

EXHIBIT E

QUALITY ASSURANCE/QUALITY CONTROL (QA/QC) PROCEDURES AND REQUIREMENTS

Exhibit E - Quality Assurance/Quality Control (QA/QC) Procedures and Requirements

Table of Contents (Con't)

<u>Section</u>	<u>Page</u>
1.0 OVERVIEW.....	5
1.1 Quality Assurance/Quality Control (QA/QC) Activities	5
1.2 Incentives/Sanctions	5
2.0 INTRODUCTION.....	6
2.1 Quality Assurance/Quality Control (QA/QC) Program Components	6
3.0 GENERAL QUALITY ASSURANCE/QUALITY CONTROL (QA/QC) PRACTICES.....	7
4.0 SPECIFIC QUALITY ASSURANCE/QUALITY CONTROL (QA/QC) MONITORING PROCEDURES...	7
4.1 Purpose	7
4.2 Laboratory Audit and Intercomparison Study Program	8
4.3 Quality Assurance/Quality Control Measurements	8
5.0 QUALITY ASSURANCE PLAN (QAP)	9
5.1 Introduction	9
5.2 Required Elements of a Quality Assurance Plan (QAP)	9
5.3 Incentives/Sanctions	12
6.0 STANDARD OPERATING PROCEDURES (SOPs)	13
6.1 Introduction	13
6.2 Format	14
6.3 Required SOPs	14
6.4 Updating and Submitting Standard Operating Procedures (SOPs)	17
6.5 Incentives/Sanctions	18
7.0 CONTRACT COMPLIANCE SCREENING (CCS)	18
7.1 Overview	18
7.2 CCS Results	18
7.3 CCS Trend Report	18
7.4 Incentives/Sanctions	19
8.0 ANALYTICAL STANDARDS REQUIREMENTS	19
8.1 Overview	19
8.2 Preparation of Chemical Standards from the Neat High Purity Bulk Material	19
8.3 Purchase of Chemical Standards Already in Solution	20
8.4 Documentation of the Verification and Preparation of Chemical Standards	23
8.5 Incentives/Sanctions	23
9.0 DATA PACKAGE AUDITS	23
9.1 Overview	23
9.2 Responding to the Data Package Audit Report	24
9.3 Incentives/Sanctions	24
10.0 RESERVED.....	24
11.0 PROFICIENCY TESTING	24
11.1 Performance Evaluation (PE) Samples	24
11.2 Semi-Annual Blind (SB) Audits	25
11.3 Incentives/Sanctions	26
12.0 ON-SITE LABORATORY EVALUATIONS	27
12.1 Overview	27
12.2 Quality Assurance (QA) On-Site Evaluation	27
12.3 Evidentiary Audit	28
12.4 Discussion of the On-Site Team's Findings	28
12.5 Incentives/Sanctions	29

Exhibit E - Quality Assurance/Quality Control (QA/QC) Procedures and Requirements

Table of Contents (Con't)

13.0	ELECTRONIC DATA AUDITS	29
13.1	Overview	29
13.2	Submission of the High Resolution Gas Chromatography/High Resolution Mass Spectrometry (HRGC/HRMS) Instrument Electronic Data	31
13.3	Responding to the High Resolution Gas Chromatography/High Resolution Mass Spectrometry (HRGC/HRMS) Electronic Data Audit Report	31
13.4	Incentives/Sanctions	31
14.0	RESERVED	31
15.0	DATA MANAGEMENT	31
15.1	Overview	31
15.2	Documenting Data Changes	32
15.3	Lifecycle Management Procedures	32
15.4	Personnel Responsibilities	32

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1.0 OVERVIEW

Quality Assurance (QA) and Quality Control (QC) are integral parts of the U.S. Environmental Protection Agency's (USEPA) Contract Laboratory Program (CLP). The QA process consists of management review and oversight at the planning, implementation, and completion stages of the environmental data collection activity, and ensures that data provided are of the quality required. The QC process includes those activities required during data collection to produce the data quality desired and to document the quality of the collected data.

1.1 Quality Assurance/Quality Control (QA/QC) Activities

During the planning of an environmental data collection program, QA activities focus on defining data quality criteria and designing a QC system to measure the quality of data being generated. During the implementation of the data collection effort, QA activities ensure that the QC system is functioning effectively, and the deficiencies uncovered by the QC system are corrected. After environmental data are collected, QA activities focus on assessing the quality of data obtained to determine its suitability to support enforcement or remedial decisions.

- 1.1.1 This exhibit describes the overall QA/QC operations and the processes by which the CLP meets the QA/QC objectives defined above. The contract requires a variety of QA/QC activities. These contract requirements are the minimum QC operations necessary to satisfy the analytical requirements associated with the determination of the different method analytes. These QC operations are designed to facilitate laboratory comparison by providing the Government with comparable data from all Contractors. These requirements do not release the analytical Contractor from maintaining their own QC checks on method and instrument performance.

1.2 Incentives/Sanctions

The Contractor may anticipate incentives by consistently providing the following: (1) high quality, technically sound data, as stipulated by the contract; (2) on-time or early delivery of the Sample Delivery Group (SDG) Cover Sheet; (3) above average Semi-annual Blind (SB) Performance Evaluation (PE) sample scores; (4) electronic deliverables that pass the initial Contract Compliance Screening (CCS) acceptance criteria; and (5) SDGs delivered on-time. Samples are distributed routinely to Contractors based on the quality of work performed, as measured by the Performance Scheduling Algorithm (PSA) (as stated in the contract). A Contractor that consistently meets the contract performance requirements as highlighted above, will earn a higher PSA score, thereby increasing the likelihood of receiving samples for analyses. If the Contractor fails to meet the requirements set forth in this Statement of Work (SOW) or elsewhere in the contract, USEPA may take, but is not limited to, the following actions (as stated in the contract): reduction in the number of samples sent under the contract; suspension of sample shipments; data package audit(s); electronic data audit(s); on-site laboratory evaluation(s); and/or remedial PE sample(s).

2.0 INTRODUCTION

Appropriate use of data generated under the large range of analytical conditions encountered in environmental analyses requires reliance on the Quality Control (QC) procedures and criteria incorporated into the methods. Inaccuracies can also result from causes other than unanticipated matrix effects, such as sampling artifacts, equipment malfunctions, and operator error. Therefore, the QC component of each method is indispensable.

The data acquired from QC procedures are used to estimate and evaluate the information content of analytical results and to determine the necessity for, or the effect of, corrective action procedures. The parameters used to estimate information content include precision, accuracy, and other quantitative and qualitative indicators. In addition, QC procedures give an overview of the activities required in an integrated program to generate data of known and documented quality required to meet defined objectives.

2.1 Quality Assurance/Quality Control (QA/QC) Program Components

- 2.1.1 The necessary components of a complete QA/QC program include internal QC criteria that demonstrate acceptable levels of performance, as determined by QA review. External review of data and procedures is accomplished by the monitoring activities of the USEPA Office of Superfund Remediation and Technology Innovation (OSRTI) Analytical Services Branch (ASB), Regional data users, the Sample Management Office (SMO), and the Quality Assurance Technical Support (QATS) Laboratory. Each external review accomplishes a different purpose. These reviews are described in specific sections of this exhibit. Laboratory evaluation samples, electronic data audits, and data packages provide an external QA reference for the program. A Contractor on-site evaluation system is also part of the external QA monitoring. A feedback loop provides the results of the various review functions to the Contractors through direct communications with the Project Officer (PO).
- 2.1.2 This exhibit does not provide specific instructions for constructing QA Plans (QAPs), QC systems, or a QA organization. It is, however, an explanation of the QA/QC requirements of the program. It outlines some minimum standards for QA/QC programs. It also includes specific items that are required in a Quality Assurance Plan (QAP) and by the QA/QC documentation detailed in this contract. Delivery of this documentation provides the Government with a complete data package, and limits the need for contact with the Contractor or an analyst, at a later date, if some aspect of the analysis is questioned.
- 2.1.3 In order to assure that the product delivered by the Contractor meets the requirements of the contract, and to improve interlaboratory data comparison, the Government requires the following from the Contractor:
- Preparation of, and adherence to, a written QAP, the elements of which are designated in Section 5.0 of this exhibit;
 - Preparation of, and adherence to, Standard Operating Procedures (SOPs), as described in Section 6.0 of this exhibit;

- Adherence to the analytical methods and associated QC requirements specified in the contract;
- Verification of analytical standards and documentation of the purity of neat materials and the purity and accuracy of solutions obtained from private chemical supply houses;
- Submission of all raw data and pertinent documentation for Regional review;
- Participation in the analysis of laboratory evaluation samples, including adherence to corrective action procedures;
- Submission, upon request, of instrument electronic data and applicable documentation for electronic data audits, including a copy of the Complete Sample Delivery Group (SDG) File (CSF);
- Participation in on-site laboratory evaluations, including adherence to corrective action procedures; and
- Submission of all original documentation generated during sample analyses for Government review.

3.0 GENERAL QUALITY ASSURANCE/QUALITY CONTROL (QA/QC) PRACTICES

The Contractor shall adhere to good laboratory practices for laboratory cleanliness with regard to glassware and apparatus. The Contractor shall also adhere to good laboratory practices with regard to reagents, solvents, and gases. For additional guidelines regarding these general laboratory procedures, see the Handbook for Analytical Quality Control in Water and Wastewater Laboratories, USEPA-600/4-79-019, USEPA Environmental Monitoring Systems Laboratory, Cincinnati, Ohio, September 1982.

4.0 SPECIFIC QUALITY ASSURANCE/QUALITY CONTROL (QA/QC) MONITORING PROCEDURES

4.1 Purpose

- 4.1.1 The purpose of this document is to provide (1) a uniform set of procedures for the analysis of 2,3,7,8 substituted tetra through octa-chlorinated dioxin and furan constituents of samples, (2) documentation of methods and their performance, and (3) verification of the sample data generated. Although it is impossible to address every analytical situation in one document, this exhibit defines the minimum requirements for each major step relevant to any dioxin analysis.
- 4.1.2 The primary function of the Contract Laboratory Program (CLP) QA/QC program is the definition of procedures for the evaluation and documentation of analytical methodologies and the reduction and reporting of data. The objective is to provide a uniform basis for sample handling, instrument and methods maintenance, performance evaluation, and analytical data gathering and reporting. In many instances where methodologies are available, specific QC procedures are incorporated into the method documentation (see Exhibit D).
- 4.1.3 The QA/QC procedures defined herein shall be used by the Contractor when performing the methods specified in Exhibit D. When QA/QC procedures are specified in Exhibit D, the Contractor shall follow those procedures, in addition to procedures specified here.

Exhibit E - Section 4
Specific QA/QC Monitoring Procedures (Con't)

4.2 Laboratory Audit and Intercomparison Study Program

The Contractor is required to participate in the Laboratory Audit and Intercomparison Study Program run by USEPA. The Contractor shall be required to analyze at least one Semi-annual Blind (SB) sample per calendar half-year during the contract period.

4.3 Quality Assurance/Quality Control Measurements

- 4.3.1 In this Exhibit, as well as other places within this Statement of Work (SOW), the term "analytical sample" discusses the required frequency or placement of certain QA/QC measurements. The term "analytical sample" is defined in the glossary, Exhibit G.
- 4.3.2 In order for the QA/QC information to reflect the status of the samples analyzed, all samples and their associated QA/QC analysis shall be analyzed under the same operating and procedural conditions.
- 4.3.3 If any QC measurement fails to meet contract criteria, the analytical measurement must not be repeated prior to taking the appropriate corrective action as specified in Exhibit D.
- 4.3.4 The Contractor shall report all QC data in the exact format specified in Exhibits B and H.
- 4.3.5 All reported measurements shall be within the instrumental calibrated ranges. The Contractor shall maintain QC data confirming instrument performance and analytical results.

5.0 QUALITY ASSURANCE PLAN (QAP)

5.1 Introduction

The Contractor shall establish a Quality Assurance (QA) program with the objective of providing sound analytical chemical measurements. This program shall incorporate the Quality Control (QC) procedures, any necessary corrective action, all documentation required during data collection, and the quality assessment measures performed by management to ensure acceptable data production. The Contractor shall follow the USEPA EPA Requirements for Quality Management Plans (QA/R-2).

5.1.1 The Contractor shall prepare a written QAP which describes the procedures that are implemented to:

- Maintain data integrity, validity, and usability;
- Ensure that analytical measurement systems are maintained in an acceptable state of stability and reproducibility;
- Detect problems through data assessment and establish corrective action procedures which keep the analytical process reliable; and
- Document all aspects of the measurement process to provide data which are technically sound and legally defensible.

