAR	sample analysis request
SAP	sampling and analysis plan
SDG	sample delivery group

SIC	Sample Information Coordinator
SIS	Sample Information Specialist
SOP	standard operating procedure
SOW	statement of work
VC	Validation Coordinator

EXECUTIVE SUMMARY

The Clinch River Remedial Investigation (CRRRI) is designed to address the transport, fate, and distribution of waterborne contaminants (radionuclides, metals, and organic compounds) released from the U.S. Department of Energy's (DOE's) Oak Ridge Reservation (ORR) and to assess potential risks to human health and the environment associated with these contaminants. The remedial investigation is entering Phase 2, which has the following items as its objectives:

- define the nature and extent of the contamination in areas downstream from the DOE ORR,
- evaluate the human health and ecological risks posed by these contaminants, and
- perform preliminary identification and evaluation of potential remediation alternatives.

This plan describes the requirements, responsibilities, and roles of personnel during sampling, analysis, and data review for the Clinch River Environmental Restoration Program (CR-ERP). The purpose of the plan is to formalize the process for obtaining analytical services, tracking sampling and analysis documentation, and assessing the overall quality of the CR-ERP data collection program to ensure that it will provide the necessary building blocks for the program decision-making process.

1. INTRODUCTION

The Clinch River Remedial Investigation (CRRRI) is designed to address the transport, fate, and distribution of waterborne contaminants (radionuclides, metals, and organic compounds) released from the U.S. Department of Energy's (DOE's) Oak Ridge Reservation (ORR) and to assess potential risks to human health and the environment associated with these contaminants. The remedial investigation is entering Phase 2, which has as its objectives the following:

- define the nature and extent of the contamination in areas downstream from the DOE ORR,
- evaluate the human health and ecological risks posed by these contaminants, and
- perform preliminary identification and evaluation of potential remediation alternatives.

These objectives are presented in the CRRRI *Phase 2 Sampling and Analysis Plan, the Quality Assurance Project Plan, and Health and Safety Plan*.

2. SCOPE

This plan describes the requirements, responsibilities, and roles of personnel during sampling, analysis, and data review for the Clinch River Environmental Restoration Program (CR-ERP). The purpose of the plan is to formalize the process for obtaining analytical services, tracking sampling and analysis documentation, and assessing the overall quality of the CR-ERP data collection program to ensure that it will provide the necessary building blocks for the program decision making process. Additional information on electronic data management processes may be found in the *Functional System Design for the Clinch River Remedial Investigation (CRRI) Information Management System* (draft).

3. ORGANIZATION AND RESPONSIBILITIES OF PROJECT PERSONNEL

The staff organization that has been designated to fulfill the responsibilities as defined below is summarized in Appendix A.

Program Manager

The **Program Manager** defines the intended and potential uses of the data by directing the development of the data quality objectives (DQOs) in the site Sampling and Analysis Plan (SAP). If departures from the SAP are identified, the Program Manager meets with quality assurance (QA) personnel and reviews documentation for the purpose of concurrence or nonconcurrence with the decisions. The Program Manager ensures that deviations are documented appropriately. If necessary, the Program Manager instructs the Analytical Services Coordinator (ASC) to cancel analysis of samples affected and to write a letter confirming cancellation of analysis to the analytical laboratory.

Information Management Group and Information Management Coordinator

The **Information Management Group (IMG)** is responsible for the design, implementation, and maintenance of the electronic data base. The IMG loads the project data into the data base and makes all authorized corrections to the data base. The IMG develops programs to load, process, and report project data. The **Information Management Coordinator (IMC)** is responsible for coordination of the data base activities.

Task Leader

The **Task Leader** assists in defining the intended and potential uses of the data by participating in the development of the DQOs in the site SAP. The Task Leader works with the ASC to prepare statements of work (SOWs), initiates and approves task maps, and ensures that chain-of-custody (COC) and sample analysis requests (SARs) are properly completed and cross-referenced prior to transfer of sample custody. The Task Leader reviews the analytical data for completeness and maintains records in accordance with the data management plan. The Task Leader also ensures 100% accountability for samples collected, analyzed, archived, and finally disposed of. A separate Task Leader is assigned to each matrix to be sampled.

Field Sampling Team Leader

The **Field Sampling Team Leader** assists in the preparation of the SAP and its implementation. He or she coordinates the actual content of the field logbooks; assigns sampling team members to teams; coordinates and prepares for field sampling activities; and oversees all field data collection, recording, and documentation activities. The Field Sampling Team Leader performs a QA review of all sampling documentation and ensures that any recording errors are corrected by the sampling team member, signed, and dated. The Field Sampling Team Leader indicates in the logbook whether the SAP was followed. If not, he/she records any departure and justification for the departure in the field logbook. The Field Team Leader reviews the daily file and conducts or directs electronic entry of sample collection

information into the bar code reader. The Field Sampling Team Leader also directs the submittal of daily files and all electronic information to the IMG. If departures are identified, the Field Sampling Team Leader meets with the Task Leader or Program Manager and recommends whether the departure requires the generation of a programmatic exception report (PER). If so, the Field Sampling Team Leader generates the PER or instructs the responsible sampling team member to do so.

Field Sampling Team Members

The **Field Sampling Team Members** collect field samples and quality control (QC) samples specified by the SAP and detailed on field collection task maps (FCTMs), complete logbooks and field COC (FCOC) forms for all samples, and perform field instrument calibration and field analyses. Field sampling team members may serve concurrently as preparation laboratory personnel.

Sample Information Coordinator

The **Sample Information Coordinator (SIC)** is responsible for (1) development and testing of both field and laboratory task maps, following guidance from the Phase 2 SAP, and input from the task leaders; (2) development and testing of additional forms [e.g., FCOCs and laboratory COCs (LCOCs), sampling schedules, sample collection information forms] used for transfer of information from initial task leader requests to sampling personnel, field data collection, and transfer of all field and processing laboratory information to the ASC and IMG; (3) testing and implementation of application hardware (i.e., bar code readers) and software; (4) development, testing and implementation of hard-copy-based daily files; (5) overseeing and training personnel in completion of forms, recording of field and lab information, integration of information and transmittal of information to the IMG and/or ASC, as appropriate; (6) in conjunction with the Field Sampling Team Leader, directing the creation, completion, and control of all documentation contained within the daily files; (7) custodial control of the bar coded sample identifier (ID) numbers and document control numbers; and (8) overseeing packaging of the samples for shipment.

Sample Information Specialist

The **Sample Information Specialist (SIS)** is responsible for (1) receiving the Weekly Sample Schedule, (2) establishing event files, (3) generating the FCTM and obtaining sample ID numbers to complete the form, (4) supplying the Preparation Laboratory Team Leader with this FCTM to begin preparation of sample kits, (5) generating FCOC forms, (6) conducting or directing electronic entry of sample collection information into the bar code reader, in conjunction with the Field Sampling Team Leader, (7) generating the Laboratory Processing Task Map (LPTM) and obtaining sample ID numbers to complete this form, (8) supplying the Preparation Laboratory Team Leader with this LPTM to begin preparing the laboratory for processing, (9) conducting or directing completion of daily files, (10) directing the submittal of daily files and all electronic information to the IMG, (11) tying up any loose ends in support of the Field Sampling Team Leader and Task Leaders.

Preparation Laboratory Team Leader/Members

The **Preparation Laboratory Team Leader and team members** direct the preparation of equipment for each sampling event. They also prepare aliquots of field samples for required

analyses by the analytical laboratory, record the date when a sample was processed on the LPTM, and assist the SIC and ASC in shipping samples to the analytical laboratories for analysis. Field sampling team members may serve concurrently as preparation laboratory personnel.

Analytical Laboratory

The **Analytical Laboratory** generates a letter of receipt indicating sample delivery group (SDG) information for each group of samples to be analyzed, analyzes the samples in accordance with the project SOW, and generates final hardcopy and electronic deliverables.

Laboratory Sample Receiving Personnel

The **Laboratory Sample Receiving Personnel** receive and take custody of samples; check and verify COC information about samples on containers, labels, and FCOC forms; check and record information about the condition of samples upon receipt at the laboratory; log in samples as they arrive at the laboratory; and initiate an internal LCOC.

Martin Marietta Energy Systems Analytical Projects Office

The **Martin Marietta Energy Systems (Energy Systems) Analytical Projects Office (APO)** develops SOWs for analytical services, determines appropriate analytical protocols to be applied to meet the DQOs, and develops technical and quality standards for requested analytical services. The APO determines the appropriate laboratories with which to place work, negotiates scheduling of provision of services and oversight to ensure that the schedule is met, assesses laboratories to ensure compliance with quality and technical standards, and ensures appropriate data transmittal to the program customer.

Analytical Services Coordinator

The **ASC** coordinates the development of applicable SOWs to procure Energy Systems or subcontract technical services to support CR-ERP and verifies that methods specified are appropriate for meeting DQOs. He or she also participates in evaluations of potential suppliers of subcontract services and reviews the results of the APO pre-award audits of contract analytical laboratories.

The **ASC** serves as a receiving and review point for all laboratory data and ensures that laboratory supplemental QC data are placed in program files. He or she ensures that the laboratory data are properly validated and verified in accordance with the CR-ERP QA requirements. The **ASC** is responsible for assembling and organizing the validation personnel. The **ASC** acts as the coordinator of the data validation program and must approve any deviations or modifications to the program. It is also the responsibility of the **ASC** to report any quality related issues to project and program management and affected staff. The **ASC** will also oversee preparation of analytical and validation corrective action documentation and PERs and will ensure that variance activities are initiated, completed, and documented appropriately.

Data Coordinator

The **Data Coordinator (DC)** is responsible for the sample documentation tracking program and tracks the analytical data from receipt from the laboratory to storage in the project files. This person also coordinates verification and validation information and interfaces with the CR-ERP Document Management Center (DMC) and also the IMG. The DC is responsible for reviewing the documentation that is received from the field team and the analytical laboratories for adherence to data deliverable requirements. The DC is also responsible for reporting any quality related issues to the ASC. The DC delivers copies of field logbook sheets containing assigned data qualifiers to the IMG. The DC ensures that all SDG data packages, diskettes, Contract Laboratory Program (CLP) Contract Compliance Screening (CCS) reports, Computer Assisted Validation Evaluation Technique (CAVEAT) reports, and data validation reports are maintained and complete. The DC ensures the effective and efficient flow of information and is responsible for tracking the complete validation process.

Program Exception Coordinator

The **Program Exception Coordinator (PEC)** is responsible for ensuring that all programmatic exceptions are tracked. The PEC also reports any quality related issues to the appropriate personnel. The PEC maintains the PER data base and produces reports as directed by the DC.

Electronic Data Specialist

The **Electronic Data Specialist (EDS)** is responsible for interfacing with laboratory personnel concerning problems with electronic deliverables.

Data Inventory Specialist

The **Data Inventory Specialist** receives a photocopy of the data package from the DC with the appropriate data inventory checklist. He or she reviews the data packages following prescribed procedures using the standardized checklists and returns the inventoried data package to the DC with review notes and any PER forms that may have been initiated as a result of the inventory process. If the data package is not a CLP deliverable, the Data Inventory Specialist manually performs the CCS process and generates summary reports for use by the data validator. The Data Inventory Specialist also participates in the QA/QC process to resolve PERs as necessary.

Screening Specialist

If the data package is a CLP deliverable and the data have been submitted in an electronic format, the **Screening Specialist** performs electronic compliance screening using CCS software and performs electronic data validation using CAVEAT to electronically generate summary reports to be used by the data validator. The Screening Specialist also participates in the QA/QC process to resolve PERs as necessary.

Data Assessor

The **Data Assessor** reviews and analyzes all the collected data according to the project DQOs and evaluates precision, accuracy, representativeness, completeness, comparability, and sensitivity parameters in order to determine final data confidence and useability.

Validation Coordinator

The **Validation Coordinator (VC)** is responsible for ensuring that the data validation is performed according to the CR-ERP SAP and requirements laid out in this document. The VC is responsible for assembling the analytical validation team and preparing the project-specific criteria for the validation for review and approval by the ASC. The VC is also responsible for ensuring that validation is performed in a timely and cost-effective manner. The VC is responsible for reporting any quality related issues to the ASC.

Field Validation Coordinator

The **Field Validation Coordinator (FVC)** is responsible for ensuring that the field data validation is performed according to CR-ERP requirements. The FVC is responsible for assembling the field validation team and preparing the project-specific criteria for the field validation, with the approval of the ASC. The FVC is also responsible for ensuring that validation is being performed in a timely and cost-effective manner. The FVC is responsible for reporting any quality related issues to the ASC.

Field Validator

The **Field Validator** verifies the accuracy, completeness, legibility, consistency, and clarity of the field logbook entries according to the specified requirements; reviews all supporting documentation; assigns qualifiers to field data; and enters the qualifiers on copies of logbook sheets. If appropriate, the Field Validator initiates a PER. Field validation deliverables are delivered to the ASC and transferred to the DC for submission to the DMC. The Field Validator signs and dates his or her notes or worksheets to certify completion of the validation.

Organic Validation Coordinator

The **Organic Validation Coordinator (OVC)** is responsible for the validation of organic data. The OVC either assembles personnel to assist in the validation or performs the validation. The OVC is also responsible for reporting any quality related issues to the VC.

Organic Validators

The **Organic Validator (OV)** is responsible for performing the validation on organic data. The validator evaluates QC information relative to technical and analytical viability. The OV is responsible for initiating action items found during the validation process, reporting any quality related issues to the OVC, generating PERs, and participating in QA/QC activities to resolve PERs, as necessary. The validator is responsible for assigning qualifiers to the data as part of the validation process.

Inorganic Validation Coordinator

The **Inorganic Validation Coordinator (IVC)** is responsible for the validation of the inorganic data. The IVC either assembles personnel to assist in the validation or performs the validation. The IVC is also responsible for reporting any quality related issues to the VC.

Inorganic Validators

The **Inorganic Validator (IV)** is responsible for performing the validation on the inorganic data. The validator evaluates QC information relative to technical and analytical viability. The IV is responsible for initiating action items found during the validation process, reporting any quality related issues to the IVC, generating PERs, and participating in QA/QC activities to resolve PERs, as necessary. The validator is responsible for assigning qualifiers to the data as part of the validation process.

Radiological Validation Coordinator

The **Radiological Validation Coordinator (RVC)** is responsible for the validation of the radiological data. The RVC either assembles personnel to assist in the validation or performs the validation. The RVC is also responsible for reporting any quality related issues to the VC.

Radiological Validator

The **Radiological Validator (RV)** is responsible for performing the validation on radiological data. The RV evaluates QC information relative to technical and analytical viability. The RV is responsible for initiating action items found during the validation process, reporting any quality related issues to the RVC, generating PERs, and participating in QA/QC activities to resolve PERs, as necessary. The validator is responsible for assigning qualifiers to the data as part of the validation process.

Validation Oversight Team

The **Validation Oversight Team** provides technical input and review during the course of the validation and a final review of some of the data packages. The team or designee reviews the data package to ensure that the qualification of the data is based on sound rationale and is reasonable and reports action items and concerns to the CR-ERP ASC.

Validation Oversight Coordinator

The **Validation Oversight Coordinator** is the individual designated to lead the Validation Oversight Team and to interface with CR-ERP staff. He or she serves with the team and is responsible for initiating and/or following up activities to ensure that oversight is completed, as necessary. It is expected that the individual will be a part of APO or the Analytical Environmental Support Group.