5.1.2 The QAP must present, in specific terms, the policies, organization, objectives, functional guidelines, and specific QA/QC activities designed to achieve the data quality requirements in this contract. Where applicable, Standard Operating Procedures (SOPs) pertaining to each element shall be included or referenced as part of the QAP. The QAP shall be paginated consecutively in ascending order. The QAP shall be available during on-site laboratory evaluations and shall be submitted within 7 days of written request by the Project Officer (PO) or the USEPA Office of Superfund Remediation and Technology Innovation (OSRTI) Analytical Services Branch (ASB) Dioxin Program Manager (PM). Additional information relevant to the preparation of a QAP can be found in USEPA and ASTM publications.

5.2 Required Elements of a Quality Assurance Plan (QAP)

The required elements of a laboratory's QAP are outlined in this section. This outline should be used as a framework for developing the QAP.

A. Organization and Personnel

1. QA Policy and Objectives (the mission and quality policy of the organization)
2. QA Management (the specific roles, authorities, and responsibilities of management and staff with respect to QA and QC activities)
 - a. Organization
 - b. Assignment of QA/QC Responsibilities
 - c. Reporting Relationships (the means by which effective communication with personnel actually performing the work are assured)
 - d. QA Document Control Procedures

Exhibit E -- Section 5
Quality Assurance Plan (QAP) (Con't)

- e. QA Program Assessment Procedures (the process used to plan, implement, and assess the work performed)
- 3. Key Personnel (Laboratory Personnel involved in QA and QC activities)
 - a. Resumes
 - b. Education and Experience Pertinent to this Contract
 - c. Training Records and Progress
- B. Facilities and Equipment
 - 1. Instrumentation and Backup Alternatives
 - 2. Maintenance Activities and Schedules
- C. Document Control
 - 1. Laboratory Notebook Policy
 - 2. Sample Tracking/Custody Procedures
 - 3. Logbook Maintenance and Archiving Procedures
 - 4. Sample Delivery Group (SDG) File Organization, Preparation, and Review Procedures
 - 5. Procedures for Preparation, Approval, Review, Revision, and Distribution of SOPs
 - 6. Process for Revision of Technical or Documentation Procedures
- D. Analytical Methodology
 - 1. Calibration Procedures and Frequency
 - 2. Sample Preparation/Extraction Procedures
 - 3. Sample Analysis Procedures
 - 4. Standards Preparation Procedures
 - 5. Decision Processes, Procedures, and Responsibility for Initiation of Corrective Action
- E. Data Generation
 - 1. Data Collection Procedures
 - 2. Data Reduction Procedures
 - 3. Data Validation Procedures
 - 4. Data Reporting and Authorization Procedures
- F. QA (The process which measures the effectiveness of QA will be established and how frequently effectiveness will be measured)
 - 1. Data QA
 - 2. Systems/Internal Audits
 - 3. Performance/External Audits
 - 4. Corrective Action Procedures (the continual improvement based on lessons learned from previous experience)
 - 5. QA Reporting Procedures
 - 6. Responsibility Designation

G. QC

1. Solvent, Reagent, and Adsorbent Check Analysis
2. Reference Material Analysis
3. Internal QC Checks
4. Corrective Action and Determination of QC Limit Procedures
5. Responsibility Designation

5.3 Updating and Submitting the Quality Assurance Plan (QAP)

5.2.1 Initial Submission

During the contract solicitation process, the Contractor is required to submit their QAP to the USEPA Contracting Officer (CO). Within 60 days after contract award, the Contractor shall maintain on-file at their facility a revised QAP, fully compliant with the requirements of this contract. The Contractor shall maintain the QAP on-file at the Contractor's facility for the term of the contract. The revised QAP will become the official QAP under the contract and may be used during legal proceedings. The Contractor shall maintain the QAP on-file at the Contractor's facility for the term of the contract. Both the initial submission and the revised QAP shall be paginated consecutively in ascending order. The revised QAP shall include:

- Changes resulting from (1) the Contractor's internal review of their organization, personnel, facility, equipment, policy and procedures, and (2) the Contractor's implementation of the requirements of the contract; and
- Changes resulting from Government review of the laboratory evaluation sample data, contractor-supplied documentation, and recommendations made during the pre-award on-site laboratory evaluation.

5.2.1.1 The Contractor shall send a copy of the latest version of the QAP within 7 days of a request from the PO or OSRTI ASB PM. The USEPA requestor will designate the recipients.

5.2.2 Subsequent Updates and Submissions: During the term of contract, the Contractor shall amend the QAP when the following circumstances occur:

- USEPA modifies technical requirements of the Statement of Work (SOW) or the contract;
- USEPA notifies the Contractor of deficiencies in the QAP document;
- USEPA notifies the Contractor of deficiencies resulting from USEPA's review of the Contractor's performance;
- The Contractor identifies deficiencies resulting from their internal review of their QAP document;
- The Contractor's organization, personnel, facility, equipment, policy, or procedures change; or
- The Contractor identifies deficiencies resulting from the internal review of their organization, personnel, facility, equipment, policy, or procedure changes.

5.2.2.1 The Contractor shall amend the QAP within 14 days of when the circumstances listed above result in a discrepancy between what was previously described in the QAP, and what is presently occurring at the Contractor's facility. When the QAP is amended, all changes in the QAP shall be clearly marked (e.g., a bar in the margin indicating

Exhibit E -- Section 5
Quality Assurance Plan (QAP) (Con't)

where the change is found in the document, or highlighting the change by underlining the change, bold printing the change, or using a different print font) and a copy is sent to the OSRTI ASB PM and Quality Assurance Technical Support (QATS). The amended section pages shall have the date on which the changes were implemented. The Contractor shall incorporate all amendments to the latest version of the QAP document. The Contractor shall archive all amendments to the QAP document for future reference by the Government.

- 5.2.2.2 The Contractor shall send a copy of the latest version of the QAP document within 7 days of a written request by the PO or the OSRTI ASB PM, as directed. The USEPA requestor will designate the recipients.

5.3 Incentives/Sanctions

The Contractor shall amend the QAP as specified within this section. The QAP describes the policies and procedures for ensuring that work processes, products, or services satisfy expectations or specifications in the contract. Failure to comply with the requirements of this section may results in sanctions, as described in the contract.

6.0 STANDARD OPERATING PROCEDURES (SOPs)

6.1 Introduction

To obtain reliable results, adherence to prescribed analytical methodology is imperative. In any operation that is performed on a repetitive basis, reproducibility is best accomplished through the use of SOPs. As defined by USEPA, an SOP is a written document which provides directions for the step-by-step execution of an operation, analysis, or action which is commonly accepted as the method for performing certain routine or repetitive tasks. The Contractor shall follow the USEPA Guidelines on Preparing Standard Operating Procedures (SOPs) (QA/G-6).

- 6.1.1 SOPs prepared by the Contractor shall be functional (i.e., clear, comprehensive, up-to-date, and sufficiently detailed to permit duplication of results by qualified analysts). The SOPs shall be paginated consecutively in ascending order.
- 6.1.2 All SOPs shall reflect activities as they are currently performed in the laboratory. In addition, all SOPs shall be:
- Consistent with current USEPA regulations, guidelines, and the Contract Laboratory Program (CLP) contract's requirements;
 - Consistent with instrument(s) manufacturer's specific instruction manuals;
 - Available to the Government during an on-site laboratory evaluation. A complete set of SOPs shall be bound together and available for inspection at such evaluations. During on-site laboratory evaluations, laboratory personnel may be asked to demonstrate the application of the SOPs;
 - Available to designated recipients within 7 days, upon request by the Project Officer (PO) or the Office of Superfund Remediation and Technology Innovation (OSRTI) Analytical Services Branch (ASB) Dioxin Program Manager (PM);
 - Capable of providing for the development of documentation that is sufficiently complete to record the performance of all tasks required by the protocol;
 - Capable of demonstrating the validity of data reported by the Contractor and explaining the cause of missing or inconsistent results;
 - Capable of describing the corrective measures and feedback mechanism utilized when analytical results do not meet protocol requirements;
 - Reviewed regularly and updated as necessary when contract, facility, or Contractor procedural modifications are made;
 - Archived for future reference in usability or evidentiary situations;
 - Available at specific workstations, as appropriate; and
- Reviewed and signed by all Contractor personnel performing actions identified in the SOP; and
- Subject to a document control procedure which precludes the use of outdated or inappropriate SOPs.

6.2 Format

The format for SOPs may vary depending upon the type of activity for which they are prepared. However, at a minimum, the following sections shall be included:

- Title page;
- Document Control;
- Scope and Applicability;
- Summary of Method;
- Definitions (acronyms, abbreviations, and specialized forms used in the SOP;
- Health and Safety;
- Personnel Qualifications;
- Interferences;
- Apparatus and Materials (list or specify, also note designated locations where found);
- Handling and Preservation;
- Instrument or Method Calibration;
- Sample Preparation and Analysis;
- Data Calculations;
- Procedures;
- Quality Control (QC) limits;
- Corrective action procedures, including procedures for secondary review of information being generated;
- Documentation description and example forms;
- Data Management and Records Management;
- Miscellaneous notes and precautions; and
- References.

6.3 Required SOPs

The Contractor shall maintain the following SOPs:

- 6.3.1 Evidentiary SOPs for required chain-of-custody and document control, which are discussed in Exhibit F.
- 6.3.2 Sample receipt and storage:
 - Sample receipt and identification logbooks;
 - Refrigerator temperature logbooks;
 - Extract storage logbooks; and
 - Security precautions.

6.3.3 Sample preparation:

- Reagent purity check procedures and documentation;
- Extraction procedures;
- Extraction bench sheets; and
- Extraction logbook maintenance.

6.3.4 Glassware cleaning

6.3.5 Calibration (balances, etc.):

- Procedures;
- Frequency requirements;
- Preventative maintenance schedule and procedures;
- Acceptance criteria and corrective actions; and
- Logbook maintenance authorization.

6.3.6 Analytical Procedures (for each analytical system):

- Instrument performance specifications;
- Instrument operating procedures;
- Data acquisition system operation;
- Procedures used when automatic quantitation algorithms are overridden;
- QC-required parameters;
- Analytical run/injection logbooks; and
- Instrument error and editing flag descriptions and resulting corrective actions.

6.3.7 Maintenance activities (for each analytical system):

- Preventative maintenance schedule and procedures;
- Corrective maintenance determinants and procedures; and
- Maintenance authorization.

6.3.8 Analytical standards:

- Standard coding/identification and inventory system;
- Standards preparation logbook(s);
- Standard preparation procedures;
- Procedures for equivalency/traceability analyses and documentation;
- Purity logbook (primary standards and solvents);
- Storage, replacement, and labeling requirements; and
- QC and corrective action measures.

6.3.9 Data reduction procedures:

- Data processing systems operation;
- Outlier identification methods;

Exhibit E -- Section 6

Standard Operating Procedures (SOPs) (Con't)

- Identification of data requiring corrective action; and
- Procedures for format and/or forms for each operation.

6.3.10 Documentation policy/procedures:

- Contractor/analyst's notebook policy, including review policy;
- Complete Sample Delivery Group (SDG) File (CSF) contents;
- CSF organization and assembly procedures, including review policy; and
- Document inventory procedures, including review policy.

6.3.11 Data validation/self-inspection procedures:

- Data flow and Chain-of-Command for data review;
- Procedures for measuring precision and accuracy;
- Evaluation parameters for identifying systematic errors;
- Procedures to assure that hardcopy and electronic deliverables are complete and compliant with the requirements in Exhibits B and H;
- Procedures to assure that hardcopy deliverables are in agreement with their comparable electronic deliverables;
- Demonstration of internal Quality Assurance (QA) inspection procedure (demonstrated by supervisory sign-off on personal notebooks, internal Performance Evaluation (PE) samples, etc.);
- Frequency and type of internal audits (e.g., random, quarterly, spot checks, perceived trouble areas);
- Demonstration of problem identification, corrective actions, and resumption of analytical processing. Sequence resulting from internal audit (i.e., QA feedback); and
- Documentation of audit reports (internal and external), response, corrective action, etc.