Quality Assurance Coordinator

The QA Coordinator (QAC) reviews each PER report for concurrence. The QAC also evaluates the effectiveness of QA activities in the program through scheduled audits and surveillances.

QA Specialist

The QA Specialist (QAS) provides guidance to resolve quality problems and ensures that corrective action is taken and appropriately documented in response to programmatic exceptions. He or she also evaluates the effectiveness of QA activities in the program through scheduled audits and surveillances.

4. IDENTIFICATION OF ANALYTICAL SERVICES REQUIREMENTS

An analytical service packet is prepared based on *Requirements for Quality Control of Analytical Data for the Environmental Restoration Program*, ES/ER/TM-16, and the CRRI SAP that includes the following information.

- APO SOW**
- CR-ERP SOW**
- methods and quantitation limits**
- sample log in form**
- sample preservation, holding times, and containers**
- summary of QC requirements**
- required deliverables**
- reporting forms**
- electronic data specifications (EDS)**
- anticipated level of radioactivity**
- purchase requisition number**

The analytical service packet is distributed to the appropriate Task Leader, IMC, the CR-ERP Program Manager, the CR-ERP QAC, the Environmental Restoration (ER) Division QAS, the APO, and any other appropriate technical reviewers, as applicable. When all questions have been addressed, the analytical service packet is transferred to the APO for procurement of analytical services.

5. SELECTION OF ANALYTICAL LABORATORIES

The SOW is sole-sourced, placed with an internal laboratory, or placed out for bid under the Energy Systems Pricing Agreement. The laboratory is selected based on the low bid and any exceptions that are placed on the work by the laboratory. After the laboratory is selected, the ASC or designee will

- have the final SOW signed;
- review the Laboratory Quality Assurance Plan (LQAP);
- review laboratory standard operating procedures (SOPs), as available;
- review APO audit reports;
- schedule or request other audits as necessary;
- review the laboratory's performance evaluation (PE) package;
- review cost estimates with financial personnel;
- conduct a readiness review with the laboratory, as needed; and
- resolve laboratory corrective actions.

If the laboratory is not part of the Energy Systems Pricing Agreement, then the procurement steps in SOP1030 will be followed. Approval of all CR-ERP procurement contracts is the ultimate responsibility of the CR-ERP Program Manager.

The analytical laboratory provides monthly progress reports (MPRs) to the APO and the ASC. The MPRs summarize laboratory throughput and quality issues. The laboratory must address any problems identified immediately, and work by the laboratory may be stopped while problems are resolved. Follow-up audits and surveillances may be performed. In addition, laboratories approved by the APO must successfully participate in evaluation over the duration of its ER work, including periodic audits.

6. TRACKING OF ANALYTICAL SERVICES

The processes of sampling and analysis and their results must be tracked from the time of approval of the SOW to the disposal of the samples. Maintaining contact with the laboratory is essential so that the progress of analysis can be monitored and early warning can be given of potential exceedances of holding times or delays in delivery of data packages. With assistance from the APO and data base personnel, the ASC and DC track the samples, results, and associated documentation and resolve any problems. Periodic printouts are available that will track the following processes:

Placement of SOW

- APO SOW umber
- project SOW umber
- SOW APO number
- matrix
- laboratory turnaround time
- laboratory identification
- cost per sample or analysis
- method identification
- laboratory city
- laboratory state
- laboratory contact
- laboratory contact telephone number
- laboratory fax number
- laboratory street
- laboratory zip code
- sample preparation holding time
- sample analysis holding time
- method maximum preparation holding time
- method maximum analysis holding time
- method preservative
- method container type
- task identification
- maximum number of samples per SOW
- SOW charge number
- SOW purchase request number
- SOW funding amount

Sample Custody

FCOC

- sampling date

LCOC

- number of samples per analysis type
- SDG number
- field sample ID

Field Validation

date field validation package inventoried
date field validation completed

Shipment of Samples

sample shipment date
sample shipment container
sample shipment laboratory receipt date
laboratory notification of sample shipment

Receipt of Samples by the Laboratory

date samples received by the laboratory
data deliverables due date
analytical batch number
laboratory sample ID

Verification of Receipt of Samples by the Laboratory

date COCs received from laboratory

Verification of Field QC Sample Analysis

date field QC results received

Audits and Surveillances

date scheduled for laboratory audit
date scheduled for validation audit
date of laboratory audit
date of validation audit

Verification of Receipt of Hard Copy Data from Laboratory

date hard copy data received from laboratory
date hard copy data inventoried

Verification of Receipt of Electronic Data from Laboratory

date electronic data received from laboratory
date electronic data copied and received by IMG

Transfer of Hard Copy Data to DMC

date hard copy data package transferred to DMC

Transfer of Electronic Data to IMG

date electronic data transferred to DMC

Receipt of Data by Data Validator

date electronic data transferred for CCS, CAVEAT
date hard copy data package transferred to validator

Receipt of Data from Data Validator

date hard copy validation deliverables received from validator
date automated reports received
date automated reports received from IMG
date electronic validation flags received from validator

Resolution of Exceptions

date each PEK closed

Data Assessment

date validation package and deliverable transferred to oversight team
data case file inventoried
date case file transferred to data assessor
data assessor(s) (could be multiple)

7. DEVELOPMENT OF SPECIFIC VALIDATION REQUIREMENTS

The following requirements will serve as the basis for data review and validation for Phase 2 of the CRRI:

- *Phase 2 SAP, Quality Assurance Project Plan, and Health and Safety Plan for the Clinch River Remedial Investigation: An Addendum to the Clinch River RCRA Facility Investigation Plan, DOE/OR/01-1111&D3;*
- *Requirements for Quality Control of Analytical Data for the Environmental Restoration Program, ES/ER/TM-16;*
- applicable analytical services packet, including all SOWs;
- analytical methods; and
- FCOCs and LCOCs.

The validators will be required to develop procedures with worksheets and checklists applicable to each method and analysis type using the documents above and any additional criteria listed in Table 7.1.

Table 7.1. Additional validation criteria

Analysis type	Additional criteria (use latest version)
Radiological analyses	<i>Laboratory Data Validation Guidelines for Evaluating Radionuclide Analyses, SAIC</i>
Inorganics (metals, cyanide)	<i>EPA Functional Guidelines</i>
Pesticides/PCBs	<i>EPA Functional Guidelines</i>
Semivolatiles	<i>EPA Functional Guidelines</i>
Wet chemistry (ammonia, anions, TKN, TOC)	None available
Mercury speciation	None available
Fish—pesticides/PCBs	None available
Fish—metals	None available
Fish—semivolatiles	<i>EPA Functional Guidelines</i>
Tissue—PCBs	<i>EPA Functional Guidelines</i>
Tissue—metals	<i>EPA Functional Guidelines</i>
Tissue—PCB congeners	None available

These procedures with accompanying worksheets and checklists will be submitted to the CR-ERP ASC for approval. The checklists or worksheets for a given method and analysis type will include standard remarks and flags relevant to the method and analysis type covered. The validator may request CR-ERP approval to apply additional remarks and/or flags if necessary, but all remarks and flags must be approved by the ASC before use.

Questions concerning validation requirements, discrepancies, or data anomalies will be resolved between the data validator or reviewer and the CR-ERP ASC and shall be documented in writing.

8. COLLECTION, PROCESSING, AND SHIPMENT OF FIELD SAMPLES

Flowcharts (Figs. 8.1, 8.2, and 8.3) depict the collection, processing, and shipment of field samples.

Preparation for Field Sampling

Based on the SAP, the Task Leaders will specify the procedures, preservation requirements, and containers needed for all sample types resulting from field and/or preparation laboratory activities. This information will serve as the basis for an application program which generates FCTMs and LPTMs. Initial maps for each task will be reviewed by the Task Leader and the ASC. Task maps, including all revisions, will be approved for distribution by the ASC and the Task Leader.

Reference tables with the contents for the FCTM and LPTM will be maintained in the CRRRI data base. Data base access controls will be used to prevent unauthorized changes to the tables. Write access to the tables will be limited to the IMC and designated EDS's. All changes to these tables will be recorded in transaction files that contain the date of change, person making the change, values before the change, and values after the change.

A **sampling schedule** is manually prepared each week by the Task Leader. This schedule will specify the task, sample location, sample date, number and type of samples to be collected, the Field Sampling Team Leader, and the Preparation Laboratory Team Leader. The schedule will be sent to the SIC, ASC, Field Sampling Team Leader, and IMC at least 5 working days prior to sampling.

The SIC (or designee) uses this schedule to complete a preliminary FCTM and LPTM, which are detailed maps laying out all the information necessary to collect and process samples according to the Phase 2 SAP. The SIC or SIS uses a data base application program to pull up a skeleton outline of the sampling and processing schemes for the task scheduled. The sample date, FCOC number, field logbook number, and pairs of site and sample types from the sample schedule are entered into the program.

The field sample ID numbers are assigned at this point. A roll of preprinted bar code stickers is supplied to the SIC to assign these numbers, following SOP2100 requirements. All sample ID numbers are retained in the data base and never reused, even if the sample is lost or broken. Therefore, these labels are under custodial control by the SIC, to avoid duplicate use. The SIC assigns the sample ID numbers to the FCTM and LPTM and removes those numbers from the roll of labels. The preliminary FCTM and LPTM are first reviewed by the ASC and Task Leader; after they are approved, they are then printed and given to the Preparation Laboratory Team Leader, along with the designated bar code labels, to prepare the sample kit. Copies of the task maps are also given to the ASC at this time. The preliminary task maps must be distributed at least two working days prior to sampling.

The Preparation Laboratory Team Leader assembles the appropriate number and type of containers needed for sample collection and processing for the task, attaches the bar code labels accordingly, and groups them (usually in a cooler). He or she then notes the lot number

Fig. 8.1. Flowchart depicting task flow for preparation of a sampling event.

Fig. 8.2. Flowchart depicting task flow for sampling documentation.

TASK
LEADER
(TL)

SAMPLING
TEAM
LEADER
(STL)

SAMPLE
INFORMATION
COORDINATOR
(SIC)

PREP LAB
TEAM LEADER/
MEMBERS

ANALYTICAL
SERVICES
COORDINATOR
(ASC)

ANALYTICAL
PROCUREMENT
OFFICE
(APO)

HEALTH
PHYSICS

ORNL
SHIPPING
DEPT.

ANALYTICAL
LAB TECHNICIAN
(ALT)

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Fig. 8.3. Flowchart depicting the task flow for sample preparation and shipping.

of each container on the task map and the kit preparation date on the FCTM, which is returned to the SIC or SIS.

The SIC or SIS updates the data base with the container lot numbers documented on the preliminary task maps by the preparation laboratory personnel. The task maps are now complete and ready to be assigned document ID numbers. A roll of preprinted bar code stickers is supplied to the SIC or SIS to assign these numbers. These numbers are never to be reused once assigned and are also under custodial control by the SIC to avoid duplicate use. The coordinator enters the next available document ID number into the data base. At this time the application program sets the sample status to "Planned." After the final task maps are received by the SIC or SIS, the document ID label is attached to the first page. Any continuation pages will have this document ID number printed at the bottom. Once the task maps are signed, they are controlled and tracked documents and the corresponding entries into the data base are under change control. Copies of the FCTM and LPTM are sent to the ASC.

A "surplus kit" of containers will also be prepared for the water and sediment tasks at the beginning of the project and restocked as necessary. This kit is taken out into the field to be used in case of loss or breakage of containers from the sample kit. These containers are prelabelled with bar coded sample ID numbers, but do NOT appear on any FCTM. They are listed in the data base as "Surplus" until their use is documented on an FCOC form. If a container is lost or broken, that sample ID number is crossed off the FCOC form in the field and replaced with the appropriate sample ID number. This surplus container usage is noted in the "remarks" section of the FCOC form. The status of this sample ID number is then changed from "Surplus" to "Collected" in the data base.

Field Sampling Documentation and Sample Processing

A sampling event is defined as a set of samples or measurements collected by a sample team on a given day. Field sampling is conducted by a Field Sampling Team Leader, a Sample Custodian, and Sampling Team Members. The Field Sampling Team Leader is primarily responsible for all aspects of a sampling event. The Sample Custodian is responsible for custody of all samples collected during that field day. Sampling Team Members and roles are tracked in the data base by sampling event and task.

Prior to sampling, an FCOC form is generated by the SIC or SIS to track the custody of all samples collected. All samples listed on the FCOC must be placed into a container in the field with a sample ID number attached. The FCOC accompanies the sampling team to the field and remains with the samples until their submittal for analysis or transfer to another COC form. Co-sampling with non-CRRI crews is possible for certain tasks. This situation is documented in the field logbook and defined in the FCTM. Preprinted sample labels and FCOC forms will be provided to these co-sampling crews.

These FCOC forms are generated by a data base application program. The SIC or SIS enters the names and roles of the sampling team into the program along with the sample kit ID assigned for this task. The application accesses the data base to obtain the information from the FCTM file. The FCOC form is now ready to be printed and assigned a document ID number. The SIC or SIS enters the next available document ID number into the data base, prints the FCOC, and attaches the label to the first page. Any continuation pages will have this document ID number printed at the bottom. The FCOC form is now a controlled

and tracked document and any corresponding modifications are under change control. Before a team goes out in the field, the Field Sampling Team Leader confirms that the field logbook has enough blank pages available to record the necessary field information for that day, which ensures that a particular sampling event will only have one field logbook associated with it.

When the team arrives at a sample location, the Global Positioning System (GPS) is activated to establish the site coordinates. Site locations are also marked on a photocopied map page as a supplement to the GPS. The Field Sampling Team Leader assigns tasks, such as data recording and sampling, to the team members. Sample collection information, such as sample ID number, site, time, and depth, are entered into the field logbook following SOP2000 requirements for each sample collected. This same information is later entered into the bar code reader to create an electronic file that will be used to generate a sample collection information form. If anything unusual occurs in the field that affects the sample collection, it is noted in the field logbook. If any information on the FCOC is inaccurate, such as sample location, a team member strikes through it, makes the necessary correction, signs and dates the correction. If a planned sample is not collected for any reason (inclement weather, no sediment, equipment malfunction), this is also noted in the field logbook. This sample ID number is struck through, initialed, and dated on the FCOC form, and an explanation is noted in the comments section. This number is then officially retired in the data base once the team returns from the field.

Upon return from the field, the Field Sampling Team Leader or designee transfers all electronic data to the IMC, along with a copy of the FCOC form. A copy of the FCOC is also distributed to the IMC and the ASC. The electronic field data and bar code reader data are transferred into working files on the project workstation. Data base application programs generate reports, which are sent to the SIC for comparison with the field logbook notes. Any errors are resolved by the Field Sampling Team Leader, and this report is returned to the IMG. The IMG will make any necessary changes to the working file and load this into the permanent data base. The sample collection information form is printed by the SIC or designee and signed, and the next available document ID number is attached. The form is then under document change control. The sample collection information form then becomes a part of the daily sampling event file.

The data base is also updated by the IMG to reflect any corrections or comments made on the FCOC form. Samples which are lost, retired, field only, or that the sampling team was unable to collect will have the sample status flag set accordingly. Statuses of "Lost" and "Unable to collect" will have comments noted on the FCOC form at the time of sampling and will be verified against the electronic bar code file.