6.3.12 Data management and handling:

- Procedures for controlling and estimating data entry errors;
- Procedures for reviewing changes to data and deliverables and ensuring traceability of updates;
- Lifecycle management procedures for testing, modifying, and implementing changes to existing computing systems to include hardware, software, and documentation or installation of new systems;
- Database security, backup, and archival procedures including recovery from system failures;
- System maintenance procedures and response time;
- Individual(s) responsible for system operation, maintenance, data integrity, and security;
- Specifications for staff training procedures;
- Virus Protection procedures for software and electronic data deliverables; and

- Storage, retrieval and verification of the completeness and readability of High Resolution Gas Chromatography/High Resolution Mass Spectrometry (HRGC/HRMS) files transferred to electronic media.

6.4 Updating and Submitting Standard Operating Procedures (SOPs)

6.4.1 Initial Submission: During the contract solicitation process, the Contractor is required to submit their SOPs to the USEPA Contracting Officer (CO). Within 60 days after contract award, the Contractor shall maintain on-file a complete revised set of SOPs, fully compliant with the requirements of this contract. The revised SOPs will become the official SOPs under the contract and may be used during legal proceedings. The Contractor shall maintain the complete set of SOPs on-file at the Contractor's facility for the term of the contract. Both the initial submission of SOPs and the revised SOPs shall be paginated consecutively in ascending order. The revised SOPs shall include:

- Changes resulting from 1) the Contractor's internal review of their procedures, and 2) the Contractor's implementation of the requirements of the contract, and
- Changes resulting from the Government's review of the laboratory evaluation sample data, contractor supplied documentation, and recommendations made during the pre-award on-site laboratory evaluation.

6.4.1.1 The Contractor shall send a complete set of the latest version of SOPs or individually requested SOPs within 7 days of a request from the PO or Contracting Officer (CO).

6.4.2 Subsequent Updates and Submissions: During the term of the contract, the Contractor shall amend the SOPs when the following circumstances occur:

- USEPA modifies the technical requirements of the Statement of Work (SOW) or the contract;
- USEPA notifies the Contractor of deficiencies in their SOP documentation;
- USEPA notifies the Contractor of deficiencies resulting from USEPA's review of the Contractor's performance;
- The Contractor's procedures change;
- The Contractor identifies deficiencies resulting from the internal review of SOP documentation; or
- The Contractor identifies deficiencies resulting from the internal review of procedures.

6.4.2.1 Existing SOPs shall be amended or new SOPs shall be written within 30 days of when the circumstances listed above result in a discrepancy between what was previously described in the SOPs, and what is presently occurring at the Contractor's facility. All changes in the SOPs shall be clearly marked (e.g., a bar in the margin indicating where the change is in the document, or highlighting the change by underlining the change, bold printing the change, or using a different print font) and a copy is sent to the OSRTI ASB PM and QATS. The amended/new SOPs shall have the date on which the changes were implemented.

Exhibit E -- Section 6
Standard Operating Procedures (SOPs) (Con't)

- 6.4.2.2 When existing SOPs are amended or new SOPs are written, the Contractor shall document the reasons for the changes and maintain the amended SOPs or new SOPs on-file. Documentation of the reasons for the changes shall be maintained on-file with the amended SOPs or new SOPs. Documentation of the reason(s) for changes to the SOPs shall also be submitted along with the SOPs.
- 6.4.2.3 The Contractor shall send a complete set of the latest version of SOPs or individually requested SOPs within 7 days of a request from the PO or the OSRTI ASB PM. The USEPA requestor shall designate the recipients.

6.5 Incentives/Sanctions

The Contractor shall amend SOPs as specified within this section. The SOPs specify analytical procedures in greater detail than appear in Exhibit D. Adherence to these requirements shall ensure that the procedures are conducted in a standard, reliable, and reproducible process as described in this SOW. Failure to comply with the requirements specified herein may result in sanctions, as described in the contract.

7.0 CONTRACT COMPLIANCE SCREENING (CCS)

7.1 Overview

- 7.1.1 CCS is one aspect of the Government's contractual right of inspection of analytical data. CCS examines the Contractor's adherence to the contract requirements based on the Complete Sample Delivery Group (SDG) File (CSF) delivered to USEPA.
- 7.1.2 CCS is performed by the Sample Management Office (SMO) at the direction of USEPA. To assure uniform review, a set of standardized procedures has been developed to evaluate the CSF submitted by a Contractor against the technical and completeness requirements of the contract. USEPA reserves the right to add and/or delete individual checks.

7.2 CCS Results

CCS results are distributed to the Contractor and all other data recipients. The Contractor has 6 business days to correct deficiencies. The Contractor shall send all corrections to the Task Order Project Officer (TOPO) and SMO within 6 business days. CCS results are used in conjunction with other information to measure overall Contractor performance and to take appropriate actions to correct deficiencies in performance.

7.3 CCS Trend Report

USEPA will periodically generate a CCS Trend Report which summarizes CCS results over a given period of time. The Government may send the CCS Trend Report to the contractor, or discuss the DCC Trend Report during an on-site laboratory evaluation. In a detailed letter to the Office of Superfund Remediation and Technology Innovation (OSRTI) Analytical Services Branch (ASB) Dioxin Program Manager (PM) and the USEPA Contracting Officer (CO), the Contractor shall address the deficiencies and the subsequent corrective actions implemented by the Contractor to correct the deficiencies within 14 days of receipt of the report or the on-site laboratory evaluation.

7.4 Incentives/Sanctions

If new Standard Operating Procedures (SOPs) are required to be written, or if existing SOPs are required to be rewritten or amended because of the deficiencies and the subsequent corrective action implemented by the Contractor, the Contractor shall write/amend and submit the SOPs per the requirements listed in Section 6. The Contractor shall correct deficiencies and resubmit the data within 6 business days, as specified within this section. Resubmission and correction of the data will ensure that the end user is reviewing contractually compliant data as described in the Statement of Work (SOW). Correct resubmission of the data may also result in a reduction in overall sanctions. Specific details on incentives can be found in the contract. If the Contractor fails to adhere to the requirements listed in this section, the Contractor will be in noncompliance with the contract and may be subjected to sanctions, as described in the contract.

8.0 ANALYTICAL STANDARDS REQUIREMENTS

8.1 Overview

USEPA may not supply analytical reference standards for either direct analytical measurements or the purpose of traceability. All contract laboratories shall be required to prepare, from materials or purchase from private chemical supply houses, those standards necessary to successfully and accurately perform the analyses required in this protocol.

8.2 Preparation of Chemical Standards from the Neat High Purity Bulk Material

- 8.2.1 If the laboratory cannot obtain analytical reference standards, the laboratory may prepare its own chemical standards. Laboratories shall obtain the highest purity possible when purchasing chemical standards. Standards purchased at less than 97% purity shall be documented as to why a higher purity could not be obtained.
- 8.2.2 If required by the manufacturer, the chemical standards shall be kept refrigerated when not being used in the preparation of standard solutions. Proper storage of chemicals is essential to safeguard them from decomposition.
- 8.2.3 The purity of a compound can sometimes be misrepresented by a chemical supply house. Since knowledge of purity is needed to calculate the concentration of solute in a solution standard, it is the Contractor's responsibility to have analytical documentation ascertaining that the purity of each compound is correctly stated. Purity confirmation, when performed, should use appropriate techniques. Use of two or more independent methods is recommended. The correction factor for impurity when weighing neat materials in the preparation of solution standards is determined using the following equation:

EQ. 1 Weight of Impure Compound

$$\text{Weight of Impure Compound} = \frac{\text{weight of pure compound}}{(\text{percent purity}/100)}$$

Where;

Weight of Pure Compound = That required to prepare a specific volume of a solution standard of a specified concentration.

Exhibit E -- Section 8
Analytical Standards Requirements (Con't)

- 8.2.4 When compound purity is assayed to be 97% or greater, the weight may be used without correction to calculate the concentration of the stock standard. If the compound purity is assayed to be less than 97%, the weight shall be corrected when calculating the concentration of the stock solution.
- 8.2.5 Mis-identification of compounds occasionally occurs and it is possible that a mislabeled compound may be received from a chemical supply house. It is the Contractor's responsibility to have analytical documentation ascertaining that all compounds used in the preparation of solution standards are correctly identified. Identification confirmation, when performed, shall use Gas Chromatography/Mass Spectrometry (GC/MS) analysis on at least two different analytical columns, or other appropriate techniques.
- 8.2.6 Calculate the weight of material to be weighed out for a specified volume, taking into account the purity of the compound and the desired concentration. A second person shall verify the accuracy of the calculations. Check balances for accuracy with a set of standard weights every 12 hours. All weighing shall be performed on an analytical balance to the nearest 0.1 mg and verified by a second person. The solvent used to dissolve the solute shall be compatible with the protocol in which the standard is to be used; the solute shall be soluble, stable, and nonreactive with the solvent. In the case of a multicomponent solution, the components must not react with each other.
- 8.2.7 Transfer the solute to a volumetric flask and dilute to the specified solution volume with solvent after ensuring dissolution of the solute in the solvent. Sonication or warming may be performed to promote dissolution of the solute. This solution shall be called the primary standard and all subsequent dilutions shall be traceable back to the primary standard.
- 8.2.8 Log notebooks are to be kept for all weighing and dilutions. All subsequent dilutions from the primary standard and the calculations for determining their concentrations are to be recorded and verified by a second person. All solution standards are to be refrigerated, if required, when not in use. All solution standards are to be clearly labeled to include the identity of the analyte or analytes, concentration, date prepared, solvent, and initials of the preparer.

8.3 Purchase of Chemical Standards Already in Solution

Solutions of analytical reference standards can be purchased by Contractors provided they meet the following criteria.

- 8.3.1 Contractors shall maintain documentation of the purity confirmation of the material to verify the integrity of the standard solutions they purchase.
- The Contractor shall purchase standards for which the quality is demonstrated statistically and analytically by a method of the supplier's choice. One way this can be demonstrated is to prepare and analyze three solutions: a high standard; a low standard, and a standard at the target concentration (see Sections 8.3.1.1 and 8.3.1.2). The supplier must then demonstrate that the analytical results for the high standard and low standard are consistent with the difference in theoretical concentrations. This is done by the Student's t-test in Section 8.3.1.4. If consistency is achieved, the supplier must then demonstrate that the concentration of the target standard lies midway between the concentrations of the low and high standards. This is done by the

Student's t-test in Section 8.3.1.5. Then, the standard is certified to be within 10% of the target concentration using the equations in Section 8.3.1.6. If the procedure above is used, the supplier must document that the following have been achieved.

8.3.1.1 Two solutions of identical concentration shall be prepared independently from neat materials. An aliquot of the first solution shall be diluted to the intended concentration (the "target standard"). One aliquot is taken from the second solution and diluted to a concentration 10% greater than the target standard. This is called the "high standard". One further aliquot is taken from the second solution and diluted to a concentration 10% less than the target standard. This is called the "low standard".

8.3.1.2 Using the equation below, six replicate analyses of each standard (a total of 18 analyses) shall be performed in the following sequence: low standard, target standard, high standard; low standard, target standard, high standard, etc.

EQ. 2 Mean

$$\text{Mean} = \frac{\sum_{i=1}^6 Y_i}{6}$$

8.3.1.3 The mean and variance of the six results for each solution shall be calculated using the following equation:

EQ. 3 Variance

$$\text{Variance} = \frac{\sum_{i=1}^6 Y_i^2 - 6(\text{MEAN})^2}{5}$$

Where:

The values Y_1, Y_2, Y_3, \dots , represent the results of the six analyses of each standard.

The means of the low, target, and high standards are designated M_1, M_2 , and M_3 , respectively.

The variances of the low, target, and high standards are designated V_1, V_2 , and V_3 , respectively.

Additionally, a pooled variance, V_p , is calculated using the following equation.

EQ. 4 Pooled Variance

$$V_p = \frac{\frac{V_1}{0.81} + V_2 + \frac{V_3}{1.21}}{3}$$

If the square root of V_p is less than 1% of M_2 , $M_2^2/10,000$, it is to be used as the value of V_p in all subsequent calculations.

8.3.1.4 The test statistic shall be calculated using the following equation:

Exhibit E -- Section 8
Analytical Standards Requirements (Con't)

EQ. 5 Test Statistic I

$$\text{Test Statistic} = \frac{\left| \frac{M_3}{1.1} - \frac{M_1}{0.9} \right|}{\left(\frac{V_p}{3} \right)^{0.5}}$$

If the test statistic exceeds 2.13, the supplier has failed to demonstrate a 20% difference between the high and low standards. In such a case, the standards are not acceptable.