Backup copies of the field logbook pages are made by the SIC or designee and submitted to the daily file, as requested. The Field Sampling Team Leader ensures that the field logbook is returned to a secure storage area after sampling is complete.

Sediment and water samples are transferred to the preparation laboratory for any processing required prior to shipment to the analytical laboratories. The LPTM includes information such as filtration method, the applicable SOP, container type, and any preservation required. When samples are processed, the Preparation Laboratory Team Member adds the date of the processing to the LPTM. This practice ensures that all planned samples are collected.

When the sample processing is done and the daily file is complete, the Field Sampling Team Leader completes the **field sampling review checklist**. The Field Sampling Team Leader resolves any concerns about the checklist with the Task Leader, documents this resolution on the checklist, signs it, and places it in the daily file. The Field Sampling Team Leader transfers the daily file to the ASC, who reviews it and signs the field sampling review checklist. The ASC then transfers the daily file to the DC. The DC processes the daily file, makes a copy for temporary storage in Building 1506, and transfers the original to the Field Data Validator.

When validation is completed, the Field Data Validator transfers the daily file and validation paperwork to the ASC. The ASC reviews the validation paperwork and transfers it and daily file to the DC. The DC submits the original daily file and validation paperwork to the DMC and distributes copies as needed.

Sample Shipment Preparation

As discussed previously, most of the samples collected from the field or created in the preparation laboratory are sent to external contract laboratories for chemical, radiological, or physical analysis. Prior to sampling, the ASC, in conjunction with the APO, selects analytical laboratories to perform the analysis required for the project. The ASC provides each laboratory with an SOW specifying the method, quantitation limits, list of target parameters, and holding time requirements.

Each sample is assigned to an SDG by the ASC for submission to an external laboratory. Each SDG consists of twenty or fewer samples. The SDG ID is equivalent to the lowest sample number for the LCOC. SDGs and consequently LCOCs and SAR forms are generated per laboratory per method per matrix, as applicable. The analytical laboratories may also assign a batch number based upon their internal procedures. Samples from one SDG could be analyzed in different batches but their results would be reported back to the project in one group. Fractions of a field sample may be analyzed by multiple laboratories during their existence. Field samples are divided in CR-ERP's preparation laboratory to provide the requisite number of sample fractions for analysis.

A Shipping File is compiled that contains all documentation involved in processing and transferring samples for analysis for any particular shipping date. All documentation must be cross-referenced using the APO SOW number and LCOC IDs. A checklist is used to verify completion of tasks (Appendix E).

The ASC and DC routinely query the tracking data base (ASAMPLE.DBF or other) to tally the number and type of samples awaiting shipment to an external laboratory. As needed, the ASC or designee assigns samples to an SDG and generates an LCOC form to accompany the samples to the laboratory. An LCOC contains samples from one and only one SDG, but an SDG may contain samples from multiple sampling events. Concurrently with generation of the LCOC, an SAR is also generated that contains the sample ID, matrix, method, analyses, turnaround time, project number, SOW number, APO number, and the shipping date. A copy of the SAR is faxed to the APO, which then issues a blanket shipping order, also by fax, to the ASC or designee, with a copy to the Oak Ridge National Laboratory (ORNL) Shipping Department. The DC must check the shipping order immediately on receipt from the APO for the correct shipping date, receipt date, and total number of samples to be shipped. The DC ensures that the Shipping Order includes the statement **"These**

samples are being maintained at 4°C with blue ice. One day shipping with morning delivery is essential."

The LCOC is generated by the ASC or designee using a data base application program, as available. The ASC or designee enters the SDG, an LCOC ID, laboratory name, shipping date, and the ID numbers of the samples to be grouped into the SDG. The LCOC ID is assigned as follows: LMMDDYYX where X is a numeral representing each individual LCOC generated for a particular shipping date (For example, if the shipping date is November 15, 1993, an LCOC ID would be L1115931). Sample shipment date is the date a sample is shipped to the analytical lab. The remaining information on the LCOC is obtained from the data base program. Each cooler is labelled with a CR-ERP identification number (e.g., CRR10001). A separate FoxPro data base (COOLER.DBF) is used to track the location and status of each cooler.

The DC faxes a notice of intent to ship samples and draft copies of the LCOC and the SAR to the analytical laboratory to notify them of the forthcoming shipment; the laboratory sends a return fax confirming that it will accept the samples. The DC assigns a document ID number to the LCOC and also to the SAR, places a copy of each form in the Shipping File, and delivers the original LCOC and sample shipment checklist to the SIC who directs preparation of the samples for shipment. The LCOC accompanies the samples until custody is transferred to the analytical laboratory's internal COC form.

Sample Container Packaging and Shipping

Samples will be shipped according to instructions contained in ESP-800 and ER/C-P2302.

Each sample container will be cleaned to remove sampled material from its exterior prior to packing for shipping (ESP-800).

The Task Leader confirms that the samples may be classified as environmental according to ER/C-P2302.

Each cooler will have a radiological survey and be cleared by Health Physics for shipment off site, per ER/C-P2302.

The SIC or designee will ensure that a sample label is attached to each bottle. Each sample bottle is double-bagged in plastic bags. As much air as possible is squeezed from the bags before sealing. Plastic, electrical, or evidence tape may be used to provide additional security. Glass containers will be separated with a divider, consisting of additional packing material or bubble wrap. Any variations must be approved by the Task Leader, with notification to the ASC.

The shipping cooler is prepared by taping the drain plug shut from the inside and outside; placing a large, heavy-duty plastic bag in the cooler to serve as a liner; and placing packing material in the bottom of the bag liner. Sponges included with the coolers may be used as packing material. Asbestos-free vermiculite, perlite, or styrofoam beads may also be used. The packing material must be compatible with the sample material being shipped.

As each sample is placed into a cooler, a checkmark must be placed beside each sample on the LCOC.

The SIC, or designee, must ensure that the coolers are properly labelled with the return address, cooler ID, and cooler number (e.g., cooler 1 of 3). The coolers should also be marked "FRAGILE" if the cooler contains glass. If a package contains liquids, the cooler should be marked "THIS SIDE UP" or "THIS END UP." All coolers should be marked with "OVERNIGHT DELIVERY." The SIC, or designee, records the cooler ID numbers on the LCOC forms. The original LCOC is signed, dated, and the time entered under "Relinquished by" by the SIC, or designee. A copy of the LCOC is made for the CR-ERP Shipping File. The original LCOC, SAR, copy of the Health Physics tag, a blank Sample Login Form, and a PER form should be placed in the first cooler of each shipment. The paperwork should be enclosed in a sealed plastic bag and taped to the inside of the cooler lid. The cooler is closed and taped with filament strapping tape. Two signed custody seals are placed on the cooler, one on the front and one on the back, in such a way that the seal must be broken if the container is opened. A copy of the LCOC, the SAR, the Shipping Order, and the Health Physics tag are placed in the shipping file.

Designated team members transport the coolers to the Shipping Department at Building 7001, ORNL, or to the designated Federal Express facility. If the coolers are shipped through ORNL, the Shipping Order and original Health Physics tag are delivered to Shipping Department personnel. Shipping personnel assign a Shipping Order Number to the shipment and notify the DC of the shipping order number. Airbill numbers are assigned by shipping personnel and placed on the outside of the cooler. A copy is made of all pertinent transportation documentation and placed in the shipping file.

When the samples are received at the laboratory, the analytical laboratory technician who accepts the incoming sample shipment will sign and date the LCOC and airbill, completing the sample transfer process. The analytical laboratory technician also documents the condition of the samples and seals on the login form. All documentation is placed in the project file for transfer to the CR-ERP. When the coolers are opened, the seals are broken and discarded.

Sample preservation, containers, and holding times are listed in Appendix B. Any problems associated with preservation, containers, or holding times must be reported to the ASC immediately.

Copies of the signed LCOC with airbill numbers and also the complete Shipping Order with signatures and requisition numbers are given to the SIC for inclusion in the Shipping File as soon as possible after sample shipment. The SIC transfers the Shipment File to the DC for follow-up. A copy of the signed LCOC is delivered by the DC to the IMG so that the data base can be updated if any samples planned for shipment were not shipped. Examples of forms are included in Appendix C.

QC Samples

For samples shipped to Brooks Rand, a trip blank prepared by Brooks Rand will be taken to the field and maintained with the samples through the sampling and shipping processes. One trip blank will be included for each sampling event involving mercury analyses. All other field and laboratory QC samples are addressed in the SAP, quality assurance project plan, or the specific SOW.

Receipt of Samples by the Laboratory

When samples are received by the laboratory, the laboratory staff will

- verify the airbill number for the shipment and record the number on the sample login form;
- verify the number of samples received, sample IDs, and requested analyses by checking the LCOC, SAR, and sample labels;
- note on the LCOC the condition of the samples at receipt;
- record the time and date of receipt and sign the LCOC;
- assign laboratory ID numbers to the samples and initiate laboratory internal COC;
- return a copy of the signed and dated LCOC with documentation that states the laboratory ID number for each sample cross-referenced to the CR-ERP sample ID, analyses planned, and any problems and their resolution;
- retain and file the airbill;
- retain the original LCOC for return with any remaining sample or when samples are disposed of; and
- retain and file a copy of the signed and dated LCOC for inclusion in the data package.

After samples are shipped, the DC will

- receive the Shipping File from the SIC;
- receive verification of receipt from the laboratory (copy of the signed and dated LCOC, laboratory assigned IDs, sample login sheet); and
- fax all COCs, SARs, and sample shipping receipts to the APO, with a copy also to the IMC.

The DC will also inventory the Shipping File according to the Sample Shipment Checklist (Appendix C).

9. INVENTORY OF FIELD DATA VALIDATION PACKAGES

The Field Validator and/or DC shall inventory each daily field data package and verify that all pertinent information is included, using the Field Data Package Checklist. The field data package shall contain the following, as applicable:

- weekly sampling schedule
- FCOC
- FCTM
- LPTM
- sample collection information form
- site maps
- geographic positioning system data
- field data forms
- field sampling review checklist
- copy of field logbook pages

Deliverables that should result from the field data package inventory are illustrated in Appendix D (sample event file inventory checklist).

10. VALIDATION OF FIELD DATA

Field data validation shall be conducted according to ER/CR-SOP2020 IAD, Rev. 0. The field data review consists of two parts. The first part, a field sampling and documentation review, occurs as soon as possible after sampling. The second part consists of a review of the field QC samples when the data are available from the analytical laboratory.

The Field Sampling Team Leader conducts and documents a review of field sampling activities as soon as reasonably possible after the responsible field personnel have completed those activities. An independent verification of the items listed on the field sampling review checklist will also be performed by a Field Validator, who is not a member of the sampling team. If appropriate, field data are flagged as indicated in the checklist.

If the Field Validator identifies any departures from the SAP, the reviewer meets with the QAC. The reviewer makes a recommendation as to whether the departure is serious enough to be considered a variance requiring generation of a PER. The QAC reviews the field logbook. If there is agreement that a PER is not required, the QAC records in the logbook the concurrence that a PER is not required and signs and dates the entry. If agreement cannot be reached, the departure is presented to the Program Manager for resolution.

If a PER is required, the reviewer initiates a PER with the assistance of the PEC. If necessary, the ASC cancels the analysis of affected samples. The reviewer is required to document the effects on the sample through the PER process. When the ASC receives a copy of the approved PER report, if necessary, sample analysis will be halted by sending a fax to the laboratory and telephoning the laboratory. The ASC follows up the fax and telephone call with a letter confirming the cancellation.

When the analyses are completed by the laboratory, the field QC results are examined by the Analytical Data Validator.

The Data Validator documents his or her findings on worksheets and in a review narrative and flags copies of logsheets or forms with appropriate qualifiers. When the review is complete and the qualifiers have been recorded on the copies of the documents, the Data Validator signs and dates the narrative to certify that the review has been conducted and transmits all documents to the DC. The DC or designee delivers copies of the documents with the qualifiers entered by the Data Validator to the data entry clerk, who enters the qualifiers into the data base via data entry screens. The data entry clerk verifies entries by performing a 100% review of electronic entries and the hard copy logsheets or by performing double data entry and running a compare program. The DC files all field data validation documentation.

Deliverables that should result from the field sampling review are listed below.

Part 1

- Field Sampling Review Checklist with supporting information (Appendix D)
- PERs (Appendix F)

Part 2

- See Section 21

11. ASSIGNMENT OF DATA VALIDATORS

The validation of data will be done by several organizations. The understanding of roles and responsibilities for each group is critical to the accuracy, timeliness, and completeness of the validation. SAIC personnel will perform data deliverable inventories, field validation, CCS and CAVEAT screening, and technical validation. Energy Systems personnel at ORNL will provide backup assistance for deliverables inventory, CCS, computer assisted validation evaluation, and analytical data validation. Energy Systems personnel will also assume primary responsibility for sample tracking and data assessment. See Appendix A for specific assignments of key personnel.

12. MANAGEMENT OF PROGRAMMATIC EXCEPTIONS

An exception can be identified at any step in the process of sampling, analysis, data reporting, and data review. Exceptions will be processed according to ER/CR-SOP1024, Rev. 0. The person who finds an exception completes a PER form and transfers the form to the PEC. The PEC delivers a copy of the form to the ASC, or designee, for concurrence. If the ASC does not concur, the PER is closed or the initiator makes whatever revision to the PER is required. When there is concurrence, a PER is opened by the PEC. The PER information is entered into the PER tracking data base. The PEC delivers the PER to the individual or organization responsible for causing the exception. The individual or organization reviews the PER and responds by recording the disposition, probable cause, and actions to prevent recurrence. The PER is returned to the PEC who distributes the completed form to a disposition team, which includes the initiator, for review of the response and approval or rejection. If the response is accepted, the PER is closed. If the response is rejected, the reason for rejection of the response is noted, and the PER is returned for further response by the responsible individual or organization. The steps outlined above are repeated until the response is accepted. The IMC, or designee, also reviews each PER for effects on the data base. During the processing of each PER, each exception is reviewed by the appropriate QA personnel for elevation of the exception to an Energy Systems nonconformance. The original closed PER is submitted to the project file and ultimately to the DMC.

13. VERIFICATION OF ELECTRONIC DATA

Data verification involves an evaluation of the project data base to ensure accountability, traceability, correctness, and completeness. Verification identifies errors that can be corrected. Accountability checks include confirming that data collectors and generators are identified and reviewing data transfer and data entry documentation. Traceability of the data base entries to hard copy sources and to electronic deliverables must be documentable. Hard copy sources include COC and sample collection forms, data packages, and data validation reports. Correctness involves verification of data transfer processes, double data entry, and comparison of data base values with the source. Completeness checks will verify that all required descriptors for both samples and individual results are present, correct, and consistent with applicable plans and procedures, and/or Oak Ridge Environmental Information System formats. These checks will review locations, coordinates, sample IDs, units, dates, laboratory sample IDs, methods, parameter names, result formats, laboratory flags, and validation flags, among others, as appropriate.

Deliverables from the data verification process will include the following items.

- Comparison of sample tracking information entered by program personnel with corresponding data entered by the analytical laboratory.
- Summary table of the number and type of samples collected for each sampling event.
- Summary table of the number and type of samples collected for each site.
- Comparison of results with historical maximum for the particular analyte and locations as determined in past studies.
- Frequency histograms or tables for all pertinent variables (including lengths, weights, holding times, qualifier prefixes, etc., and all analyte concentrations).
- Identification of potential outliers that are greater than three standard deviations from the mean for each analyte for each site and matrix.