8.3.1.5 The test statistic shall be calculated using the following equation:

EQ. 6 Test Statistic II

$$\text{Test Statistic} = \frac{\left| M_2 - \left(\frac{M_1}{1.8} \right) - \left(\frac{M_3}{2.2} \right) \right|}{\left(\frac{V_p}{4} \right)^{0.5}}$$

If the test statistic exceeds 2.13, the supplier has failed to demonstrate that the target standard concentration is midway between the high and low standards. In such a case, the standards are not acceptable.

8.3.1.6 The 95% confidence intervals for the mean result of each standard shall be calculated using the following equations:

EQ. 7 Interval for Low Standard

$$\text{Interval for Low Standard} = M_1 \pm 2.13 \left(\frac{V_p}{6} \right)^{0.5}$$

EQ. 8 Interval for Target Standard

$$\text{Interval for Target Standard} = M_2 \pm 2.13 \left(\frac{V_p}{6} \right)^{0.5}$$

EQ. 9 Interval for High Standard

$$\text{Interval for High Standard} = M_3 \pm 2.13 \left(\frac{V_p}{6} \right)^{0.5}$$

8.3.1.6.1 These intervals shall not overlap. If overlap is observed, the supplier has failed to demonstrate the ability to discriminate the 10% difference in concentrations. In such a case, the standards are not acceptable.

8.3.1.6.2 In any event, the Contractor is responsible for the quality of the standards employed for analyses under this contract.

8.4 Documentation of the Verification and Preparation of Chemical Standards

It is the responsibility of the Contractor to maintain the necessary documentation to show that the chemical standards used in the performance of the Contract Laboratory Program (CLP) analysis conform to the requirements previously listed.

- 8.4.1 Weighing logbooks, calculations, raw data, etc., whether produced by the Contractor or purchased from chemical supply houses, shall be maintained by the Contractor and may be subject to review during on-site inspection visits. In those cases where the documentation is supportive of the analytical results of data packages sent to the Government, such documentation is to be kept on-file by the Contractor for a period of one year.
- 8.4.2 Upon request by the Office of Superfund Remediation and Technology Innovation (OSRTI) Analytical Services Branch (ASB) Dioxin Program Manager (PM), the Contractor shall submit their most recent previous year's documentation (12 months) for the verification and preparation of chemical standards within 14 days of receipt of the request to the designated recipients.
- 8.4.3 USEPA will periodically generate a report discussing deficiencies in the Contractor's documentation for the verification and preparation of chemical standards, or they may discuss the deficiencies during an on-site laboratory evaluation. In a detailed letter to the OSRTI ASB PM and the CLP Quality Assurance (QA) Coordinator, the Contractor shall address the deficiencies and the subsequent corrective action implemented by the Contractor to correct the deficiencies within 14 days of receipt of the report or the on-site laboratory evaluation.
- 8.4.4 If new Standard Operating Procedures are required to be written or if existing SOPs are required to be rewritten or amended because of deficiencies and the subsequent corrective action implemented by the Contractor, the Contractor shall write/amend and submit the SOPs per the requirements listed in Exhibit E, Section 6.

8.5 Incentives/Sanctions

The Contractor shall obtain the highest purity possible when purchasing chemical standards specified within this section. The use of high purity standards will ensure a more accurate identification and quantitation of analytes described in the Statement of Work (SOW). Failure to meet the requirements set forth in this section may result in sanctions, as described in the contract.

9.0 DATA PACKAGE AUDITS

9.1 Overview

Data package audits may be performed by the Government for program overview and specific Regional concerns. Data packages may be periodically selected from recently received Cases and evaluated for the technical quality of hardcopy raw data, Quality Assurance (QA), and the adherence to contractual requirements. This function provides external monitoring of program Quality Control (QC) requirements. Data package audits are used to assess the technical quality of the data and evaluate overall laboratory performance. Audits provide the Government with an in-depth inspection and evaluation of the Case data package with regard to achieving QA/QC acceptability.

Exhibit E -- Sections 11 & 12
On-Site Laboratory Evaluations

9.2 Responding to the Data Package Audit Report

- 9.2.1 After completion of the data package audit, the Government may send a copy of the data package audit report to the Contractor, or discuss the data package audit report on an on-site laboratory evaluation. In a detailed letter to the Project Officer (PO) and the designated recipient, the Contractor shall discuss the corrective actions implemented to resolve the deficiencies listed in the data package audit report within 14 days of receipt of the report.
- 9.2.2 If new SOPs are required to be written, or if existing SOPs are required to be rewritten or amended because of deficiencies and subsequent corrective action implemented by the Contractor, the Contractor shall write/amend the SOPs per the requirements listed in Exhibit E, Section 6.

9.3 Incentives/Sanctions

The Contractor shall discuss the corrective actions implemented to resolve the deficiencies listed in the data package audit report within 14 days of receipt of the comments from USEPA, as specified within this section. The data package audits ensure that the policies and procedures identified in this Statement of Work (SOW) meet the requirements of this contract. If the Contractor fails to adhere to the requirements listed in this section, the Contractor will be in noncompliance with the contract and may be subjected to sanctions as described in the contract.

10.0 RESERVED

11.0 PROFICIENCY TESTING

As a means of measuring and evaluating both the Contractor's and the method's analytical performance, the Contractor shall participate in USEPA's Proficiency Testing Program. USEPA's Proficiency Testing Program involves the analysis of Case-specific Performance Evaluation (PE) samples and the Semi-annual Blind (SB) audits. The Contractor's PE and SB sample results will be used by USEPA to assess and verify the Contractor's continuing ability to produce acceptable analytical data in accordance with the contractual requirements. The Contractor must receive a passing score of 75% to be in compliance with the contract.

11.1 Performance Evaluation (PE) Samples

- 11.1.1 The PE sample(s) may be scheduled with the Contractor as frequently as on a Sample Delivery Group (SDG)-by-SDG basis.
- 11.1.2 PE samples will be provided as either single-blinds (recognizable as a PE sample, but of unknown composition), or as double-blinds (not recognizable as a PE sample and of unknown composition). The Contractor will not be informed of either the analytes/parameters or the concentrations in the PE samples.
- 11.1.3 The Contractor may receive the PE samples as either full volume samples or ampulated/bottled concentrates from USEPA or a designated USEPA Contractor. The PE samples shall come with instructions concerning the unique preparation procedures, if any, required to reconstitute the PE samples (i.e., the required dilution of the PE sample concentrate). PE samples are to be extracted and analyzed with the rest of the routine samples in the SDG. The Contractor shall prepare and analyze the PE

sample using the procedure described in the sample preparation and method analysis sections of Exhibit D. All contract required Quality Control (QC) shall also be met. The PE sample results are to be submitted in the SDG deliverable package per normal reporting procedures detailed in Exhibit B. If these requirements are not met, the Region may reject all the data associated with the SDG.

- 11.1.4 In addition to PE sample preparation and analysis, the Contractor shall be responsible for correctly identifying and quantitating the analytes/parameters included in each PE sample. When PE sample results are received by USEPA, the PE sample results will be evaluated for correct analytical identification and quantitation. The results of the PE sample evaluation will be provided to the Contractor via coded evaluation sheets, by analyte/parameter. USEPA will notify the Contractor of unacceptable performance. USEPA reserves the right to adjust the PE sample acceptance windows to compensate for any unanticipated difficulties with a particular PE sample.

11.2 Semi-Annual Blind (SB) Audits

- 11.2.1 A SB Audit is a unique analytical Case containing only PE samples (i.e., referred to as SB samples). The SB samples will be scheduled by the USEPA OSRTI ASB through the Sample Management Office (SMO). SB samples assist USEPA in monitoring Contractor performance.
- 11.2.2 SB samples will be provided as single-blinds (recognizable as a PE sample but of unknown composition). The Contractor will not be informed of either the analytes or the concentrations in the PE samples.
- 11.2.3 The Contractor may receive the SB samples as either full volume samples or ampulated/bottled concentrates from USEPA or a designated USEPA Contractor. The SB samples shall come with instructions concerning the unique preparation procedures, if any, required to reconstitute the SB samples (i.e., the required dilution of the SB sample concentrate). The Contractor shall prepare and analyze the SB samples using the procedure described in the sample preparation and method analysis sections of Exhibit D. All contract required QC shall be met, including spike and duplicate analyses. The SB sample results are to be submitted in the SDG deliverable package per normal reporting procedures detailed in Exhibit B.
- 11.2.4 In addition to SB sample preparation and analysis, the Contractor shall be responsible for correctly identifying and quantitating the analytes included in each SB sample. When SB sample results are received by USEPA, the SB sample results will be scored for correct analytical identification, quantitation, and timeliness. The SB sample scoring will be provided to the Contractor via coded evaluation sheets, by analyte. USEPA will notify the Contractor of unacceptable performance. The Contractor's SB sample performance will be assessed into one of the following three categories:
 - 11.2.4.1 Acceptable, No Response Required: Score greater than or equal to 90%. The data meets most or all of the scoring criteria. No response is required.
 - 11.2.4.2 Acceptable, Response Explaining Deficiencies Required: Score greater than or equal to 75%, but less than 90%. Deficiencies exist in the Contractor's performance. Corrective action response required.
 - 11.2.4.3 Unacceptable Performance, Response Explaining Deficiencies Required: Score less than 75%. Corrective action response required.

Exhibit E -- Section 11
Proficiency Testing (Con't)

- 11.2.5 In the case of Section 11.2.4.2 or 11.2.4.3, the Contractor shall describe the deficiency(ies) and the action(s) taken in a corrective action letter to the USEPA Contracting Officer, Project Officer (PO), the Analytical Services Branch Dioxin Program Manager (ASB PM), and the CLP Quality Assurance (QA) Coordinator within 14 days of receipt of notification from USEPA.
- 11.2.6 In the case of Section 11.2.4.2 or 11.2.4.3, if new Standard Operating Procedures (SOPs) are required to be written, or if existing SOPs are required to be rewritten or amended because of deficiencies and subsequent corrective action implemented by the Contractor, the Contractor shall write/amend the SOPs per the requirements listed in Exhibit E, Section 6.
- 11.2.7 A Remedial SB Audit is a unique analytical Case containing only SB samples. A Remedial SB Audit may be scheduled by the USEPA OSRTI ASB with the Contractor(s) for any of the following reasons: unacceptable PE sample performance, unacceptable SB sample performance, and/or major change in the laboratory (e.g., relocation, new owner, or high turnover of key personnel). The Contractor shall be on Contracting Officer (CO) Hold until the Remedial SB Audit package is submitted. Sections 11.2.2 through 11.2.7 apply to the Remedial SB Audit process.
- 11.2.8 The Contractor shall be notified by the USEPA Contracting Officer concerning agreement or disagreement with the proposed remedy for unacceptable performance.

11.3 Incentives/Sanctions

The Contractor shall analyze PE and SB samples with acceptable analytical results in accordance with the contractual requirements as described in this section. If the Contractor fails to adhere to the requirements listed in this section, the Contractor will be in noncompliance with the contract and may be subjected to sanctions as described in the contract.

12.0 ON-SITE LABORATORY EVALUATIONS

12.1 Overview

As dictated by a contract laboratory's performance, the Project Officer (PO) or their authorized representative may conduct an on-site laboratory evaluation. On-site laboratory evaluations are carried out to monitor the Contractor's ability to meet selected terms and conditions specified in the contract. The evaluation process may incorporate two separate categories: Quality Assurance (QA) Evaluation and an Evidentiary Audit.

12.2 Quality Assurance (QA) On-Site Evaluation

QA evaluators inspect the Contractor's facilities to verify the adequacy and maintenance of instrumentation, the continuity, experience and education of personnel, and the acceptable performance of analytical and Quality Control (QC) procedures.

12.2.1 The Contractor should expect that items to be monitored will include, but not be limited to, the following:

- Size and appearance of the facility;
- Quantity, age, availability, scheduled maintenance, and performance of instrumentation;
- Availability, appropriateness, and utilization of the Quality Assurance Plan (QAP) and Standard Operating Procedures (SOPs);
- Staff qualifications, experience, and personnel training programs; Analysis of Performance Evaluation (PE) samples;
- Reagents, standards, and sample storage facilities;
- Standard preparation logbooks and raw data;
- Bench sheets and analytical logbook maintenance and review; and
- Review of the Contractor's sample analysis/data package inspection/data management procedures.

12.2.2 Prior to an on-site evaluation, various documentation pertaining to performance of the specific Contractor is integrated into a profile package for discussion during the evaluation. Items that may be included are:

- Previous on-site reports;
- Performance Evaluation (PE) or Semi-annual Blind (SB) sample scores;
- Regional review of data;
- Regional QA materials;
- Data audit reports;
- Results of Contract Compliance Screening (CCS); and
- Data trend reports.

12.3 Evidentiary Audit

Evidence auditors conduct an on-site laboratory evaluation to determine if laboratory policies and procedures are in place to satisfy evidence handling requirements, as stated in Exhibit F. The evidence audit comprises a procedural audit, an audit of written SOPs, and an audit of analytical project file documentation.

12.3.1 Procedural Audit

The procedural audit consists of review and examination of actual SOPs and accompanying documentation for the following laboratory operations:

- Sample receiving;
- Sample storage;
- Sample identification;
- Sample security;
- Sample tracking (from receipt to completion of analysis);
- Analytical project file organization and assembly; and
- Proper disposal of samples and cogenerated wastes.

12.3.2 Written SOPs Audit

The written SOPs audit consists of review and examination of the written SOPs to determine if they are accurate and complete for the following laboratory operations:

- Sample receiving;
- Sample storage;
- Sample identification;
- Sample security;
- Sample tracking (from receipt to completion of analysis); and
- Analytical project file organization and assembly.

12.3.3 Analytical Project File Evidence Audit

The analytical project file evidence audit consists of review and examination of the analytical project file documentation. The auditors review the files to determine:

- The accuracy of the document inventory;
- The completeness of the file;
- The adequacy and accuracy of the document numbering system;
- Traceability of sample activity;
- Identification of activity recorded on the documents; and
- Error correction methods.

12.4 Discussion of the On-Site Team's Findings

The QA and evidentiary auditors discuss their findings with the PO and/or authorized representatives prior to debriefing the Contractor.

During the debriefing, the auditors present their findings and recommendations for corrective actions necessary to the Contractor personnel. A report which discusses deficiencies found during the on-site audit will be sent to the Contractor to provide further clarification of findings. In a detailed letter to the PO and CLP Quality Assurance Coordinator, the Contractor shall discuss the deficiencies and the subsequent corrective actions implemented by the Contractor to resolve the deficiencies within 14 days of receipt of report or the on-site laboratory evaluation.

If new SOPs are required to be written, or if existing SOPs are required to be rewritten or amended because of the deficiencies and the subsequent corrective action implemented by the Contractor, the Contractor shall write/amend the SOPs per the requirements listed in Exhibit E, Section 6.

12.5 Incentives/Sanctions

The Contractor shall submit to on-site evaluations, as specified within this section. The on-site evaluations ensure that the policies and procedures identified in this Statement of Work (SOW) meet the requirements of this contract. If the Contractor fails to adhere to the requirements listed in this section, the Contractor will be in noncompliance with the contract and may be subjected to sanctions as described in the contract.

13.0 ELECTRONIC DATA AUDITS

13.1 Overview

13.1.1 Periodically, USEPA may request the High Resolution Gas Chromatography/High Resolution Mass Spectrometry (HRGC/HRMS) electronic instrument data from Contractors for a specific Case to perform electronic data audits. Generally, electronic data submissions and audits are requested for the following reasons:

- Program overview;
- Indication of data quality problems;
- Support for on-site audits; and
- Specific Regional requests.

13.1.2 Depending upon the reason for an audit, the instrument electronic data from a recent Case, a specific Case, or a Performance Evaluation (PE) sample may be requested. Electronic data audits provide a mechanism to assess adherence to contractual requirements, and to ensure the consistency of data reported on the hardcopy/electronic deliverables with that generated on the HRGC/HRMS analytical instruments. This function provides external monitoring of program Quality Control (QC) requirements and checks adherence of the Contractor to internal Quality Assurance (QA) procedures. In addition, electronic data audits enable the USEPA to evaluate the utility, precision, and accuracy of the analytical methods.

13.1.3 The Contractor shall store all raw and processed HRGC/HRMS data in appropriate instrument manufacturer's format uncompressed and with no security codes. This electronic data shall include data for samples, blanks, Laboratory Control Samples (LCSs), initial calibrations, calibration verifications, system performance checks, Window Defining Mixtures (WDMs), isomer specificity checks, and column performance standards, as well as all Contractor-generated spectral libraries and quantitation reports required to generate the data package. The

Exhibit E -- Section 13
Electronic Data Audits (Con't)

Contractor shall maintain a written reference logbook of data files of the Sample Number, calibration data, standards, and blanks. The logbook shall include Sample Numbers and standard and blank IDs, identified by Case and Sample Delivery Group (SDG).

- 13.1.4 The Contractor is required to retain the HRGC/HRMS instrument electronic data for 3 years after submission of the reconciled Complete SDG File (CSF). When submitting HRGC/HRMS instrument electronic data to the USEPA, the following materials shall be delivered in response to the request:
- 13.1.4.1 All associated raw data files for samples, including laboratory evaluation and QC samples, blanks, LCSs, initial calibration and calibration verification standards, and system instrument performance check solutions [WDM, Column Performance Solution (CPS), and perfluorokerosene (PFK)].
- 13.1.4.2 All processed data files and quantitation output files associated with the raw data files described in Section 13.1.4.1.
- 13.1.4.3 All associated identifications and calculation files used to generate the data submitted in the data package.
- 13.1.4.4 A copy of the Contractor's written reference logbook relating data files to Sample Numbers, calibration data, standards, blanks, and LCSs. The logbook shall include Sample Numbers and Lab File identifiers for all samples, blanks, and standards, identified by Case and SDG.
- 13.1.4.5 A printout of the directory of all files in each directory, including all subdirectories and the files contained therein.
- 13.1.4.6 A copy of the Complete Sample Delivery Group (SDG) File (CSF), if audit request is made within the period during which the Contractor must retain a copy.
- 13.1.4.7 A statement attesting to the completeness of the HRGC/HRMS instrument electronic data submission, signed and dated by the Contractor's Laboratory Manager. The Contractor shall also provide a statement attesting that the data reported have not been altered in any way. These statements shall be part of a cover sheet that includes the following information relevant to the data tape submission:
- Contractor name;
 - Date of submission;
 - Case number;
 - SDG number;
 - HRGC/HRMS make and model number;
 - Instrument operating software and version;
 - Data system computer;
 - System operating software;
 - Data system network;
 - Data backup software;
 - Data analysis software;
 - Media type and volume of data (in MB) backed up; and

- Names and telephone numbers of two Contractor contacts for further information regarding the submission.

13.2 Submission of the High Resolution Gas Chromatography/High Resolution Mass Spectrometry (HRGC/HRMS) Instrument Electronic Data

- 13.2.1 Upon request of Project Officer (PO), the Contractor shall send the required HRGC/HRMS instrument electronic data and all necessary documentation to the designated recipient within 7 days of notification.

NOTE: The HRGC/HRMS data shall be shipped according to the procedures described in Exhibit F.

13.3 Responding to the High Resolution Gas Chromatography/High Resolution Mass Spectrometry (HRGC/HRMS) Electronic Data Audit Report

After completion of the HRGC/HRMS data audit, the USEPA may send a copy of the HRGC/HRMS electronic data audit report to the Contractor or may discuss the HRGC/HRMS electronic data audit report at an on-site laboratory evaluation. In a detailed letter to the PO, the Contractor shall discuss the corrective actions implemented to resolve the deficiencies listed in the HRGC/HRMS electronic data audit report within 14 days of receipt of the report or on-site laboratory evaluation.

- 13.3.1 If new Standard Operating Procedures (SOPs) are required to be written or SOPs are required to be amended because of the deficiencies and the subsequent corrective action implemented by the Contractor, the Contractor shall write/amend and submit the SOPs per the requirements listed in Exhibit E, Section 6.

13.4 Incentives/Sanctions

The Contractor shall submit to electronic data audits and adhere to the requirements specified in this section. Resubmission and correction of electronic data will ensure that the end user is reviewing contractually compliant data described in the contract. If the Contractor fails to adhere to the requirements listed in this section, the Contractor will be in noncompliance with the contract and may be subjected to sanctions as described in the contract.

14.0 RESERVED

15.0 DATA MANAGEMENT

15.1 Overview

- 15.1.1 Data management procedures are defined as procedures specifying the acquisition, entry, update, correction, deletion, storage, and security of computer readable data and files. These procedures shall be developed by the contractor, be in written form and contain a clear definition for all databases and files used to generate or resubmit deliverables. Key areas of concern include: system organization (including personnel and security); documentation operations; traceability; and Quality Control (QC).

- 15.1.2 Data manually entered from hardcopy shall be subject to QC checks and the error rates estimated. Systems should prevent entry of incorrect or out-of-range data and alert data entry personnel of errors. In addition, data entry error rates shall be estimated and recorded on a monthly basis

by re-entering a statistical sample of the data entered and calculating discrepancy rates by data element.

15.2 Documenting Data Changes

The record of changes in the form of corrections and updates to data originally generated, submitted, and/or resubmitted shall be documented to allow traceability of updates. Documentation shall include the following for each change:

- Justification or rationale for the change;
- Initials of the person making the change(s). Data changes shall be implemented and reviewed by a person or group independent of the source generating the deliverable;
- Documentation of changes shall be retained according to the schedule of the original deliverable;
- Resubmitted diskettes or other deliverables shall be re-inspected as a part of the laboratory's internal inspection process prior to resubmission. The entire deliverable, not just the changes, shall be inspected;
- The Laboratory Manager shall approve changes to originally submitted deliverables; and
- Documentation of data changes may be requested by laboratory auditors.

15.3 Lifecycle Management Procedures

Lifecycle management procedures shall be applied to computer software systems developed by the Contractor to be used to generate and edit contract deliverables. Such systems shall be thoroughly tested and documented prior to utilization.

- 15.3.1 A software test and acceptance plan including test requirements, test results, and acceptance criteria shall be developed, followed, and available in written form.
- 15.3.2 System changes shall not be made directly to production systems generating deliverables. Changes shall be made first to a development system, and tested prior to implementation.
- 15.3.3 Each version of the production system shall be given an identification number, a date of installation, and a date of last operation, and will be archived.
- 15.3.4 System and operations documentation shall be developed and maintained for each system. Documentation shall include a user's manual and operations and maintenance manuals.
- 15.3.5 This documentation shall be available for on-site review and/or upon written request by the Project Officer (PO) or OSRTI ASB Dioxin PM (PM).

15.4 Personnel Responsibilities

Individual(s) responsible for the following functions shall be identified:

- System operation and maintenance including documentation and training;
- Database integrity, including data entry, data updating and QC; and
- Data and system security, backup, and archiving.

EXHIBIT F

CHAIN-OF-CUSTODY, DOCUMENT CONTROL,
AND WRITTEN STANDARD OPERATING PROCEDURES (SOPs)

Exhibit F - Chain-of-Custody, Document Control, and
Written Standard Operating Procedures (SOPs)

Table of Contents

<u>Section</u>	<u>Page</u>
1.0 INTRODUCTION	3
1.1 Purpose of Evidence Requirements	3
2.0 STANDARD OPERATING PROCEDURES (SOPs)	4
2.1 Sample Receiving	4
2.2 Sample Identification	5
2.3 Sample Security	5
2.4 Sample Storage	5
2.5 Sample Tracking and Document Control	5
2.6 Computer-Resident Sample Data Control	6
2.7 Complete Sample Delivery Group (SDG) File (CSF) Organization and Assembly	7
3.0 WRITTEN STANDARD OPERATING PROCEDURES (SOPs)	9
3.1 Sample Receiving	9
3.2 Sample Identification	10
3.3 Sample Security	10
3.4 Sample Storage	10
3.5 Sample Tracking and Document Control	11
3.6 Computer-Resident Sample Data Control	12
3.7 Complete Sample Delivery Group (SDG) File (CSF) Organization and Assembly	12

1.0 INTRODUCTION

A sample is physical evidence collected from a facility or the environment. Controlling evidence is an essential part of the hazardous waste investigation effort. To ensure that the U.S. Environmental Protection Agency's (USEPA's) sample data and records supporting sample-related activities are admissible and have weight as evidence in future litigation, Contractors are required to maintain USEPA furnished samples under chain-of-custody and to account for all samples and supporting records of sample handling, preparation, and analysis. Contractors shall maintain sample identity, sample custody, and all sample-related records according to the requirements in this exhibit.

1.1 Purpose of Evidence Requirements

The purpose of the evidence requirements include:

- Ensuring traceability of samples while in possession of the Contractor;
- Ensuring sample chain-of-custody while in possession of the Contractor;
- Ensuring the integrity of sample identity while in possession of the Contractor;
- Ensuring sample-related activities are recorded on documents or in other formats for USEPA sample receipt, storage, preparation, analysis, and disposal;
- Ensuring all laboratory records for each specified Sample Delivery Group (SDG) will be accounted for when the project is completed, and
- Ensuring that all laboratory records directly related to Government furnished samples are assembled and delivered to the Government or, prior to delivery, are available upon USEPA's request.