14. PRELIMINARY EVALUATION OF FIELD AND LABORATORY DATA

A preliminary evaluation of all critical field and laboratory samples shall be performed by the ASC as soon as the data are available. Critical samples shall be identified by a checklist that is completed when the LCOC is reviewed by the ASC (Appendix C).

15. REVIEW OF DATA BY THE ANALYTICAL LABORATORY

The laboratory data review step is done by the laboratory performing the analyses. ER TM-16 specifies that the LQAP contain a discussion of data evaluation procedures for each analytical method, as well as for each entire data set. The process for data review and approval must be outlined as well as the process for identifying the person with authority to release the data. Each SOW requires also that the laboratory is responsible for ensuring 100% agreement between the hard copy and electronic deliverables when both are required.

16. RECEIPT OF DATA DELIVERABLES

The ASC receives the data package and electronic deliverables from the analytical laboratory and transfers them to the DC. The DC stamps the data package with the date of receipt and enters the date of receipt and laboratory SDG in the sample tracking data base by sample IDs. The DC then takes the data package to the DMC where a unique accession number is assigned and placed on the data package. The data package is then photocopied, either by DMC staff or the DC, and the original data package is transferred to the DMC. The DC or designee reviews the copy to ensure that all data was copied successfully and delivers it to the Data Inventory Specialist for inventory. The DC also provides copies of results and QC data from the package to the ASC for review.

The DC records the date of receipt on the diskettes, and then the DC or EDS makes and labels three copies of the electronic deliverable and distributes them to the IMC, the data analyst who will conduct CCS/CAVEAT screening, and to the project file. The original electronic deliverable is then transferred to the DMC.

17. INVENTORY OF HARD COPY DATA DELIVERABLES

The Data Inventory Specialist completes the appropriate inventory checklist and notes all exceptions (i.e., items that are missing, incorrect, or incomplete). If the data package is complete and without problems or mistakes, the Data Inventory Specialist attaches notes, checklists, and forms and returns the package to the DC. If any exception items are found during the review process, the verifier identifies the item(s) in the notes and photocopies the page(s) necessary to completely document the exception. The Data Inventory Specialist initiates an exception report and forwards it to the DC. The data package is returned to the DC pending resolution of the PER.

18. PROCESSING OF ELECTRONIC DATA DELIVERABLES

The DC transfers one copy of the electronic CLP diskette deliverables to the data analyst for CCS and CAVEAT processing. The IMG transfers the electronic deliverables to the main computer data base and begins additional electronic validation of available QC results.

19. CONTRACT COMPLIANCE SCREENING

In CCS, the data is reviewed against contractual specifications for compliance. If the data comprise a CLP deliverable, they will be screened using CCS and CAVEAT software. Software-generated reports are produced for each data package and transferred to the DC. If they do not comprise a CLP deliverable, the screening will be performed manually at the direction of the ASC. If any exception items are found during the review process, the reviewer identifies the item(s) in the notes and photocopies the page(s) necessary to completely document the exceptions. The data analyst initiates an exception report and forwards it to the DC. The data package is returned to the DC pending resolution of the PER.

20. ELECTRONIC VALIDATION OF QC RESULTS

Computer checks of available QC information shall be evaluated according to method criteria by the EDS and the ASC. Results of these checks shall be compared with other available checks, such as CCS, CAVEAT, and data validation reports. Duplicates and spikes will be evaluated electronically for all data, as applicable, so that assessments of precision and accuracy may be made. Data not within established control limits will be reported as exceptions and will be flagged as such.

These checks shall include but not be limited to a summary of

- percent recoveries for all surrogates and spikes to evaluate accuracy,
- holding times,
- duplicates to evaluate precision,
- blanks to assess contamination levels,
- CR-ERP required detection limits versus reported detection limits, and
- laboratory control samples (LCSs).

21. TRANSFER OF HARD COPY DATA DELIVERABLES TO THE DATA VALIDATORS

The DC will transfer the data package, applicable CCS and CAVEAT reports, worksheets, and guidelines to the DVC, as appropriate. Appropriate data packages shall be the first data package produced by each laboratory for each method and every tenth data package produced thereafter. If problems are found during verification and validation of the first data package, each succeeding data package is validated until the problems are judged to be of minimal effect on the data quality. The last data package will also be validated for each laboratory for each method.

22. VALIDATION OF ANALYTICAL DATA

Comprehensive validation will be performed initially on approximately 10% of the data packages for Phase 2 (approximately 160 data packages with 20 samples per package). The data packages to be validated will be designated by CR-ERP and will include the first and last data package submitted by the laboratory for each method and sample type. All data validation deliverables, except for a summary narrative, are due 10 working days from receipt of the data package or 10 working days from closure of the PER. More validation may be required if severe problems are encountered during the minimum comprehensive validation effort.

After verifying the completeness and integrity of the documentation, the data validator signs and dates the completed data review/validation report and associated worksheet forms. As part of the data validation process, the validator will identify any exceptions. If an exception is identified, the validator will generate a PER. Handling of PERs is discussed in Sect. 11 and also Appendix F. Review and validation deliverables include a data review and validation package and an electronic deliverable, which are discussed below.

CR-ERP will furnish an electronic file containing sample IDs and analytes to facilitate data entry of validation flags.

Data review and validation deliverables will consist of the following items.

- **Data Review and Validation Package**

A batch narrative summarizing by analysis and/or method type the problems found that affect data quality for the batch. Each narrative shall include the typed name, title, and address of the data reviewer as well as his or her signature and the date. Each narrative shall also state which validation procedure was used.

A list of data qualifiers and their meanings for use in data evaluation.

Copies of data reporting forms (CLP Form 1 or equivalent, stamped *Copy*) with validation flags.

A completed checklist for each batch that lists those QA/QC items that have been reviewed and/or validation worksheets, as applicable.

The closed PER that applies to the batch, if applicable.

- **Diskette Containing Electronic Entry of Validation Flags for Each Sample and Analyte**

- **Summary Narrative**

Upon completion of data validation activities for a given type of analysis (e.g., organics, inorganics, radiological), a summary narrative will be prepared by the appropriate Data Validation Coordinator. The summary narrative by (1) analysis, (2) method type, (3) matrix, and (4) laboratory will detail the problems that affected the data quality for a particular method, matrix, and laboratory. Each summary narrative shall include the name, title, and address of the data reviewer as well as his or her signature and the date.

23. RECEIPT OF VALIDATION DELIVERABLES

After verifying, signing, and dating the data review/validation reports and worksheet forms, the Data Validator transmits the data package and review documentation to the DC. The DC receives and logs the receipt of the validated data package with the associated review/validation report, completed worksheets, and any additional QA/QC documentation (e.g., PER).

24. INVENTORY OF PROJECT CASE FILES

The DC performs an inventory of each complete case file. All copies of documents shall be complete and legible. Original documents that include information relating to more than one case or SDG shall be filed by lowest SDG number. The copy(s) shall be placed in the other applicable files and marked *copy* in red ink. In order to provide document accountability of the completed file, each item in the case file shall be inventoried and assigned a serialized number. A table of contents shall preface each file.

25. TRANSFER OF DATA VALIDATION PACKAGE TO DATA ASSESSOR

After the inventory of the case file is complete, the file shall be transferred to a data assessor for further evaluation.

26. ASSESSMENT OF DATA

Data assessment will be formally conducted as the final component of the comprehensive data validation process, although the process of assessing the data actually begins when the data are received from the laboratory. This component involves the integration and evaluation of all information associated with a result. Individual Statistical Analysis System (SAS) applications are developed by CR-ERP program staff for data assessor use. Representative sample data are verified by hand calculations. Documentation of these manual checks will be placed in files with the associated analyses, and copies will be sent to the DMC. Documentation provided to the data assessor includes the following items:

- field data package inventory checklist,
- field data package,
- analytical data package inventory checklist,
- electronic data verification output,
- analytical CCS and CAVEAT reports,
- analytical data validation report, as applicable,
- summary of precision information from the data base, and
- summary of accuracy information from the data base.

The data assessor is generally the principal investigator responsible for comparing the data with the original assumptions and integrating all relevant information. Documentation will be provided to the responsible personnel as soon as available so that the conceptual model may be evaluated and modified as needed. The data assessor shall evaluate the field and laboratory data and supporting documentation and assess the reasonableness of the data as compared with (1) the conceptual understanding of the system, (2) data from similar sites, (3) historic data, (4) trend analysis of the concentration of the analytes, or (5) other criteria, based on the reviewer's professional judgment. Sensitivity, precision, accuracy, representativeness, completeness, and comparability for field and analytical data shall be reviewed and compared with project objectives. The total error associated with the sample data shall be assessed and documented. Data that do not support project DQOs shall be identified and a justification for their unacceptability documented.

The data assessor collects all the data that have been generated—historical and newly collected—to review and analyze according to sensitivity, precision, accuracy, representativeness, completeness, and comparability parameters to determine usability. He or she will also utilize statistical techniques to evaluate environmental data and to assist in designing appropriate sample plans based on the data. Precision and accuracy are the most common types of statistical information. Interpreting accuracy, precision, and completeness can be key in understanding the significance of the reported values and assessing the confidence associated with any decision. When data assessment is completed, the following characteristics of the data should be known:

- Data authenticity

Nonauthentic data may originate from either intentional or accidental reporting of incorrect data. Data entry errors, transcription errors, calculations errors, software failures, poor recording procedures, inadequate training, and lack of management oversight may result in the accidental reporting of incorrect data. Intentional reporting

of nonauthentic data may result from unauthorized access to samples and/or sample data, lack of ethics, or manipulation of logbooks, worksheets, or instrument listings.

- **Data integrity**

Data have integrity if (1) they are reported as the results of procedures that ensured that proper analysis and sampling methods were selected and followed correctly, (2) results were not compromised as a result of intentional or accidental reporting of incorrect values, and (3) documents were maintained that demonstrate the procedures used.

- **Validation and certification**

The data validation process involves an evaluation of the data to determine if data meet required criteria. If the data meet all the requirements of the DQOs as stated in the SAP, Quality Assurance Project Plan, and the requested method, then the data may be certified. The data may also be certified with exceptions.

- **Data usability**

If the data meet the DQOs, then the data are usable.

- **Outliers**

Outliers may result from unusual loss or contamination, transcription errors, dilution errors, sample misidentification, bad reagents or standards, calculation errors, faulty instruments, incorrect application of the analytical method, system malfunctions and loss of sample integrity.

- **Sensitivity, precision, accuracy, completeness, comparability, and representativeness**

Sensitivity is the capability of methodology or instrumentation to discriminate between samples with differing concentrations of analytes. Sensitivity is defined by the limit of detection, limit of quantitation, instrument detection limit, and the method limit of detection.

Precision is the degree of mutual agreement between independent measurements made under specified conditions. Standard deviation, relative standard deviation, and relative percent difference are used to express precision.

$$RSD = CV = 100 (\text{STANDARD DEVIATION}/\text{MEAN})$$

$$RPD = 100 [(X_1 - X_2)/((X_1 + X_2)/2)]$$

Accuracy is the closeness of agreement between an observed value and an accepted reference value. When applied to a set of observations, accuracy will be a combination of a random component and of a common systematic error component (*bias*). *Bias* is calculated as

$$B = x_i - T \quad \text{or} \quad B = (x_i - x_a) - K$$

where x_r = measure value for reference value,
 x_s = measure value for spiked sample,
 x_u = measure value for unspiked sample,
 K = known value of the spike in the sample, and
 T = true value.

Percent recovery may be expressed as the following:

$$\%R = 100 (x_r/T), \text{ or } \%R = 100 (x_s - x_u)/K$$

Completeness is a measure of the amount of valid data obtained from the analytical measurement system. It is typically expressed as the total number of samples taken for which acceptable analytical data are generated, divided by the total number of samples collected and multiplied by 100.

Comparability is the confidence with which one data set can be compared to another data set produced by different laboratories, etc. The use of accepted methods, SOPs, and participation in intra-laboratory PE testing demonstrates comparability.

Representativeness expresses the degree to which the data accurately reflect the analyte or parameter of interest at an environmental site.

27. FLAGGING OF DATA

Data qualifiers, flags, and remarks become necessary when the data to be reported need to be qualified or described in some way. Every instance of the use of a qualifier, flag, or remark is an effort to best describe the circumstances and quality of that piece of data and is based on all the information available to the chemist or reviewer. Indicated assignment of flags by the CCS or CAVEAT software, the CR-ERP electronic validation software, or the manual validation will be applied as follows.

Flags may be assigned based on information from six different sources, which are field data validation, CCS, CAVEAT, CR-ERP electronic data validation, analytical validation, and data assessment. Whether the flags are extrapolated to other data depends on the reason for assignment of the flag. Flag assignments are based on method QC, sample QC, and other QC.

Method QC consists of the analyses necessary for setting up for the sample analyses and the analyses that are common to the sample batch, including instrument tuning (for GC/MS analyses), calibration standards, blanks, LCSs, spikes, and duplicates. Using the electronic data base and the key variables listed below, problems experienced with method QC can be evaluated for other sample batches and flags assigned appropriately.

QC Parameter	Key Variables
Instrument Tuning	Date tuning compound analyzed
Calibration Standards	Date initial calibration performed Date continuing calibration performed Instrument or column ID
Blanks	Date prepared Instrument Date analyzed Matrix Preparation type
Laboratory Control Samples	Source Instrument Date analyzed
Spikes	Instrument Date analyzed Date prepared
Duplicates	Instrument Date analyzed Batch Associated sample ID Date prepared

Sample QC criteria are specific to each sample. For organic analyses, these include internal standards, surrogate spikes, and the identification and quantitation of target analytes and tentatively identified compounds. Inorganic sample QC includes ICP serial dilutions, furnace AA duplicate injections and post-digestion spikes, and the identification and quantitation of target analytes. Flags would not be extrapolated to other samples unless identical quality problems were evident.

Other QC consists of additional analyses that are necessary to assess the field and laboratory procedures and to utilize the data. This QC includes container certifications, field blanks, field replicates, detection limit determinations, holding times, precision and accuracy determinations, and PE sample analyses. The effects of each of these QC items would be evaluated to determine whether sample flags could be applicable to other samples.

28. CONTROL OF DOCUMENTATION

All forms must be completed in black waterproof ink. Corrections should be made by drawing a line through and initialing and dating the change, then entering the correct information. Erasures or use of white-out are not permitted. Only yellow highlighters should be used to mark documentation, as needed.

Control of CR-ERP documents shall be maintained at all times as follows:

- All deliverables shall be transferred to the DMC upon completion of work.
- Secure and demonstrable custody of the sample data shall be maintained. The sample data will be considered to be in custody if
 - it is in the individual's actual possession;
 - it is in the individual's view; or
 - it is placed in a designated secure area, such as a locked file cabinet or room.
- SOPs on document control must be submitted to the CR-ERP ASC, or designee, by subcontractors utilized during the data review process.
- Any sample data received by subcontracting personnel shall be used only for the purpose of meeting the technical specifications and shall not be released to personnel that are not authorized by the CR-ERP.

Appendix A
ORGANIZATION

ORGANIZATION CHART

Project Manager
Task Leaders

Field Sampling Team Leaders

Field Sampling Team Members

Sample Information Coordinator
Field Team QA Reviewer
Analytical Services Coordinator
Analytical Project Office
Analytical Laboratories
Shipping Coordinator
Information Management and Analysis Task Leader
Information Management Coordinator
Verification Software Developer
Electronic Data Specialists

Programmatic Exception Coordinator
Data Coordinators

Inventory Task Leader
Data Inventory Specialists

CCS/CAVEAT Screening Specialist

QA/QC Coordinator
QA Specialist
Data Verifier
Validation Coordinator
Field Validation Coordinator
Field Validators

Organic Validation Coordinator
Organic Validator
Inorganic Validation Coordinator
Inorganic Validator
Radiological Validation Coordinator
Radiological Validators

Validation Oversight Coordinator
Data Assessors

Sample Information Specialists

Bob Cook
Clell Ford
Dan Levine
Marshall Adams
L. Shugart
R. Harris
J. Field
K. Campbell
C. Lane
T. Stephens
S. Madix
C. Rash
S. Madix
R. Harris
Susan Holladay
Joe Pardue
Appendix G
Susan Madix
Craig Brandt
Denise Schmoeyer
Betsy Horwedel
W. Ernest Peters
Tim Morrison
Connie Chavannes
Judy Van Winkle
Fred Preston
L. Rollins
J. Nave
E. Bergman
H. Livingston
K. Murphy
F. Preston
L. Rollins
D. Landers
M. Widener
K. Newman
L. Rollins
Suzanne Benson
Tom Koepp
TBD
Susan Holladay
Ronnie Moody
D. Keefer
M. Klidzeja
Susan Rizk
Som Rao
Allen Volesky
Som Rao
Stan Stevens
Tom Rucker
Christi Kingsley
Energy Systems
Clell Ford
Dan Levine
Marshall Adams
Glen Suter
Gordon Blaylock
Susan Holladay
J. Field
K. Campbell
C. Knight

Functional Group Organization Chart for Phase 2 Sampling, Analysis, and Data Review

Appendix B

SAMPLE PRESERVATION, CONTAINERS, AND HOLDING TIMES

WATER SAMPLE PRESERVATION, CONTAINER, AND HOLDING TIMES

Analysis Category	Measurement ^a	Method ^a	Required sample size ^c	Container	Preservative	Holding Time ^b
Organics	Semivolatiles ^a	Low Level CLP	1000 ml (±4000 ml)	Glass, amber w/Teflon head cap, 1-Liter or 1-Gal	Cool, 4°C	7 d extraction 40 d analysis
Organics	Pesticides/PCBs ^a	Low Level CLP	1000 ml (±4000 ml)	Glass, amber w/Teflon head cap, 1-Liter or 1-Gal	Cool, 4°C	7 days extraction 40 days analysis
Radiochemical Analysis	Gross alpha or beta Isotopic U Strontium-90	900.0 908.0 905.0 901.0	150 ml(±500 ml) 150 ml 1 L (±3 L) 1 L	Cubiclester	HNO ₃ TO pH < 2.0	6 months
Radiochemical Analysis	Tritium	906.0	250 ml	Glass, wide-mouth w/Teflon head cap, 8-oz.	None required	6 months
Radiochemical Analysis	Gamma spectroscopy	901.1	500 ml	Polyethylene, w/polyethylene head closure, 500-ml marbottle	HNO ₃ TO pH < 2.0	6 months
Radiochemical Analysis	Gamma spectroscopy	****	Variable	Cartridge filter, 0.45 um		6 months
Inorganics	Methyl Mercury ^a Total Mercury ^a	BR-0004 BR-0003	125 ml (±250 ml)	Teflon, narrow mouth, Nalgene	HCL TO pH < 2.0, Cool, 4°C	28 days
Inorganics	Micb., except mercury ^a Mercury ^a	6020 CLP-M 245.1 CLP-M	1000 ml	Polyethylene, w/polyethylene closure, 1-Liter	HNO ₃ TO pH < 2.0	6 months 28 days
Inorganics	Bromide, Chloride, Sulfate Fluoride	300.0 340.2	500 ml	Polyethylene, w/polyethylene closure, 500-ml	Cool, 4°C	28 days
Inorganics	Nitrate plus nitrite	300.0	250 ml	Polyethylene, w/polyethylene closure, 250-ml	Cool, 4°C, H ₂ SO ₄ TO pH < 2	28 days
Inorganics	Cyanide ^a	335.2 CLP-M	1000 ml	Polyethylene, w/polyethylene closure, 1-Liter	Cool, 4°C NaOH to pH > 12	14 days
Inorganics	Ammonia as N	350.1	500 ml	Polyethylene, w/polyethylene closure, 500-ml	Cool, 4°C, H ₂ SO ₄ TO pH < 2	28 days
Inorganics	Total Kjeldahl N	351.2	500 ml	Polyethylene, w/polyethylene closure, 500-ml	Cool, 4°C, H ₂ SO ₄ TO pH < 2	28 days
Inorganics	TOC	415.2 CLP-M	250 ml	Glass, w/Teflon head cap, 250-ml	Cool, 4°C, H ₂ SO ₄ TO pH < 2	28 days

^a Measurements marked * will be performed for both filtered and unfiltered aliquots of the sample. Required field sample size will be twice that listed above.

^b Methods marked **** are laboratory specific.

^c Sample sizes marked with * are required for 1 out of 20 samples per sampling event for quality control.

^d Holding times begin at time of collection, except that the analysis holding time begins on the date of sample extraction.

SOIL SAMPLE PRESERVATION, CONTAINER, AND HOLDING TIMES

Analysis category	Measurement	Method ^a	Required sample size (g)	Container	Preservative	Holding time ^b
Organics	Semivolatiles	CLP OLM01.8	250	Glass, widemouth w/Teflon lined cap, 8-oz.	Cool, 4°C	14 d extraction 40 d analysis
Organics	Pesticides/PCBs	CLP OLM01.8	250	Glass, widemouth w/Teflon lined cap, 8-oz.	Cool, 4°C	14 d extraction 40 d analysis
Radiochemical analysis	Isotopic U Strontium-90 Technetium-99 Gamma spectroscopy	****	500	Polyethylene, w/polyethylene closure, 16-oz.		6 months
Radiochemical analysis	Gamma spectroscopy	****	100	90 ml aluminum can		6 months
Inorganics	Metals, except mercury Mercury TKN	CLP ILM02.1 CLP ILM02.1 351.3	500	Glass, widemouth w/Teflon lined cap, 16-oz.	Cool, 4°C	6 months 28 days 28 days
Inorganics	Methyl Mercury Total Mercury	BR-0004 BR-0003	30	Teflon vial	Cool, 4°C	28 days
Physical	Dry Density Particle Size Moisture Content Specific Gravity TOC	ASTM D422 ASTM D4959 ASTM D854 ASTM D2974	500 115 200 25 50	Glass, widemouth w/Teflon lined cap, 16-oz.	Cool, 4°C	28 days

^aMethods marked **** are laboratory specific.

^bHolding times begin at time of collection, except that the analysis holding time begins on the date of sample extraction.

Appendix C
SAMPLE PROCESSING FORMS

FIELD CHAIN OF CUSTODY

[illegible]

FIELD CHAIN OF CUSTODY

CONTINUATION PAGE[illegible]

Field Collection Task Map

Clinch River ER Project - Phase 2

Field Matrix: _____

Task: _____

Sampling Date: _____

Kit Identifier: _____

Kit Preparation Date: _____

Field COC Number: _____

Field Log Book Number: _____

Site	Field ID	Collection Device	Collection SOP	Sample Container			Process	Preserv.	Analysis	Sample Type
				Size	Type	Lot				

Completed by: _____

Date: _____

Document ID: _____

Field Collection Task Map

Clinch River ER Project - Phase 2

Field Matrix: _____
Task: _____
Outfall: _____
Sampling Date: _____

Kit Identifier: _____
Kit Preparation Date: _____
Field COC Number: _____
Field Log Book Number: _____

[illegible]

Completed by: _____
Date: _____

Document ID:

Field Collection Task Map

Clinch River ER Project - Phase 2

Field Matrix: _____
 Task: _____
 Sampling Date: _____

Kit Identifier: _____
 Kit Preparation Date: _____
 Field Log Book Number: _____

Site	Fld ID	Coll Device	Coll SOP	Sample Container			Process	Preserv.	Analysis	Samp Type	Org.	Fld COC	Analy Lab
				Size	Type	Lot							

Completed by: _____
 Date: _____

Document ID: _____

HYDROLAB DATA FORM **CLINCH RIVER ER PROJECT - PHASE 2**

Sample Date: _____ Sample Time: _____
 Location: _____ Process SOP No.: 2370
 Recorder Signature: _____

Z m	TEMP deg C	pH	D.O. mg/L	COND mmno/ cm	O ₂ Redct Potent	Sample ID	Remarks
0							
0.5							
1							
1.5							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							

LAB CHAIN OF CUSTODY

[illegible]

LAB CHAIN OF CUSTODY

CONTINUATION PAGE[illegible]

Field Matrix: _____

Task: _____

[illegible]

Completed by: _____
Date: _____
LPTM1 Rev 1 25OCT93

Document ID:

Laboratory Processing Task Map Clinch River ER Project - Phase 2

Field Matrix: _____

Task: _____

[illegible]

Completed by: _____

Date : _____

LPTM2 Rev 1 25OCT93

Document ID:

SAMPLE ANALYSIS REQUEST FORM

CLINCH RIVER ER PROJECT - PHASE 2

[illegible]

The signature below certifies that the above named sample materials are properly classified, described, packaged, marked, and labeled as environmental samples and are in proper conditions for transportation according to applicable Department of Transportation regulations.

Signature of Shipper: _____ Date: _____

DATE SAMPLES SHIPPED:

Analytical Project Office No.:

Statement of Work No.:

Purchase Requisition No.:**Purchase Agreement No.:****Shipping Order No.:**

COMMENTS:

SAMPLE COLLECTION INFORMATION

[illegible]

WATER CURRENT METER DATA FORM

CLINCH RIVER ER PROJECT - PHASE 2

Sample Date: _____

Sample Time: _____

Location: _____

Process SOP No.: 2373

Recorder Signature: _____

[illegible]

WEEKLY SEDIMENT SAMPLING SCHEDULE

[illegible]

Completed by: _____

Date: _____

WEEKLY WATER SAMPLING SCHEDULE

Scheduled Sampling Date	Task	Site	(Check sample types to be collected.)												Special Instructions	Sampling Team Leader	Prep. Lab. Team Leader	
			OTHER	HG		ORG		RAD		Q C Samples								
			REG	REG	SPK	REG	SPK	REG	SPK	FR	FRB	FB	TB	LRB				MQB

Sample Type: REG=Regular; SPK=Matrix Spike; FR=Field Dup.; FB=Field Blank; TB=Trip Blank; FRB=Field Rinse Blank; LRB= Lab Rinse Blank; MQB=Mill-Q Blank.

Completed by:_____

Date: _____

Appendix D

**FIELD DATA INVENTORY
AND VALIDATION CHECKLISTS**

**CLINCH RIVER ENVIRONMENTAL RESTORATION PROGRAM
DAILY FILE INVENTORY CHECKLIST**

Page 1 of 1

Sampling Date:

Matrix:

Task:

Field Sampling Team Leader: 1) Place a check mark for each item submitted. 2) Identify each COC form, logbook, and data form used for the sampling event as indicated. 3) Sign and date below.

Field Data Validator: 1) Verify that items checked by the sample team leader are present by checking each appropriate box. 2) Sign and date below.

Field Sampling Team Leader	Field Data Validator	Items to be Supplied by the Field Sampling Team to the DMC
		Field Sampling Review Checklist
		Field Collection Task Map
		Field Chain-of-Custody Form (List FCOC #)
		Sample Collection Information Form
		Documentation of Sample Collection Site(s) (Text for pre-established and permanently marked site, site map, or printout of GPS)
		Data Forms (Check below or list those included) Hydrolab Data Form _____ Hydrolab Calibration Form _____ Water Current Meter Data Form _____ Water NTU Data Form _____ Water Alkalinity and pH Data Form _____ Total Suspended Particles Data Form _____
		Photocopies of relevant field logbook pages _____ _____
		Laboratory Processing Task Map
		Additional Documentation (Describe.) 1) Weekly Sampling Schedule 2) Sampling Equipment Checklist 3) Barcode data print-out
Field Sampling Team Leader:		Comments (PERs?):
Date:		
Task Leader (if changes):		Comments (Give details of changes):
Date:		
Field Data Validator:		Comments:
Date:		

Appendix E
DATA INVENTORY AND REVIEW FORMS

CR-ERP ANALYTICAL SERVICES CHECKLIST

TASK: _____ APO SOW #: _____ CRERP SOW #: _____

PLEASE INITIAL AND DATE EACH ITEM WHEN COMPLETION IS VERIFIED.

Item	Yes	No
Has the SOW been reviewed? <div style="text-align: right;"> Task leader IMG Risk assessors Program manager QA/QC Coordinator QA Specialist Others </div>		
Has the SOW been received by the APO and assigned an APO SOW #?		
Has the SOW been received by potential laboratories?		
Have all comments been addressed?		
Has a cost estimate been received from the laboratory based on the final draft of the SOW?		
Has a work order been assigned to cover the cost of the SOW?		
Has the SOW been signed by appropriate parties?		
Has the CR-ERP received notification of laboratory selection from the APO?		
Has the laboratory passed a preaward audit?		
Is the LQAP on file?		
Are all pertinent SOPs on file?		
Have all CR-ERP requests of the laboratory been satisfied?		
Has the laboratory demonstrated proficiency through analysis of performance evaluation samples?		
Have all lab corrective actions been completed?		
Has the laboratory issued an acceptance letter?		
Has a purchase requisition been prepared?		
Has the readiness review been completed?		
Comments:		

CR-ERP SAMPLE SHIPMENT CHECKLIST

APO SOW #: _____ LAB: _____ SHIP DATE: _____

LAB COC #: _____ / _____ / _____ / _____

LAB SDG #: _____ / _____ / _____ / _____

INITIAL AND DATE EACH ITEM WHEN COMPLETION IS VERIFIED:

ITEM	YES	NO
ANALYTICAL SERVICES COORDINATOR (ASC) // DATA COORDINATOR (DC)		
1. Is the Field Sampling Review Checklist complete? (ASC/DC)?		
2. Have the samples been released by the Field Sampling Team Leader for analysis (ASC/DC)?		
3. Do the LCOCs correctly reflect the approved FCTMs, FCOCs, and LPTMs (ASC/DC)?		
4. Has the Field Sampling Review Checklist been reviewed by the ASC (DC)?		
5. Are the SDG # and LCOC # assigned (DC)?		
6. Has a Sample Shipment Report been given to the SIC for shipping preparation (DC)?		
7. Have document numbers been assigned to the SAR and LCOC (DC)?		
8. Has the SAR been faxed to the APO (DC)?		
9. Have the SAR, LCOC, and Lab Acceptance forms been faxed to the lab (DC)?		
10. Has a Shipping Order been requested for issue by the APO (DC)?		
11. Has the Shipping Order been received and is it correct (check dates, sample totals, delivery) (DC)?		
12. Has the HP technician been notified of Green Tag need (DC)?		
13. Has the ASC submitted a signed "Expected Mercury Concentration Range" data sheet for Brooks Rand shipment (DC)?		
14. Have the final LCOC, SAR, and preliminary Shipping Order been transferred to the SIC (DC)?		
15. If shipment is for Saturday Delivery has all of the special markings been applied to the shipping order/s (DC)?		
SAMPLES INVENTORY COORDINATOR (SIC)		
16. Have the samples been checked off the LCOC and packed into the coolers (SIC)?		
17. Have the samples been tagged by HP (SIC)?		
18. Has the original LCOC been checked for completeness, accuracy, and signed to relinquish custody for shipment (SIC)?		