Exhibit F -- Section 2
Standard Operating Procedures (SOPs)

2.0 STANDARD OPERATING PROCEDURES (SOPs)

The Contractor shall implement the following SOPs for sample receiving, sample identification, sample security, sample storage, sample tracking and document control, computer-resident sample data control, and Complete Sample Delivery Group (SDG) File (CSF) organization and assembly to ensure accountability of sample chain-of-custody, as well as control of all sample-related records.

2.1 Sample Receiving

- 2.1.1 The Contractor shall designate a sample custodian responsible for receiving Government furnished samples.
- 2.1.2 The Contractor shall designate a representative to receive Government furnished samples in the event that the sample custodian is not available.
- 2.1.3 Upon receipt, the condition of shipping containers and sample containers shall be inspected and recorded on Form DC-1 by the sample custodian or a designated representative.
- 2.1.4 Upon receipt, the condition of the custody seals (intact/broken) shall be inspected and recorded on Form DC-1 by the sample custodian or a designated representative.
- 2.1.5 The sample custodian or a designated representative shall verify and record on Form DC-1, the agreement or disagreement of information recorded on all documents received with samples and information recorded on sample containers.
- 2.1.6 The sample custodian or a designated representative shall verify and record the following information on Form DC-1 as samples are received and inspected:
 - Presence or absence and condition of custody seals on shipping and/or sample containers;
 - Custody seal numbers, when present;
 - Condition of the sample bottles;
 - Presence or absence of airbills or airbill stickers;
 - Airbill or airbill sticker numbers;
 - Presence or absence of Traffic Report/Chain of Custody Records (TR/COC);
 - Sample tags listed/not listed on TR/COCs;
 - Presence or absence of cooler temperature indicator bottle;
 - Cooler temperature;
 - Date of receipt;
 - Time of receipt;
 - EPA Sample Numbers;
 - Presence or absence of sample tags;
 - Sample tag numbers;

- Assigned laboratory numbers;
- Remarks regarding condition of sample shipment;
- Samples delivered by hand; and
- Problems and discrepancies.

2.1.7 The sample custodian or a designated representative shall sign, date, and record the time on all accompanying forms, when applicable, at the time of sample receipt (e.g., TR/COCs or packing lists, and airbills).

NOTE: Initials are not acceptable.

2.1.8 The Contractor shall contact the Sample Management Office (SMO) to resolve problems and discrepancies including, but not limited to: absent documents; conflicting information; absent or broken custody seals; absent temperature indicator bottle; and unsatisfactory sample condition (e.g., leaking sample container).

2.1.9 The Contractor shall record resolution of all problems and discrepancies communicated through SMO.

2.2 Sample Identification

2.2.1 The Contractor shall maintain the identity of Government furnished samples and prepared samples (including extracted samples, digested samples, and distilled samples) throughout the laboratory.

2.2.2 Each sample and sample preparation container shall be labeled with the EPA Sample Number or a unique laboratory sample identification number.

2.3 Sample Security

2.3.1 The Contractor shall demonstrate that sample custody is maintained from receiving through retention or disposal. A sample is in custody if:

- It is in your possession; or
- It is in your view after being in your possession; or
- It is locked in a secure area after being in your possession; or
- It is in a designated secure area, accessible only to authorized personnel.

2.3.2 The Contractor shall demonstrate security of designated secure areas.

2.4 Sample Storage

The Contractor shall designate storage areas for Government furnished samples and prepared samples.

2.5 Sample Tracking and Document Control

2.5.1 The Contractor shall record all activities performed on Government furnished samples.

2.5.2 Titles which identify the activities recorded shall be printed on each page of all laboratory documents. (Activities include, but are not limited to: sample receipt; sample storage; sample preparation, and sample analysis.) When a document is a record of analysis, the instrument type and parameter group shall be included in the title.

Exhibit F -- Section 2
Standard Operating Procedures (SOPs) (Con't)

- 2.5.3 When columns are used to organize information recorded on laboratory documents, the information recorded in the columns shall be identified in a column heading.
- 2.5.4 Reviewers' signatures shall be identified on laboratory documents when reviews are conducted.
- NOTE: Individuals recording review comments on computer-generated raw data are not required to be identified unless the written comments address data validity.
- The laboratory name shall be identified on pre-printed laboratory documents.
- 2.5.5 Each laboratory document entry shall be dated in the format MM/DD/YYYY (e.g., 01/01/2009) and signed (or initialed) by the individual(s) responsible for performing the recorded activity at the time the activity is recorded.
- 2.5.6 Notations on laboratory documents shall be recorded in ink.
- 2.5.7 Corrections to laboratory data reporting forms and raw data shall be made by drawing single lines through the errors and entering the correct information. Information shall not be obliterated or rendered unreadable. Corrections and additions to information shall be signed (or initialed) and dated.
- 2.5.8 Unused portions of laboratory documents shall be lined-out.
- 2.5.9 Pages in bound and unbound logbooks shall be sequentially numbered.
- 2.5.10 Instrument-specific run logs shall be maintained to enable the reconstruction of run sequences.
- 2.5.11 Logbook entries shall be in chronological order.
- 2.5.12 Logbook entries shall include only one SDG per page, except in the event where SDGs "share" Quality Control (QC) samples (e.g., instrument run logs and extraction logs).
- 2.5.13 Information inserted into laboratory documents shall be affixed permanently in-place. The individual responsible for inserting information shall sign and date across the insert and logbook page at the time information is inserted.
- 2.5.14 Each page in bound and unbound logbooks shall be dated (MM/DD/YYYY) and signed (no initials) at the bottom by the individual recording the activity (if a single entry is made on a page) or by the last individual recording information on the page (if multiple entries are on the same page).
- 2.5.15 The Contractor shall document disposal or retention of Government furnished samples, remaining portions of samples, and prepared samples.
- 2.6 Computer-Resident Sample Data Control
- 2.6.1 Contractor personnel responsible for original data entry shall be identified at the time of data input.
- 2.6.2 The Contractor shall make changes to electronic data in a manner which ensures that the original data entry is preserved, the editor is identified, and the revision date is recorded.
- 2.6.3 The Contractor shall routinely verify the accuracy of manually entered data, electronically entered data, and data acquired from instruments.

- 2.6.4 The Contractor shall routinely verify documents produced by the electronic data collection system to ensure accuracy of the information reported.
- 2.6.5 The Contractor shall ensure that the electronic data collection system is secure.
- 2.6.5.1 The electronic data collection system shall be maintained in a secure location.
- 2.6.5.2 Access to the electronic data collection system functions shall be limited to authorized personnel through utilization of software security techniques (e.g., log-ons or restricted passwords).
- 2.6.5.3 Electronic data collection systems shall be protected from the introduction of external programs or software (e.g., viruses).
- 2.6.6 The Contractor shall designate archive storage areas for electronic data and the software required to access the data.
- 2.6.7 The Contractor shall designate an individual responsible for maintaining archives of electronic data, including the software.
- 2.6.8 The Contractor shall maintain the archives of electronic data and necessary software in a secure location that shall be accessible only to authorized personnel.
- 2.7 Complete Sample Delivery Group (SDG) File (CSF) Organization and Assembly
- 2.7.1 The Contractor shall designate a Document Control Officer responsible for the organization and assembly of the CSF.
- 2.7.2 The Contractor shall designate a representative responsible for the organization and assembly of the CSF in the event that the Document Control Officer is not available.
- 2.7.3 The Contractor shall maintain documents relating to the CSF in a secure location.
- 2.7.4 All original laboratory forms and copies of SDG-related logbook pages shall be included in the CSF.
- 2.7.5 Copies of laboratory documents in the CSF shall be photocopied in a manner to provide complete and legible replicates.
- 2.7.6 Documents relevant to each SDG including, but not limited to, the following shall be included in the CSF:
- Logbook pages;
 - Bench sheets;
 - Screening records;
 - Preparation records;
 - Repreparation records;
 - Chromatograms;
 - Analytical records;
 - Re-analysis/Re-extraction records;
 - Records of failed or Attempted analysis;
 - Custody records;
 - Sample tracking records;
 - Raw data summaries;
 - Computer printouts;
 - Correspondence;
 - FAX originals;
 - Other.

Exhibit F -- Section 2

Standard Operating Procedures (SOPs) (Con't)

- 2.7.7 The Document Control Officer or a designated representative shall ensure that sample tags are encased in clear plastic bags before placing them in the CSF.
- 2.7.8 CSF documents shall be organized and assembled on an SDG-specific basis.
- 2.7.9 Original documents which include information relating to more than one SDG (e.g., TR/COCs, calibration logs) shall be filed in the CSF of the lowest SDG number, and copies of these originals shall be placed in the other CSF(s). The Document Control Officer or a designated representative shall record the following statement on the copies in (indelible) *dark ink*:

COPY
ORIGINAL DOCUMENTS ARE INCLUDED IN CSF

Signature

Date

- 2.7.10 All CSFs shall be submitted with a completed Form DC-2. All resubmitted CSFs shall be submitted with a new or revised Form DC-2.
- 2.7.11 Each item in the CSF and resubmitted CSFs shall be inventoried and assembled in the order specified on Form DC-2. Each page of the CSF shall be stamped with a sequential number. Page number ranges shall be recorded in the columns provided on Form DC-2. Intentional gaps in the page numbering sequence shall be recorded in the "Comments" section on Form DC-2. When inserting new or inadvertently omitted documents, the Contractor shall identify them with unique accountable numbers. The unique accountable numbers and the locations of the documents shall be recorded in the "Other Records" section on Form DC-2.
- 2.7.12 Before shipping each CSF, the Document Control Officer or a designated representative shall verify the agreement of information recorded on all documentation and ensure that the information is consistent and the CSF is complete.
- 2.7.13 The Document Control Officer, or a designated representative, shall document the shipment of deliverable packages, including what was sent, to whom the packages were sent, the date, and the carrier used.
- 2.7.14 Shipments of deliverable packages, including re-submittals, shall be sealed with custody seals by the Document Control Officer or a designated representative in a manner such that opening the packages would break the seals.
- 2.7.15 Custody seals shall be signed and dated by the Document Control Officer or a designated representative when sealing deliverable packages.

3.0 WRITTEN STANDARD OPERATING PROCEDURES (SOPs)

The Contractor shall develop and implement the following written SOPs for sample receiving, sample identification, sample security, sample storage, sample tracking and document control, computer-resident sample data control, and Complete Sample Delivery Group (SDG) File (CSF) organization and assembly to ensure accountability for USEPA sample chain-of-custody and control of all Government furnished sample-related records.

3.1 Sample Receiving

3.1.1 The Contractor shall have written SOPs for sample receiving which accurately reflect the procedures used by the laboratory.

3.1.2 The written SOPs for sample receiving shall ensure that the procedures listed below are in-use at the laboratory.

3.1.2.1 The condition of shipping containers and sample containers are inspected and recorded on Form DC-1 upon receipt by the sample custodian or a designated representative.

3.1.2.2 The condition of custody seals are inspected and recorded on Form DC-1 upon receipt by the sample custodian or a designated representative.

3.1.2.3 The agreement or disagreement of information recorded on shipping documents with information recorded on sample containers is verified and recorded on Form DC-1 by the sample custodian or a designated representative.

3.1.2.4 The following information is recorded on Form DC-1 by the sample custodian or a designated representative as samples are received and inspected:

- Presence or absence of custody seals on shipping and or sample containers;
- Custody seal numbers, when present;
- Presence or absence of Traffic Report/Chain of Custody Records (TR/COCs) or packing lists;
- Airbill or airbill sticker numbers;
- Sample tag numbers listed/not listed on TR/COCs;
- Cooler temperature;
- Date of receipt;
- Time of receipt;
- EPA Sample Numbers;
- Presence or absence of sample tags;
- Sample tag numbers;
- Assigned laboratory numbers;
- Samples delivered by hand; and
- Problems and discrepancies.

Exhibit F -- Section 3

Written Standard Operating Procedures (SOPs) (Con't)

- 3.1.2.5 All accompanying forms are signed, dated, and the time is recorded, when applicable, at the time of sample receipt (e.g., TR/COCs or packing lists, and airbills) by the sample custodian or a designated representative.

NOTE: Initials are not acceptable.