CR-ERP SAMPLE SHIPMENT CHECKLIST

INITIAL AND DATE EACH ITEM WHEN COMPLETION IS VERIFIED:

ITEM	YES	NO
19. Have the original LCOC and copies of the SAR and HP tag form been placed in the appropriate coolers (SIC)?		
20. Has the cooler ID # been noted on the LCOC (SIC)?		
21. Has the preservation method been verified for each sample (SIC)?		
22. Have two custody seals been placed on each cooler (SIC)?		
23. Has each cooler been labelled appropriately according to the requirements of the Technical Plan (SIC)?		
24. Has a copy of the HP green tag been placed into the shipping file (SIC)?		
25. Is the SAR complete and signed by the shipper (SIC)?		
DATA COORDINATOR (DC)		
26. Has the ORNL Shipping Order number (assigned by ORNL shipping & receiving) been recorded on each shipping order (DC)?		
27. Have the airbill tracking numbers been recorded on each Shipping Order (DC)?		
28. Has a copy of the LCOC been distributed to the IMC?		
29. Has a copy of the LCOCs, SARs, Sample Login Forms, Shipping Orders, and Shipping Receipts been distributed to the APO?		
SHIPPING FILE INVENTORY		
30. Lab Notification of Impending Sample Shipment (completed SAR) (DC)?		
31. Confirmation of acceptance of samples (SAR signed by laboratory) (DC)?		
32. APO Notification of Impending Sample Shipment (completed SAR) (DC)?		
33. Blanket Shipping Order from APO (DC)?		
34. Lab Chain-of-Custody (DC)?		
35. HP tag (copy) (DC)?		
36. Final Shipping Order (DC)?		
37. Signed LCOC from the laboratory (DC)?		
38. Sample Login Form from the laboratory (DC)?		
39. Misc. documentation of CR-ERP sample IDs and laboratory assigned IDs (DC)?		

CR-ERP DATA VALIDATION CHECKLIST

TASK: _____ APO SOW #: _____ CRERP
 SOW#: _____

LAB COC #: _____ SDG #: _____ SAMPLING
 DATE: _____

PLEASE INITIAL AND DATE EACH ITEM WHEN COMPLETION IS VERIFIED.

Item	Yes	No
Has a sampling event file been created in the DMC?		
Has the Field Data Validation Package been inventoried and is all documentation present?		
Has Field Data Validation occurred?		
Has a preliminary evaluation of blanks and critical samples been performed?		
Have the preliminary verification steps been completed?		
Did the lab meet the reporting deadlines?		
Has the electronic copy of the data been received and logged into the DMC?		
Has the hardcopy of the data been received and logged into the DMC?		
Have the hardcopy deliverables been inventoried for completeness?		
Have the electronic deliverables been inventoried for completeness?		
Have the electronic deliverables been transferred to SAIC for compliance screening and CAVEAT?		
Have the electronic validation of the QC results been completed by IMG?		
Have the data verification checks been placed in the validation package?		
Has the data package been transferred to the data validator(s)?		
Have all data validation deliverables been received?		
Have the validation flags and codes been transferred to the database management system?		
Has the data verification been completed?		
Has the project file been inventoried?		
Has the project file been transferred to the data assessors?		
Has the data evaluation been completed?		
Comments:		

CR-ERP FIELD SAMPLING REVIEW CHECKLIST

DATE COLLECTED _____ FIELD COC # _____ TASK _____

Item	Yes	No
Were all SOPs readily available to the technical personnel in approved written format?		
Were deviations and/or exceptions from SOPs noted?		
Were deviations and/or exceptions from the SAP noted?		
Were special instructions given to sampling team members? If so, were they documented on the weekly sampling schedule?		
Were the planned number of samples taken?		
Were correct sampling collection procedures followed?		
Were the correct sample containers used for the type of sample collected?		
Were the sample containers cleaned properly?		
Were the samples prepared and preserved as required?		
Were the samples stored properly?		
Was sample custody maintained at all times?		
Were samples labelled appropriately?		
Were the appropriate QC samples collected?		
EQUIPMENT RINSATE BLANKS		
FIELD BLANKS		
TRIP BLANKS		
FIELD DUPLICATE		
SAMPLE SPLIT		
Were samples field-surveyed with an appropriate monitoring device?		
Did monitoring device readings exceed acceptable levels (>100 cpm)?		
Were the field forms completed properly?		
Were all SOP required parameters recorded in a bound notebook?		
Were all sample locations documented?		
Is the appropriate documentation to link sample and field information to the sampling point and sampling date in the daily file? (FCOC, FCTM, GPS)		
Were the task maps and lab notebooks signed and dated?		

CR-ERP FIELD SAMPLING REVIEW CHECKLIST
Page 2

DATE COLLECTED _____ **FIELD COC #** _____ **TASK** _____

I consider these samples to be appropriate for submission for sample analysis, unless otherwise stated below.

Field Sampling Team Leader:

Name _____ **Date** _____

List critical samples below:

Analytical Services Coordinator

Name _____ **Date** _____

Field Validator

Name _____ **Date** _____

CR-ERP FINAL DATA ASSESSMENT

SDG _____ CHAIN OF CUSTODY # _____ SAMPLE TRACKING FORM _____

Please initial and date each item when verification is complete.

Item	Yes	No
Is the readiness review checklist in the file?		
Is the field sampling review checklist in the file?		
Is the data verification review checklist in the file?		
Is the analytical review checklist in the file?		
Is a summary table of the number and type of samples collected at the site in the file?		
Are sample results reasonable when compared with current and historical data?		
Is a table or histogram available for all pertinent variables that visually identifies outliers?		
Have all outliers been evaluated to determine possible cause?		
Have the analytical quality control criteria that are available in the database been verified electronically?		
If data are not within control limits, are corrective actions available and the necessary codes applied to the data?		
Have all holding times been tabulated and deviations noted?		
Have available surrogate recoveries been evaluated and deviations noted?		
Have duplicates been evaluated and deviations noted?		
Have matrix spikes and duplicates been evaluated and deviations noted?		
Have method blanks been evaluated and deviations noted?		
Have trip blanks been evaluated and deviations noted?		
Have instrument blanks been evaluated and deviations noted?		
Have equipment rinsates been evaluated and deviations noted?		
Do any of the detection limits exceed regulatory limits or action levels?		
Have laboratory control samples been evaluated and deviations noted?		
Do data from related analyses correlate?		

CR-ERP FINAL DATA ASSESSMENT

Page 2

SDG _____ CHAIN OF CUSTODY # _____ SAMPLE TRACKING FORM _____

Comments:

DATA ASSESSORS:

Name _____ Date _____

Name _____ Date _____

Name _____ Date _____

Appendix F
PROGRAMMATIC EXCEPTION REPORTING FORMS

CLINCH RIVER ENVIRONMENTAL RESTORATION PROGRAM PROGRAMMATIC EXCEPTION REPORT

PER Number: _____ **Sampling Date** _____

Initiator of Report: _____

Date Issued: _____ **Response Due Date:** _____

Primary Responsible Organization/Individual: _____

Secondary Responsible Organization/Individual: _____

CR-ERP Task Name and Number: _____ **Task Leader:** _____

SDG: _____ Sample ID: _____

Batch: _____ **Lab Sample ID:** _____

DISPOSITION TEAM: QA Coordinator __ ASC __ Task Leader __ IMS Data Base Manager __

Initiator

DISPOSITION TEAM LEADER: _____

Programmatic Exception (Reference specified requirements and provide attachments as necessary):

Initiator: _____

Name	Date
-------------	-------------

Concurrence _____

Name	Date
------	------

Route to: QA Coordinator ☐ ASC ☐ Task Leader ☐ IMS Data Base Manager ☐

DMC/Project File _____ **Responsible Party** _____ **PER Coordinator File** _____

Page 1 of _____

**Response, Root Cause, Remedial Action to be Taken, Corrective Action(s) To Prevent Recurrence, Cost/
Scheduling Impacts:**

Proposed by: _____
Name Date

IMS Data Base Manager Review

☐ Not Applicable ☐ Acceptable ☐ Changes Made
☐ Not acceptable ☐ No Changes Required

IMS Data Base Manager Date

Closure Approval: ☐ Elevate to MMES NCR ☐ Do Not Elevate to MMES NCR

CR-ERP Program Approval (Disposition Team Leader): _____ **Date:** _____

Concurrence:

QA Specialist _____ **Date:** _____

QA Coordinator _____ **Date:** _____

Page 2 OF ____

**FIELD OR ANALYTICAL DATA PACKAGE
PROGRAMMATIC EXCEPTION REPORT CHECKLIST**

PER Number _____ Sampling Date _____

Chain-of-Custody

- ☐ 1A Missing (List ID Numbers) _____
☐ 1B Incomplete, Incorrect, or Illegible _____
☐ 1C Other _____

Identification Numbers

- ☐ 2A CR-ERP Sample ID# Incorrect _____
☐ 2B SDG # Incorrect _____
☐ 2C Lab # Incorrect _____
☐ 2D Batch # Incorrect _____
☐ 2E Other _____

Dates

- ☐ 3A Date Received Incorrect _____
☐ 3B Prep Date Incorrect _____
☐ 3C Sample Analysis Date Incorrect _____
☐ 3D Other _____

Incomplete or Incorrect Data Package

- ☐ 4A Case Narrative _____
☐ 4B Cover Page (ID List) _____
☐ 4C Form 1 _____
☐ 4D Other Forms (Describe) _____
☐ 4E Lab Summary Sheet _____
☐ 4F Data Package Page Numbering _____
☐ 4G Other _____

Holding Times

- ☐ 5A Missed _____
☐ 5B Other(Specify) _____

Incomplete or Incorrect Data

- ☐ 6A Data Reporting Units Incorrect _____
☐ 6B Sample Analysis Problem _____
☐ 6C Calibration Data _____
☐ 6D Tuning/Method Problem _____
☐ 6E Other _____

Disks

- ☐ 7A Disk/Hard Copy Inconsistent _____
☐ 7B Sample Analysis Problem _____
☐ 7C Missing Disk _____
☐ 7D Disk Structure or Format Incompatible _____
☐ 7E Other _____

Other

- ☐ 8A Other (Specify) _____

REQUEST FOR FURTHER RESPONSE TO PROGRAMMATIC EXCEPTION REPORT

PER Number _____

CR-ERP Task Name and Number _____

Sampling Date _____

SDG _____

Batch _____

Case/Order Number _____

(Example)

All responses acceptable except:

1. Not acceptable. Form 10 for sample 5014 is labelled sample 5004.

AIM

Association for Information and Image Management

1100 Wayne Avenue, Suite 1100
Silver Spring, Maryland 20910
301/587-8202

Centimeter

Inches

MANUFACTURED TO AIM STANDARDS
BY APPLIED IMAGE, INC.

2 of 2

Appendix G

PHASE 2 ANALYTICAL LABORATORIES

CLINCH RIVER ER ANALYTICAL SERVICES

APO #	CR-ERP #	Comments	Charge #	Lab	PR #	Maximum # samples
SOW-46A	CRERP-0001	Arsenic Study, June Sampling, 1992	PKK10001	K-25		
SOW-41	CRERP-0002	Great Blue Heron Study, 1992	PKK40500	Southwest		86
	CRERP-0003	TVA Fish Biocont. Study, 1991, PCBs		TVA-Chatt.		127
SOW-72	CRERP-0004	Arsenic Study, October Sampling, 1992	PX601C03	ORNL		
	CRERP-0005	TVA Source Study, Sediment and Water		TVA-Chatt.		434
	CRERP-0006	TVA Fish Study, Fall '92, Spring '93, PCBs		TVA-Chatt.		395
SOW-89	CRERP-0007	Arsenic Study, December Sampling, 1992	PX601C22	K-25		
	CRERP-0008	TVA Fish Study, Spring 1993, Metals		TVA-Chatt.		183
SOW-219A	CRERP-0009	Geese/Deer Tissue- Rads	PX603G44	TMA/Eberline-OR	GXJ59	127
SOW-218	CRERP-0010	Mink Study - fish analysis	PX603G45	Southwest	HNQ81	94
	CRERP-0011	Toxicity Studies		ESD/TVA		
	CRERP-0012	TVA Sediment Transport Modeling		TVA- UC		
SOW-191	CRERP-0013	Phase 2 Water Sample Analysis	PX601G36	Lockheed	GXJ11	600
SOW-192	CRERP-0014	Phase 2 Sediment Sample Analysis	PX601G37	TMA/ARLI	GXJ53	1000
SOW-217	CRERP-0015	Phase 2 Rad Analyses - Alpha, Beta, Gamma	PX601G38	Ecotek	HNQ87	2170
SOW-193	CRERP-0016	Phase 2 Speciation - Mercury	PX601G39	Brooks Rand	EXK71	740
SOW-196	CRERP-0017	Great Blue Heron Study - 1993	PX603G40	Southwest	EXK72	120
	CRERP-0018	Mink Study - tissue analysis	PX603G46			
	CRERP-0019	Phase 2 Rad Analyses - Gamma		ESD RAL		3550
	CRERP-0020	TVA Fish Study, Fall 1993,PCBS		TVA		395
	CRERP-0021	TVA Fish Study, Spring 1994		TVA		58
SOW-194	CRERP-0022	Pore Water Analysis	PX601C41	Lockheed	GXJ12	550
SOW-195	CRERP-0023	Particle Size Analysis	PX601G42	Southwest	GXJ16	1000
SOW-251	CRERP-0024	Phase 2 Semivolatiles in Fish	PX603G47			58
SOW-219B	CRERP-0025	Geese/Deer Tissue - Nonrads	PX603G48	EcoTek	GXJ60	137
SOW-152	CRERP-0026	Chlorophyll-a	PX601G43	Savannah		
	CRERP-0027	Cyanide - Source Area Study				45

Appendix H
SUBCONTRACT DATA VALIDATION SOW

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**STATEMENT OF WORK
FOR TECHNICAL SUPPORT
FOR THE CLINCH RIVER ENVIRONMENTAL RESTORATION PROGRAM,
OAK RIDGE, TENNESSEE**

1. BACKGROUND

The Clinch River Remedial Investigation focuses on the portions of the Clinch and Tennessee rivers that may have been adversely affected by contaminants released from the Department of Energy Oak Ridge Reservation from the early 1940s to the present. The scope of the Clinch River Remedial Investigation includes Sampling & Analysis activities, human health and ecological risk analyses, and preliminary identification and evaluation of potential remediation alternatives for the Clinch River/Watts Bar Reservoir system. Sampling of reference sites for purposes of comparison with contaminant levels or ecological conditions in the Clinch River/Watts Bar Reservoir is included in the Clinch River Remedial Investigation scope. During the Phase 2 investigation, additional Sampling & Analysis will be conducted for site characterization and risk analysis as identified by Phase 1 results. The objectives of the Phase 2 study are (1) to perform iterative screening risk analyses as additional data become available, (2) to quantitatively estimate potential risks to human and ecological health and (3) to focus additional sampling efforts. The Clinch River Environmental Restoration Program requires the timely review and validation of Phase 2 data. This Statement of Work has been prepared to outline Subcontractor responsibilities in providing technical support to the Clinch River Environmental Restoration Program.

2. OBJECTIVES

The objective of the requested work scope is to provide the Subcontractor with clear, concise instructions for performing activities related to analytical services coordination and review and validation of analytical laboratory data for inorganic, organic, and radiological analyses, and possibly toxicological and geotechnical analyses. The review and validation effort is to be conducted using U.S. Environmental Protection Agency (EPA) guidelines and/or project specified data validation guidelines to guarantee uniformity and comprehensiveness of data review and validation. The review must be conducted within 5 days of the sampling event and 30 days of receipt of the data packages so that timely feedback on sample analysis and data results can be utilized in the decision process. This review will ensure that Phase 2 data used in Clinch River Environmental Restoration Program decision making activities are of known quality. In addition, cost effective management of the data review and validation contract will be ensured through program management requirements defined in this Statement of Work.

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3. SCOPE

The scope of this work statement includes management and technical support to the Clinch River Environmental Restoration Program in the areas of analytical services, data management, data review, and data validation.

4. TASK DESCRIPTION

The work assignments defined in this Statement of Work have been divided into seven tasks, which are outlined below. Additional information on task deliverables and schedules is summarized in Section 5. The period of performance for these tasks will extend from October 1993 to June 1995.

Task 1 - Field Data Validation - The Subcontractor is to provide technical staff and materials onsite to support the Clinch River Environmental Restoration Program in performing field data validation of up to 400 daily sampling events, as requested by the Analytical Services Coordinator. As part of this task, the Subcontractor will complete an inventory checklist for each sampling event file and document any nonconforming items, in accordance with Clinch River Environmental Restoration Program procedures. A narrative and checklist for each sampling event file will be required summarizing the problems that affect data quality. Deliverables must be completed within 5 working days from the sampling event date.

Task 2 - Data Package Inventory - The Subcontractor is to provide technical staff and materials to support Clinch River Environmental Restoration Program in inventorying up to 2000 data packages for completeness. The approximate number of analytes per method is given in Table 1. As part of this task, the Subcontractor will develop an inventory checklist for each individual method used for review and approval by the Analytical Services Coordinator, complete an inventory checklist for each data package and document any nonconforming items, in accordance with Clinch River Environmental Restoration Program procedures. Deliverables must be completed within 5 working days from receipt of the data package.

Task 3 - Compliance Screening and Computer Automated Validation - The Subcontractor is to provide technical staff and materials to support Clinch River Environmental Restoration Program in the screening of up to 1100 electronic deliverables from analytical laboratories using EPA's Contract Compliance Screening software and Computer-Automated Validation software. As part of this task, the Subcontractor will electronically produce a report(s) that will indicate any nonconformances found or document that no nonconformances were found. This task may be performed using the Subcontractor and/or Clinch River Environmental Restoration Program workstations, as available. Ninety percent of the deliverables must be completed within 5 working days from receipt of the data diskette, with the remaining ten percent to be completed as soon as scheduling permits, but no longer than 10 working days from receipt of the data

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diskette.

Task 4 - Comprehensive Data Validation - The Subcontractor shall develop a formal validation procedure with worksheets and checklists for review and approval by the Analytical Services Coordinator. The procedure, worksheets, and checklists for each method and analysis type shall be based on the Clinch River Environmental Restoration Program Sampling and Analysis Plan, the Statements of Work, the analytical method, the applicable EPA guidelines, and/or Environmental Restoration Division guidelines. The checklists or worksheets for a given method and analysis type will include standard remarks and flags relevant to the method and analysis type covered. The Subcontractor may request Clinch River Environmental Restoration Program approval to apply additional remarks and/or flags if necessary, but all remarks and flags must be approved by Clinch River Environmental Restoration Program before use. The checklists or worksheets must be developed in the most cost effective manner, utilizing existing documents whenever possible for their generation. The Clinch River Environmental Restoration Program will determine the priority for the order in which procedures will be developed so that those needed earliest will be developed first. The Subcontractor shall provide up to 3 copies of all deliverables, with draft versions clearly marked as DRAFT. Clinch River Environmental Restoration Program comments on draft documents shall be provided within 5 working days of submittal with final documents to be provided within 5 working days following receipt of comments by the Subcontractor. Assistance will be supervised closely, and the Clinch River Environmental Restoration Program Analytical Services Coordinator and/or Program Manager will review and approve all documents.

The Subcontractor will perform comprehensive validation of a minimum of 5-10 percent of the data packages for Phase 2, a minimum of **approximately 160** data packages (~20 samples per package). The data packages to be validated will be designated by Clinch River Environmental Restoration Program and will include the first and last data package submitted by the laboratory for a given Clinch River Environmental Restoration Program task. All data validation deliverables, except for the summary narrative, are due 10 working days from receipt of the data package or 10 working days from closure of the NCR. More validation may be required if severe problems are encountered during the minimum comprehensive validation effort.

As part of the data validation process, the validator will identify any nonconformances. If a nonconformance is identified, the validator will generate a nonconformance report (NCR). Handling of NCRs is discussed under Task 5 below. Review and validation deliverables include a data review and validation package and an electronic deliverable, which are discussed in Section 5.

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Task 5 - Resolution of Nonconformances - The Subcontractor will resolve nonconformances with applicable personnel and document all resolutions in a manner agreeable to the Clinch River Environmental Restoration Program Analytical Services Coordinator or designee. This task is inclusive of all Clinch River Phase 2 data. An estimated 60 % of the data packages and sampling event files will need resolution of nonconformances. All data validation deliverables, except for the summary narrative, and applicable nonconformance reports are due 10 working days from receipt of the data package.

Task 6 - General Support - At the written direction of the Analytical Services Coordinator, the Subcontractor will provide additional technical support for completion of Tasks 2 through 5 as requested by Clinch River Environmental Restoration Program for an estimated 500 data packages. This support will include data package inventory, EPA Compliance Screening and computer-automated data validation, comprehensive data review and validation, and resolution of nonconformances. The same percentages as above apply.

Task 7 - On-site Analytical Services Support - The Subcontractor shall provide technical support to complete the following deliverables.

Subtask 7.1 Audits - The subcontractor shall participate in up to 10 audits or surveillances of analytical laboratories and generate audit reports. Included in this task is review of performance sample results. Two iterations of each deliverable shall be submitted.

Subtask 7.2 Development of Procedures or Laboratory Statement of Works - The Subcontractor shall develop Statements of Work for analytical services, develop documentation for radiological laboratory services, develop procedures for analytical services, data management, or data review and validation as directed by the Analytical Services Coordinator. For estimating purposes, the Subcontractor shall assume development of 3 submittals per month.

Subtask 7.3 Documents or Data Review - The Subcontractor shall review Laboratory Quality Assurance Plans, and review analytical results or other documents as directed by the Analytical Services Coordinator. Comments from review of the documents or data shall be presented in two iterations. For estimating purposes, the Subcontractor shall estimate review of three documents or data packages per month.

Subtask 7.4 Data Tracking and Reports - The Subcontractor shall track the status of all samples and other related documentation as directed by the Analytical Services Coordinator. This includes but is not limited to sample identification, data package identification, chain-of-custody completeness, and other related activities to ensure 100%

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tracking of all samples through analysis, archiving, and final disposition. The Subcontractor shall provide status reports of (1) sample analyses (2) data validation activities, and (3) resolution of nonconformances.

The Subcontractor shall also act as the data liaison between the Clinch River Environmental Restoration Program Analytical Services Staff and data recipients.

5. DELIVERABLES AND SCHEDULE

For Task 4, Clinch River Environmental Restoration Program will furnish an electronic diskette containing sample IDs and analytes to facilitate data entry of validation flags. Data review and validation deliverables will consist of the following:

1. Data Review and Validation Package
 - a. A batch narrative summarizing by analysis and/or method type the problems found that affect data quality for the batch. Each narrative shall include the typed name, title, and address of the data reviewer as well as his or her signature and the date. Each narrative shall also state which validation procedure was used.
 - b. A list of data qualifiers and their meanings for use in data evaluation.
 - c. Copies of data reporting forms (CLP Form 1 or equivalent, stamped COPY) with validation flags.
 - d. A completed checklist for each batch that lists those QA/QC items that have been reviewed and/or validation worksheets, as applicable.
 - e. The closed NCR that applies to the batch, if applicable.
2. Electronic entry of validation flags for each sample and analyte.
3. A summary narrative by analysis/method type/matrix/lab of the problems that affected the data quality for that particular method/matrix/lab. Each narrative shall include the name, title, and address of the data reviewer as well as his or her signature and the date.

In addition to the task deliverables outlined above, the subcontractor shall submit monthly letter reports to the Clinch River Environmental Restoration Program Analytical Services Coordinator summarizing contract progress to date. Each report shall address any problems encountered in completing the various tasks as well as any changes in scope or direction from

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the original proposal, including schedule impacts. The actual effort expended versus scheduled levels of effort, planned and actual percent completion, and planned and actual cost shall be reported on a task basis. The monthly progress reports shall be submitted by the tenth calendar day of each month for the duration of the Task Order.

In addition, whenever work is anticipated to extend beyond October 1 of a given year, the Subcontractor shall submit on or before August 15 an Annual Project Status. The Annual Project Status shall be an updated, comprehensive estimate and schedule of the Subcontractor's cost associated with the completion of its responsibilities under this Task Order. This summary shall be organized by negotiated tasks with cost distributed over a monthly schedule.

Within two weeks of the notice to proceed, the Subcontractor shall prepare a Cost Account Plan in accordance with Martin Marietta Energy Systems Draft Procedure ER/C-P1702, "Cost Account Planning."

6. PROJECT COSTS

All costs for the project shall be tracked and invoiced by task. A cost proposal shall be submitted by the Subcontractor and will identify levels of effort and costs by task. Routine cost reporting shall be provided through the monthly progress reports (see Section 5 above), with the specified cost/schedule control forms to be utilized in that reporting.

7. SPECIAL CONSIDERATIONS

Document Control

The Subcontractor shall maintain control of Clinch River Environmental Restoration Program documents as follows:

1. All data packages and data review deliverables shall be transferred to the Clinch River Analytical Services Coordinator, or designee, upon completion of work.
2. The Subcontractor shall at all times maintain secure and demonstrable custody of the sample data. The sample data will be considered to be in custody if:
 - it is in the individual's actual possession;
 - it is in the individual's view; or
 - it is placed in a designated secure area, such as a locked file cabinet or room.

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3. The Subcontractor's standard operating procedures on document control must be submitted to the Clinch River Environmental Restoration Program Analytical Services Coordinator, or designee, upon acceptance of the Statement of Work.
4. Any sample data received by the subcontractor shall be used only for the purpose of meeting the technical specifications and shall not be released to personnel that are not authorized by Clinch River Environmental Restoration Program.

Compliance

Audits to verify compliance with Clinch River Environmental Restoration Program specifications may be performed by the Clinch River Environmental Restoration Program or its designee at any time during the fulfillment of the contract or thereafter.

Training

As requested by Clinch River Environmental Restoration Program, the Subcontractor will provide resumes and/or documentation of training of Subcontractor personnel performing work under this contract. Martin Marietta Energy Systems, Inc. will provide training to satisfy work-related requirements that are specific to the Department of Energy facilities managed by Martin Marietta Energy Systems. In addition, any training required for specific projects or tasks (e.g., project standard operating procedures) will be provided by Martin Marietta Energy Systems. All other training will be provided by the subcontractor.

Other

All material gathered and/or developed in the performance of task listed in this Statement of Work shall be the property of the Department of Energy and shall not be used or distributed by the Subcontractor without the specific written permission of the Department of Energy.

Neither the Subcontractor nor the Subcontractor's personnel shall give out any news releases or conduct media interviews concerning the work performed under this Statement of Work. All media inquiries should be directed to the Martin Marietta Energy Systems Public Relations Office.

The Martin Marietta Energy Systems project manager will provide single copies of all Martin Marietta Energy Systems documents necessary to complete the activities identified in this Statement of Work.

Appendix I

SUMMARY OF DATA VALIDATION PROCESS

CLINCH RIVER ENVIRONMENTAL RESTORATION PROGRAM**PHASE 2 DATA VALIDATION**

Document No. _____
Laboratory _____
No. Of Samples _____

SDG _____
Analytical Batch _____
Sample Matrix _____

Requirement	Yes	No
1. Does the data satisfy the DQOs as specified in the SAP?		
2. Does the data satisfy the validation requirements in ES/ER/TM-16?		
3. Does the data satisfy the SOW requirements?		
4. Was the analytical method followed, without deviation?		
5. Was custody maintained throughout sampling and analysis?		

SPECIFIC VALIDATION GUIDELINES:

When professional judgment is exercised either because no guidelines are in place, or because of technical circumstances that warrant deviations from the above guidelines, explanations shall be recorded below or attached:

Authorized Reviewer's Signature:

Date:

Oversight Reviewer's Signature:

Date:

CR-ERP Signature:

Date:

SUMMARY OF DATA VALIDATION PROCESS

Level of review	Samples	Analytes	Parameters	Responsible party
Field QA Team Review	All	All	COCs All field documents	Field QA Reviewer
Field Data Package Inventory	All	All	All field documents COCs	DC
Field Data Validation	All	All	All field documents COCs	Field Validator
Data Verification	All	All	All data base variables	IMG
Preliminary Evaluation of Data	Critical field qc samples	All	Selected preliminary analytical results	ASC
Lab Data Review				LAB
Inventory of Lab Data Deliverables	All	All	All documents	DC
Inventory of Electronic Deliverables	All	All	Electronic files	IMG
Compliance Screening	All screenable electronic files	All	Electronic files	SAIC
CAVEAT	All screenable electronic files	All	Electronic files	SAIC
IMG Electronic Validation	Key Variables Spikes Duplicates Laboratory control samples	All	Electronic files	IMG
Analytical Data Validation	10% ⁺	All	Data Packages	Data Validator
Inventory of Case File	All	All	Project Deliverables	DC
Data Assessment	All	All	All Deliverables	Data Assessor

Appendix J
DATA FLAGS

**DATA FLAGS, SUFFIXES
AND REMARKS USED BY THE CR-ERP**

Data qualifiers, flags, and remarks become necessary when the data to be reported need qualifying or describing in some way. Every instance of the use of a qualifier, flag, or remark use is an effort to best describe the circumstances and quality of that piece of data and is based on all the information available to the chemist or reviewer.

DATA FLAGS AND SUFFIXES FOR ORGANIC CLP ANALYSES

- U -** The analyte was analyzed for, but was not detected above the reported sample quantitation limit.
- J -** The analyte was positively identified; the associated numerical value is the approximate concentration of the analyte in the sample.
- N -** The analysis indicates the presence of an analyte for which there is presumptive evidence to make a "tentative identification."
- NJ -** The analysis indicates the presence of an analyte that has been "tentatively identified," and the associated numerical value represents its approximate concentration.
- UJ -** The analyte was not detected above the reported sample quantitation limit. However, the reported quantitation limit is approximate and may or may not represent the actual limit of quantitation necessary to accurately and precisely measure the analyte in the sample.
- R -** The sample results are rejected due to serious deficiencies in the ability to analyze the sample and meet quality control criteria. The presence or absence of the analyte cannot be verified.
- P -** This flag is used for a pesticide/Aroclor target analyte when there is greater than 25% difference for detected concentrations between the two gas chromatograph (GC) columns. The lower of the two values is reported on Form I and flagged with an "P."
- C -** This flag applies to pesticide results where the identification has been confirmed by gas chromatography/mass spectrometry (GC/MS). If GC/MS confirmation was attempted but was unsuccessful, do not apply this flag.