- 3.1.2.6 The Sample Management Office (SMO) is contacted to resolve problems and discrepancies including, but not limited to: absent documents; conflicting information; absent or broken custody seals and unsatisfactory sample condition (e.g., leaking sample container).
- 3.1.2.7 The resolution of problems and discrepancies communicated through SMO is recorded.

3.2 Sample Identification

- 3.2.1 The Contractor shall have written SOPs for sample identification which accurately reflect the procedures used by the laboratory.
- 3.2.2 The written SOPs for sample identification shall ensure that the procedures listed below are in use at the laboratory.
- 3.2.2.1 The identity of Government furnished samples and prepared samples is maintained throughout the laboratory when:
- The Contractor assigns unique laboratory sample identification numbers, thus the written SOPs shall include a description of the procedure used to assign these numbers;
 - The Contractor uses prefixes or suffixes in addition to laboratory sample identification numbers, thus the written SOPs shall include their definitions; and
 - The Contractor uses methods to uniquely identify fractions/parameter groups and matrix type, thus the written SOPs shall include a description of these methods.
- 3.2.2.2 Each sample and sample preparation container is labeled with the Government assigned number or a unique laboratory sample identification number.

3.3 Sample Security

- 3.3.1 The Contractor shall have written SOPs for sample security which accurately reflect the procedures used by the laboratory.
- 3.3.2 The written SOPs for sample security shall include the items listed below.
- 3.3.2.1 Procedures which ensure the following:
- Sample custody is maintained, and
 - The security of designated secure areas is maintained.
- 3.3.2.2 A list of authorized personnel who have access to locked storage areas.

3.4 Sample Storage

- 3.4.1 The Contractor shall have written SOPs for sample storage which accurately reflect the procedures used by the laboratory.

3.4.2 The written SOPs for sample storage shall describe locations, contents, and identities of all storage areas for Government furnished samples and prepared samples in the laboratory.

3.5 Sample Tracking and Document Control

3.5.1 The Contractor shall have written SOPs for sample tracking and document control which accurately reflect the procedures used by the laboratory.

3.5.2 The written SOPs for sample tracking and document control shall include the items listed below.

3.5.2.1 Examples of all laboratory documents used during sample receiving, sample storage, sample transfer, sample analyses, CSF organization and assembly, and sample retention or disposal.

3.5.2.2 Procedures which ensure the following:

- All activities performed on Government furnished samples are recorded;
- Titles which identify the activities recorded are printed on each page of all laboratory documents;
- Information recorded in columns is identified with column headings;
- Reviewers' signatures are identified on laboratory documents;
- The laboratory name is included on pre-printed laboratory documents;
- Laboratory document entries are signed and dated in the format MM/DD/YYYY (e.g., 01/01/2009);
- Entries on all laboratory documents are recorded in ink;
- Corrections and additions to laboratory documents are made by drawing single lines through the errors, entering the correct information, and initialing and dating the new information;
- Unused portions of laboratory documents are lined-out;
- Pages in bound and unbound logbooks are sequentially numbered;
- Instrument-specific run logs are maintained to enable the reconstruction of run sequences;
- Logbook entries are recorded in chronological order;
- Entries are recorded for only one SDG per page, except in the event where SDGs "share" Quality Control (QC) samples (e.g., instrument run logs and extraction logs);
- Each page in bound and unbound logbooks shall be dated (MM/DD/YYYY) and signed (no initials) at the bottom by the individual recording the activity (if a single entry is made on a page) or by the last individual recording information on the page (if multiple entries are on the same page);
- Information inserted in laboratory documents is affixed permanently, signed, and dated across the insert; and
- The retention or disposal of Government furnished samples, remaining portions of samples, and prepared samples is documented.

3.6 Computer-Resident Sample Data Control

3.6.1 The Contractor shall have written SOPs for computer-resident sample data control which accurately reflect the procedures used by the laboratory.

3.6.2 The written SOPs for computer-resident sample data control shall include the items listed below.

3.6.2.1 Procedures which ensure the following:

- Contractor personnel responsible for original data entry are identified;
- Changes to electronic data are made such that the original data entry is preserved, the editor is identified, and the revision date is recorded;
- The accuracy of manually entered data, electronically entered data, and data acquired from instruments is verified;
- Report documents produced by the electronic data collection system are routinely verified to ensure the accuracy of the information reported;
- Electronic data collection system security is maintained;
- Archives of electronic data and accompanying software are maintained in a secure location; and
- Off-site backup and storage of electronic data is maintained.

3.6.2.2 Descriptions of archive storage areas for the electronic data and the software required to access data archives.

3.6.2.3 A list of authorized personnel who have access to electronic data collection system functions and to archived data.

3.7 Complete Sample Delivery Group (SDG) File (CSF) Organization and Assembly

3.7.1 The Contractor shall have written SOPs for CSF organization and assembly which accurately reflect the procedures used by the laboratory.

3.7.2 The written SOPs for CSF organization and assembly shall ensure that the procedures listed below are in-use at the laboratory.

- Documents relating to the CSF are maintained in a secure location;
- All original laboratory forms and copies of SDG-related logbook pages are included in the CSF;
- Laboratory documents are photocopied in a manner to provide complete and legible replicates;
- All documents relevant to each SDG are included in the CSF;
- Sample tags are encased in clear plastic bags by the Document Control Officer or a designated representative before being placed in the CSF;
- The CSF is organized and assembled on an SDG-specific basis;
- Original documents that contain information relating to more than one SDG are filed in the CSF of the lowest SDG, and copies are referenced to originals in the event that an original document contains information relating to more than one SDG;

Exhibit F -- Section 3

Written Standard Operating Procedures (SOPs) (Con't)

- Each CSF is submitted with a completed Form DC-2, and re-submitted CSFs are submitted with a new or revised Form DC-2;
- Each page of the CSF is stamped with a sequential number and the page number ranges are recorded in the columns provided on Form DC-2. Intentional gaps in the page numbering sequence are recorded in the "Comments" section of Form DC-2. Inserted documents are recorded in the "Other Records" section of Form DC-2;
- Consistency and completeness of the CSF are verified by the Document Control Officer or a designated representative;
- Shipments of deliverable packages are documented by the Document Control Officer or a designated representative;
- Deliverable packages are shipped by the Document Control Officer or a designated representative using custody seals in a manner such that opening the packages would break the seals; and
- Custody seals are signed and dated by the Document Control Officer or a designated representative before placing them on deliverable packages.

EXHIBIT G
GLOSSARY OF TERMS

Exhibit G -- Glossary of Terms

ALiquOT - A measured portion of a sample or solution, taken for sample preparation and/or analysis.

ANALYSIS DATE/TIME - The date and military time (24-hour clock) of the injection of the sample, standard, or blank into the High Resolution Gas Chromatography/High Resolution Mass Spectrometry (HRGC/HRMS).

ANALYTICAL SERVICES BRANCH (ASB) - The division of the United States Environmental Protection Agency's (USEPA) Office of Superfund Remediation and Technology Innovation (OSRTI) responsible for overall management of the Contract Laboratory Program (CLP).

CALIBRATION STANDARD (CS) - A solution prepared from a secondary standard and/or stock solutions, and used to calibrate the response of the instrument with respect to analyte concentration.

CALIBRATION VERIFICATION STANDARD - The Mid-Point Calibration Standard (CS3) that is used to verify the initial calibration of the system.

CASE - A finite, usually predetermined, number of samples collected over a given time period from a particular site. Case numbers are assigned by the Sample Management Office (SMO). A Case consists of one or more Sample Delivery Groups (SDGs).

CLASS A GLASSWARE - Defined by ASTM standards as glassware used in measurement with the smallest degree of uncertainty or tolerance associated with the measurement of volume. For example, a Class A 5 mL volumetric flask will have ± 0.02 mL tolerance. Class A glassware usually has a large "A" prominent near the label.

CLEANUP STANDARD - A standard containing $^{37}\text{Cl}_4$ -2,3,7,8-TCDD that is added to all extracts prior to cleanup. The purpose of this standard is to measure the efficiency of the cleanup process.

COLUMN PERFORMANCE SOLUTION (CPS) - When the Window Defining Mixture (WDM) and the Isomer Specificity Check solutions are combined, the solution is identified as the CPS.

CONGENER - Individual compound belonging to a group or class of compounds with a similar general structure.

CONTAMINATION - A component of a sample or an extract that is not representative of the environmental source of the sample. Contamination may stem from other samples, sampling equipment, while in transit, from laboratory reagents, laboratory environment, or analytical instruments.

CONTRACT COMPLIANCE SCREENING (CCS) - A screening of electronic and hardcopy data deliverables for completeness and compliance with the contract. This screening is done under USEPA direction by the Sample Management Office (SMO) contractor.

CONTRACT LABORATORY PROGRAM (CLP) - Supports USEPA's Superfund effort by providing a range of state-of-the-art chemical analytical services of known quality. This program is directed by the Analytical Services Branch (ASB) of the USEPA Office of Superfund Remediation and Technology Innovation (OSRTI).

CONTRACT REQUIRED QUANTITATION LIMIT (CRQL) - Minimum level of quantitation acceptable under the contract Statement of Work (SOW).

DATE - MM/DD/YYYY - Where MM = 01 for January, 02 for February, ... 12 for December; DD = 01 to 31; YYYY = 1999, 2000, 2001, 2002, etc.

DAY - Unless otherwise specified, day shall mean calendar day.

ESTIMATED DETECTION LIMIT (EDL) - The concentration of an analyte required to produce a signal with peak height of at least 2.5 times the background signal level. The EDL is calculated for each 2,3,7,8-substituted isomer for which the response of the primary and secondary ions is less than 2.5 times the background level.

ESTIMATED MAXIMUM POSSIBLE CONCENTRATION (EMPC) - The EMPC is calculated for 2,3,7,8-substituted isomers for which the quantitation and/or confirmation ion(s) has signal to noise in excess of 2.5, but does not meet identification criteria.

EXTRACTABLE - A compound that can be partitioned into an organic solvent from the sample matrix, and is amenable to Gas Chromatography (GC).

FIELD BLANK - Any sample that is submitted from the field and is identified as a blank. This includes trip blanks, rinsates, equipment blanks, etc.

FIELD QC - Any Quality Control (QC) samples submitted from the field to the laboratory. Examples include, but are not limited to, field blanks, field duplicates, and field spikes.

FIELD SAMPLE - A portion of material obtained from an assigned site to be analyzed that is contained in single or multiple containers and identified by a unique EPA Sample Number.

GEL PERMEATION CHROMATOGRAPHY (GPC) - A size-exclusion chromatographic technique that is used as a cleanup procedure for removing large organic molecules, particularly naturally occurring macro-molecules such as lipids, polymers, viruses, etc.

HOLDING TIME - The elapsed time expressed in days from the date of receipt of the sample by the Contractor until the date of its analysis.

HOMOLOGUE - A group of compounds that have the same molecular weight, but not necessarily the same structural arrangement.

HPLC - High Performance Liquid Chromatograph or High Performance Liquid Chromatography.

HRGC - High Resolution Gas Chromatograph or Gas Chromatography.

HRMS - High Resolution Mass Spectrometer or Mass Spectrometry.

IN-HOUSE - At the Contractor's facility.

INITIAL CALIBRATION - Analysis of analytical standards for a series of different specified concentrations. It is used to define the linearity and dynamic range of the response of the Mass Spectrometer (MS) to the target compounds.

INTEGRATION SCAN RANGE - Range from the scan number of the scan at the beginning of the area of integration to the scan number at the end of the area of integration.

INTEGRATION TIME RANGE - The Retention Time (RT) at the beginning of the area of integration to the RT at the end of the area of integration.

Exhibit G -- Glossary of Terms (Con't)

INTERNAL STANDARD - $^{13}\text{C}_{12}$ -1,2,3,4-TCDD and $^{13}\text{C}_{12}$ -1,2,3,7,8,9-HxCDD standards are added to every blank, Quality Control (QC) sample, and sample extract aliquot just prior to analysis.

ISOMER - Chemical compounds that have the same molecular formula, but differ in structural arrangement and properties. For example, 1,2,3,4-TCDD and 2,3,7,8-TCDD are structural isomers.

LABELED COMPOUNDS - Isotopically labeled compounds in Exhibit D (see Table 1) that are added to every sample and are present at the same concentration in every blank, Quality Control (QC) sample, and calibration solution. The labeled compounds (internal standards) are added to the sample before extraction and are used to measure the concentrations of the analytes.

LABORATORY - Synonymous with Contractor, as used herein.

LABORATORY CONTROL SAMPLE (LCS) - Aliquot of a reference matrix fortified (spiked) with known quantities of specific compounds and subjected to the entire analytical procedure to determine the accuracy of the method by measuring recovery.