DATA FLAGS AND SUFFIXES FOR ORGANIC CLP ANALYSES

- B -** This flag is used when the analyte is found in the associated blank as well as in the sample. It indicates possible/probable blank contamination and warns the data user to take appropriate action. This flag must be used for a tentatively identified compound (TIC) as well as for a positively identified target compound.
- E -** This flag identifies compounds whose concentrations exceed the calibration range of the GC/MS instrument for that specific analysis. All such compounds with a response greater than full scale should have the concentration flagged with an "E" on the Form I for the original analysis.
- D -** This flag identifies all compounds identified in an analysis at a secondary dilution factor. A "DL" suffix is appended to the sample number on the Form I for the diluted sample, and all concentration values reported on that Form I are flagged with the "D" flag. This flag alerts data users that any discrepancies between the concentrations reported may be due to dilution of the sample or extract.
- A -** This flag indicates that a TIC is a suspected aldol-condensation product.
- X -** This flag is laboratory specified. It must be fully described in the case narrative.

SAMPLE SUFFIXES FOR ORGANIC CLP ANALYSES

- MS -** Matrix spike sample
- MSD -** Matrix spike sample duplicate
- RE -** Reextracted and reanalyzed sample
- DL -** Sample analyzed at a secondary dilution

OTHER IDENTIFICATION SCHEMES FOR ORGANIC CLP ANALYSES

- VBLK## -** Volatile blanks
- SBLK## -** Semivolatile blanks
- PBLK## -** Pesticide/Aroclor method blanks
- IBLK## -** Pesticide/Aroclor instrument blanks
- FSTD### -** Volatile and semivolatile standards (such as VSTD050)
- INDAL## -** Individual mix A (low point)
- INDAM## -** Individual mix A (medium point)
- INDAH## -** Individual mix A (high point)

INDBL##	-	Individual mix B (low point)
INDBM##	-	Individual mix B (medium point)
INDBH##	-	Individual mix B (high point)
RESC##	-	Resolution check
PEM##	-	Performance evaluation mixture
TOXAPH##	-	Toxaphene
AR1016##	-	Aroclor 1016
AR1221##	-	Aroclor 1221
AR1232##	-	Aroclor 1232
AR1242##	-	Aroclor 1242
AR1248##	-	Aroclor 1248
AR1254##	-	Aroclor 1254
AR1260##	-	Aroclor 1260

DATA QUALIFIERS, FLAGS, AND SUFFIXES FOR INORGANIC CLP ANALYSES

CONCENTRATION QUALIFIERS

- B** - The reported value was obtained from a reading that was less than the contract required detection limit (CRDL) but greater than or equal to the instrument detection limit (IDL).
- U** - An analysis was conducted for the analytes, but it was not detected.

QUALITY QUALIFIERS

- E** - The reported value is estimated because of the presence of interference.
- M** - Duplicate injection precision has not been met.
- N** - Spiked sample recovery is not within control limits.
- S** - The reported value was determined by the method of standard additions (MSA).
- W** - Postdigestion spike for Furnace atomic absorption (AA) analysis is out of control limits, while sample absorbance is less than 50% of spike absorbance.
- *** - Duplicate analysis is not within control limits.

+ - Correlation coefficient for the MSA is less than 0.995.

METHOD QUALIFIER

P - Inductively coupled plasma (ICP)

A - Flame AA

F - Furnace AA

CV - Manual cold-vapor AA

AV - Automated cold-vapor AA

AS - Semiautomated spectrophotometric

C - Manual spectrophotometric

T - Titrimetric

NR - Analysis not required for the analyte.

DATA VALIDATION FLAGGING CODES**Holding Times**

- A01 Extraction holding times are exceeded.
- A02 Extraction holding times are grossly exceeded.
- A03 Analysis holding times are exceeded.
- A04 Analysis holding times are grossly exceeded.
- A05 Samples are not preserved properly.
- A06 Professional judgement was used to flag data.

GC/CM Tuning

- B01 Mass calibration is in error, even after applying expanded criteria.
- B02 Mass calibration not run every 12 hours.
- B03 Mass calibration did not meet ion abundance criteria.
- B04 Professional judgement was used to flag data.

Initial/Continuing Calibration—Organics

- C01 Initial calibration RRF < 0.05.
- C02 Initial calibration % RSD > 30%.
- C03 Initial calibration sequence was not followed as required.
- C04 Continuing calibration RRF < 0.05.
- C05 Continuing calibration % D > 25%.
- C06 Continuing calibration not analyzed at required frequency.
- C07 Resolution criteria are not met.
- C08 RPD criteria are not met.
- C09 % RSD criteria are not met.
- C10 Retention time of compounds is outside windows.
- C11 Compounds are not adequately resolved.
- C12 Breakdown of endrin or DDT is > 20%.
- C13 Combined breakdown of endrin/DDT is > 30%.
- C14 Professional judgement was used to flag data.

Initial/Counting Calibration - Inorganics & Total Petroleum Hydrocarbons

- D01 ICV or CCV were not performed for every analyte.
- D02 ICV recovery above upper control limit.
- D03 ICV recovery below lower control limit.
- D04 CCV recovery above upper control limit.
- D05 CCV recovery below lower control limit.
- D06 Standard curve is not established with the minimum number of standards.
- D07 Instrument is not calibrated daily or each time instrument is set up.
- D08 Correlation coefficient is < 0.995.
- D09 Mid range cyanide standard was not distilled.
- D10 Professional judgement was used to flag data.

ICP and Furnace Requirements

- E01 Interference check sample recovery outside limits.
- E02 Duplicate injections are outside allowable limits.
- E03 Post digestion spike recovery is outside allowable limits.
- E04 MSA was required and not performed.
- E05 Correlation coefficient was < 0.995 .
- E06 MSA spikes were not at the correct concentration.
- E07 Serial dilution criteria were not met.
- E08 Professional judgement was used to flag data.

Blanks

- F01 Sample flagged as a result of method blank.
- F02 Sample flagged as a result of field blank.
- F03 Sample flagged as a result of equipment rinse.
- F04 Sample flagged as a result of trip blank.
- F05 Gross contamination exists.
- F06 Concentration of contaminant is detected at a level below the CRQL.
- F07 Concentration of contaminant is detected at a level less than the action limit, but greater than the CRQL.
- F08 Concentration of the contaminant is detected at a level that exceeds the action level.
- F09 No laboratory blanks were analyzed.
- F10 Blank has a negative value $> 5X$'s the IDL.
- F11 Blanks not analyzed at required frequency.
- F12 Professional judgement was used to flag data.

Surrogate Recovery

- G01 Surrogate recovery above upper control limits.
- G02 Surrogate recovery below lower control limits.
- G03 Surrogate recovery is $< 10\%$.
- G04 Surrogate recovery is zero.
- G05 Surrogate is not present.
- G06 Professional judgement was used to flag data.

Matrix Spike/Matrix Spike Duplicate or RS/RSD

- H01 Recovery above upper control limit.
- H02 Recovery below lower control limit.
- H03 Recovery is $< 10\%$.
- H04 MS/MSD pairs exceed the RPD limits.
- H05 No action is taken on MS/MSD results.
- H06 Professional judgement was used to flag data.

Matrix Spike

- I01 Recovery above upper control limit.
- I02 Recovery below lower control limit.
- I03 Recovery less than 30%.
- I04 No action is taken on MS data.
- I05 Professional judgement was used to flag data.

Laboratory Duplicate

- J01 RPD falls outside of the control limits.
- J02 Sample results are greater than 5X the CRDL.
- J03 Sample results are less than 5X the CRFDL.
- J04 Professional judgement was used to flag data.

Internal Area Summary

- K01 Area counts are outside of limits.
- K02 Extremely low area counts or performance exhibits a major drop off.
- K03 IS retention time varies by more than 30 seconds.
- K04 Professional judgement was used to flag data.

Pesticide Cleanup Checks

- L01 10% recovery was obtained during either check.
- L02 Recoveries during either check were greater than 120%.
- L03 Professional judgement was used to flag data.

Target Compound Identification

- M01 Incorrect identifications were made.
- M02 Qualitative criteria were not met.
- M03 Cross contamination occurred.
- M04 Confirmatory analysis was not performed.
- M05 No results provided.
- M06 Analysis occurred outside 12 hr GC/MS window.
- M07 Professional judgement was used to flag data.

Compound Quantitation and Reported CRQLs

- N01 Quantitation limits affected by large off-scale peaks.
- N02 MDLs reported by the laboratory exceed corresponding PRDLs.
- N03 Professional judgement used to flag data.

Tentatively Identified Compounds (TICs)

- 001 Compound is suspected laboratory contaminant and was not detected in the blank.
- 002 TIC result is not above 10X the level found in the blank.
- 003 Professional judgement was used to flag data.

Laboratory Control Samples (LCSs)

- P01 Recovery above upper control limits.
- P02 Recovery below lower control limit.
- P03 Recovery < 50%.
- P04 No action is taken on the LCS data.
- P05 LCS was not analyzed at required frequency.

Field Duplicate

- Q01 No action is taken on the basis of field duplicate RPDs.

Appendix K

ENERGY SYSTEMS DEVIATION REQUEST FORM

MARTIN MARIETTA ENERGY SYSTEMS, INC.

DEVIATION REQUEST

DEVIATION NO.

DIVISION

TYPE: ☐ MATERIAL ☐ PART ☐ SYSTEM ☐ ASSEMBLY ☐ OTHER

PROJECT TITLE

PROGRAM

ITEM NAME

SPECIFICATION

DRAWING NO.

SHOP ORDER

WORK/PURCHASE ORDER

DESCRIPTION OF DEVIATION

COST IMPACT

NAME

TITLE

DATE

JUSTIFICATION AND LIMITATIONS

☐ QAA/P REVISION REQUIRED

☐ CHECK IF DRAWING OR DOCUMENT IS TO BE REVISED

☐ DESIGN REQUEST INITIATED

NAME

TITLE

DATE

APPROVED BY:

TASK LEADER

DATE

OTHER

DATE

LEAD DESIGNER

DATE

OTHER

DATE

ITEM USER

DATE

QAC

DATE

DEVIATION REQUEST Continuation Sheet

DEVIATION NO.
PAGE
OF

QA PROGRAM

DESCRIPTION OF DEVIATION

NAME

TITLE

DATE

JUSTIFICATIONS AND LIMITATIONS

NAME

TITLE

DATE

UCN-34988
13 2-761

INSTRUCTIONS FOR USE

1. For each proposed deviation, the Task Leader (TL) or person(s) delegated by the TL shall complete the Description Deviation portion of this form and shall sign and date this portion on completion at the indicated place.
2. Indicate estimated cost impact.
3. The Deviation Request (DR) Continuation Sheet shall be used as necessary to adequately explain Step 1.
4. Upon evaluation by management of the correctness and completeness of Steps 1 and 2, the TL or his designee shall complete the portion, Justification and Limitations in the necessary detail, and shall sign and date this portion. Check if drawing, document, or QAA/P is to be revised.
5. The DR Continuation Sheet shall be used as necessary to adequately explain Step 3.
6. The portion, Approved By, requires signature of all personnel substantially participating in the approval of the deviation, giving date and their title.
7. Each DR(s), where the deviation results in a design or engineering change, requires the signature of the Lead Designer with the date of such signature.
8. All DR's require the signature of the person using the final item or responsibility for its performance in service, or the signature of his supervisor; unless such authority is specifically delegated by the QA Plan or QA Program Index or management responsible for manufacture.
9. The DR and each attached DR Continuation Sheet shall be signed and dated at the appropriate places.
10. The QAC shall, upon satisfactory completion of the information required on the DR, sign and date the DR.

Appendix L
MASTER LISTS/CODES

MASTER LISTS

CONTAINERS

ALUMINUM CAN, 90 ML	ALUMCAN
CARTRIDGE FILTER, 0.45 UM	CARTFLTR
CUBITAINER, 1-GAL	CUB1GAL
GLASS, AMBER W/TEFLON LINED CAP, 1-GAL	AGLS1GAL
GLASS, AMBER W/TEFLON LINED CAP, 1-LITER	AGLS1LI
GLASS, W/TEFLON LINED CAP, 250-ML	GLS250ML
GLASS, WIDEMOUTH W/TEFLON LINED CAP, 8-OZ	GLS8OZ
GLASS, WIDEMOUTH W/TEFLON LINED CAP, 16-OZ	GLS16OZ
MARINELLI BEAKER, W/POLYETHYLENE LINED CLOSURE, 500-ML	MBRK500
POLYETHYLENE, W/POLYETHYLENE CLOSURE, 1-LITER	HDPE1L
POLYETHYLENE, W/POLYETHYLENE CLOSURE, 500-ML	HDPE500ML
POLYETHYLENE, W/POLYETHYLENE CLOSURE, 250-ML	HDPE250ML
POLYETHYLENE, W/POLYETHYLENE CLOSURE, 16-OZ	HDPE16OZ
TEFLON, NARROW MOUTH, NALGENE	TFL
TEFLON VIAL, 30 ML	TFL30ML

PRESERVATIVES

COOL, 4°C	CHILL
HNO ₃ TO PH <2.0	HNO3
HCL TO PH <2.0, COOL, 4°C	HCL
H ₂ SO ₄ TO PH <2.0, COOL, 4°C	H2SO4
NAOH TO PH >12.0, COOL, 4°C	NAOH
DRY	DRY
FREEZE	FREZ

TASK CODES

INVESTIGATION OF CURRENT CONTAMINANT SOURCES	W1.1
TEMPORAL AND SPATIAL CHANGES IN WBR WATER	W1.2
SUSPENDED MATTER QUANTIFICATION	W1.3
CONTAMINANTS DOWNSTREAM FROM OUTFALLS	W1.4
WATER TOXICITY	W2
INVESTIGATION OF CURRENT CONTAMINANT SOURCES	S1.A
SEDIMENT CONTAMINANT CHARACTERIZATION	S1.B
BENTHIC INVERTEBRATES	S1.3C
NEAR-SHORE SEDIMENT CHARACTERIZATION	S2
SEDIMENT TOXICITY	S3
CONTAMINANT TRANSPORT MODELING	S4

SAMPLER TYPES

NISKIN	NS
PERISTALTIC PUMP	PP
KEMMERER SAMPLER	KS
PONAR GRAB SAMPLER	PG
ECKMAN GRAB SAMPLER	EG
MULTIPLE(4) HEAD GRAVITY CORER	GC4
SINGLE(1) HEAD GRAVITY CORER	GC1
VIBRA COREK	VC
VANDORN SAMPLER	VS
ELECTRO SHOCK	ES
GILL NET	GN

SEDIMENT TYPES

COHESIVE MUD	CM
SOFT MUD	SM
SANDY MUD	SDM
SAND AND GRAVEL	SG
SUBMERGED SOIL	SS

ANALYSIS CATEGORY

RADIOCHEMICAL	RAD
ORGANICS	ORG
INORGANICS	INO
PHYSICAL	PHYSC
TOXICITY	TOX
PORE WATER EXTRACTION	PWX

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