LABORATORY RECEIPT DATE - The date on which a sample is received at the Contractor's facility, as recorded on the shipper's delivery receipt and Sample Traffic Report/Chain of Custody Record (TR/COC).

m/z - Mass-to-charge ratio, synonymous with "m/e".

MATRIX - The predominant material of which the sample to be analyzed is composed. For the purpose of this Statement of Work (SOW), a sample matrix is either water, soil, sediment, sludge, tissue, ash, oil, or oily matrices. Matrix is not synonymous with phase (liquid or solid).

MATRIX EFFECT - In general, the effect of a particular matrix on the constituents with which it contacts. This is particularly pronounced for clay particles which may adsorb chemicals and catalyze reactions. Matrix effects may prevent extraction of target analytes. In addition, non-target analytes may be extracted from the matrix and cause interferences.

METHOD BLANK - An analytical control consisting of reference material, labeled compounds, internal standards, and cleanup standards that is carried throughout the entire analytical procedure. The method blank is used to define the level of laboratory, background, and reagent contamination.

NARRATIVE (SDG Narrative) - Portion of the data package which includes laboratory, contract, Case and Sample Number identification, and descriptive documentation of any problems encountered in processing the samples, along with corrective action taken and problem resolution. Complete Sample Delivery Group (SDG) Narrative specifications are included in Exhibit B.

PERCENT SOLIDS (%S) - An approximation of the dry solids content in a soil/sediment sample made by drying an aliquot of the sample for 12 hours at 110°C. The Percent Solids determined in this manner also excludes contributions from all compounds that may volatilize at or below 110°C. The Percent Solids is calculated as follows:

$$\% \text{Solids} = \frac{\text{Weight of Sample Aliquot After Drying}}{\text{Weight of Sample Aliquot Before Drying}} \times 100\%$$

PERFLUOROKEROSENE (PFK) - The mixture of compounds used to calibrate the exact m/z scale in the High Resolution Mass Spectrometer (HRMS).

PERFORMANCE EVALUATION (PE) SAMPLE - A sample of known composition provided by USEPA for Contractor analysis. Used by USEPA to evaluate Contractor performance.

PROTOCOL - Describes the exact procedures to be followed with respect to sample receipt and handling, analytical methods, data reporting and deliverables, and document control. Used synonymously with Statement of Work (SOW).

QUALITY ASSURANCE TECHNICAL SUPPORT (QATS) - A contractor-operated facility operated under the QATS contract, awarded and administered by USEPA.

REAGENT WATER - Water demonstrated to be free from the analytes of interest and potentially interfering substances.

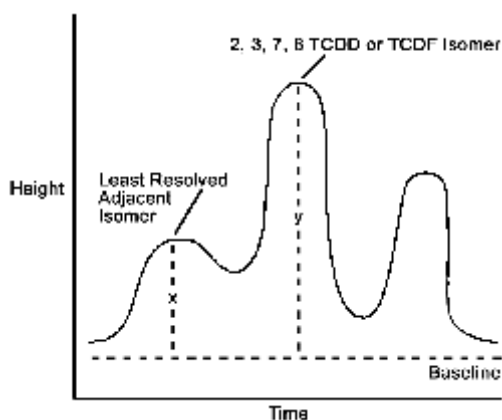
RELATIVE PERCENT DIFFERENCE (RPD) - As used in this Statement of Work (SOW) and elsewhere to compare two values, the RPD is based on the mean of the two values, and is reported as an absolute value (i.e., always expressed as a positive number or zero).

RELATIVE RESPONSE (RR) - A measure of the relative mass spectral response of the native compound compared to its labeled compound analog. RRs are determined using the area responses of both the primary and secondary exact m/z 's for each compound in each calibration standard.

RELATIVE RESPONSE FACTOR (RRF) - The ratio of the response of a given compound to its corresponding internal standard. Response factors are determined using the area responses of both the primary and secondary exact m/z 's for each compound in each calibration standard.

RELATIVE STANDARD DEVIATION (%RSD) - The standard deviation times 100, divided by the mean. Also termed Coefficient of Variation.

RESOLUTION - Also termed separation or Percent Resolution (%R), the separation between the least resolved adjacent isomer and the 2,3,7,8-TCDD or TCDF isomer, calculated by dividing the height of the 2,3,7,8-TCDD or TCDF isomer peak (y) by the height from the valley of the least resolved adjacent peak to the baseline (x), multiplied by 100.



RESPONSE or INSTRUMENTAL RESPONSE - A measurement of the output of the High Resolution Gas Chromatograph/High Resolution Mass Spectrometer (HRGC/HRMS) detector in which the intensity of the signal is proportionate to the amount (or concentration) detected. Measured by peak area or peak height.

Exhibit G -- Glossary of Terms (Con't)

RETENTION TIME (RT) - The time a target analyte is retained on a Gas Chromatograph (GC) column before elution. The identification of a target analyte is dependent on a target compound's retention time falling within the specified retention time window established for that compound. The RT is dependent on the nature of the column's stationary phase, column diameter, temperature, flow rate, and other parameters.

SAMPLE - A portion of material to be analyzed that is contained in single or multiple containers, and identified by a unique Sample Number.

SAMPLE DELIVERY GROUP (SDG) - A unit within a sample Case that is used to identify a group of samples for delivery. An SDG is defined by the following, whichever is most frequent:

- Each Case, if field samples received, or
- Each 20 field samples [excluding Performance Evaluation (PE) samples] within a Case, or
- Each 7 calendar day period during which field samples in a Case are received (said period beginning with the receipt of the first sample in the SDG).

Samples may be assigned to SDGs by matrix (e.g., all soil samples in one SDG, all water samples in another) at the discretion of the laboratory.

SAMPLE MANAGEMENT OFFICE (SMO) - A Contractor-operated facility operated under the Sample Management Office contract, awarded and administered by USEPA.

SAMPLE NUMBER (EPA Sample Number) - A unique identification number designated by USEPA to each sample. The Sample Number appears on the sample TR/COC which documents information on that sample.

SELECTED ION MONITORING (SIM) - A mode of Mass Spectrometry (MS) operation in which specific m/e ratios are monitored, as opposed to scanning the entire mass range.

SIGNAL TO NOISE (S/N) RATIO - The ratio of analyte signal to random background signal. The noise is defined as the height of the largest signal [excluding signal due to chlorinated dibenzo-p-dioxins/chlorinated dibenzofurans (CDDs/CDFs) or other chemicals] within the 100 scan window. The signal is defined as the height of the CDD/CDF peak.

SOIL - Used herein synonymously with soil/sediment, sediment, and sludge.

SOLID PHASE EXTRACTION (SPE) - An extraction technique in which an analyte is extracted from an aqueous sample by passage over or through a material capable of reversibly adsorbing the analyte. Also termed Liquid-Solid Extraction.

SOP - Standard Operating Procedure.

SOW - Statement of Work.

SOXHLET/DEAN-STARK EXTRACTOR (SDS) - An extraction device applied to the extraction of solid and semi-solid materials.

STOCK SOLUTION - A solution containing an analyte that is prepared using a reference material traceable to the USEPA, the National Institute of Science and Technology (NIST), or a source that will attest to the purity and authenticity of the reference material.

TARGET COMPOUND LIST (TCL) - A list of compounds designated by the Statement of Work (SOW) (See Exhibit C) for analysis.

TIME - When required to record time on any deliverable item, time shall be expressed in Military Time (i.e., a 24-hour clock).

TRAFFIC REPORT/CHAIN OF CUSTODY RECORD (TR/COC) - A USEPA sample identification form filled out by the sampler, that accompanies the sample during shipment to the laboratory and is used to document sample identity, sample chain-of-custody, sample condition, and sample receipt by the laboratory.

TOXICITY EQUIVALENCE FACTOR (TEF) - A coefficient relating the risks from a particular compound to another compound.

TWELVE-HOUR TIME PERIOD - For dioxin/furan analyses performed by High Resolution Gas Chromatography/High Resolution Mass Spectrometry (HRGC/HRMS), the 12-hour time period in the analytical sequence begins at the moment of injection of the Window Defining Mixture (WDM) that precedes sample analyses, and ends after 12 hours have elapsed according to the system clock.

USEPA ASB DIOXIN PROGRAM MANAGER - The USEPA Analytical Service Branch (ASB) official who manages the Contract Laboratory Program Dioxin program.

WINDOW DEFINING MIXTURE (WDM) - Prior to analyzing the calibration solutions, blanks, samples, and Quality Control (QC) samples, the Retention Time (RT) WDM is analyzed to define the beginning RTs for the dioxin and furan isomers and evaluate descriptor switching times.

EXHIBIT H

FORMAT FOR ELECTRONIC DATA DELIVERABLES

Exhibit H - Format for Electronic Data Deliverables

Table of Contents

<u>Section</u>	<u>Page</u>
1.0 FORMAT CHARACTERISTICS	3
2.0 DATA ELEMENTS	4
3.0 BATCHES	6
4.0 DELIVERABLE	6
5.0 DOCUMENT TYPE DEFINITION (DTD)	7
5.1 Introduction	7
5.2 SEDD Specification 5.2 General Stage 2a DTD	7
6.0 DATA ELEMENT INSTRUCTION TABLES	19
6.1 Specification 5.2 Stage 2a	19

1.0 FORMAT CHARACTERISTICS

- 1.1 This constitutes an implementation of the Staged Electronic Data Deliverable (SEDD) based on analytical results and ancillary information required by the contract. Because this implementation is specific to the contract, not all data elements listed in the cross-program Document Type Definition (DTD) are required. This implementation is based on SEDD Specification 5.2 that can be found at:

<http://www.epa.gov/superfund/programs/clp/seddspec52.htm>

- 1.1.1 The SEDD deliverable consists of an eXtensible Markup Language (XML) file(s) compliant with the XML specification 1.0 of the World Wide Web Consortium (W3C). The deliverable must be well-formed based on the W3C XML specification and must be valid based on the DTD.
- 1.1.2 The Contractor shall create the deliverable using the UTF-8 (Unicode Transformation Format - 8 bit) character set.
- 1.1.3 The initial line of the deliverable shall be: `<?xml version="1.0" encoding="UTF-8"?>`.
- 1.1.4 The second line of the deliverable shall be a DOCTYPE line that contains the filename of the DTD. The DOCTYPE line shall be `<!DOCTYPE Header SYSTEM "SEDD_5-2_GENERAL_2a_2.dtd">` where "Header" denotes the name of the root element, and "SEDD_5-2_GENERAL_2a_2.dtd" denotes the filename of the DTD.
- 1.1.5 The use of XML comment lines is permitted at any position in the file after the first two lines.
- 1.2 This implementation includes detailed specifications for the required format of the content of each data element for each fraction. The content of each data element is specified as either literal (contained in quotes) which must appear exactly as shown (without quotes), or as a variable for which descriptions and formats are listed. Exhibit H, Section 2.0 describes requirements for each data element.
- 1.2.1 For this implementation, numeric data elements may contain numeric digits, a decimal place, and a leading minus sign. Values without a leading minus sign are assumed to be positive. Values must be reported to the specified precision or significance.
- 1.2.2 The values reported by the Contractor are used for data assessment. The Contractor shall not use rounded intermediate values in calculating the final result, and no rounding shall be performed until reaching the final result.
- 1.2.3 The completeness of analytical data provided in the EDD will be verified against the analytical data requested on the Traffic Report/Chain of Custody (TR/COC). The laboratory code, case number, contract number, SDG number, sample number, and fraction shall be identical in the EDD and the TR/COC and the SDG coversheet submitted by the Contractor for the SDG.
- 1.2.4 The following variables must be present where required and correct: QC Type; instrument ID; analysis date and time; method ID; collected date; matrix; client analysis ID; client analyte ID; preparation batch; and percent recovery.

2.0 DATA ELEMENTS

- 2.1 The Staged Electronic Data Deliverable (SEDD) consists of data elements arranged hierarchically by data nodes (parent elements). Figure 1 depicts the data node hierarchy. Each data element consists of a start tag, content, and an end tag. An element may contain other elements (child elements).

NOTE: There shall be no more than one occurrence of each child element within a node, unless the child element also behaves as a parent element. For example, in each SamplePlusMethod node, there may be only one occurrence of the element ClientSampleID, but there may be more than one occurrence of the element Analysis.

The tags, nodes, and hierarchy are specified in the Document Type Definition (DTD) against which the deliverable will be validated (see Exhibit H, Section 5.0). The frequency requirements for each of the data nodes applicable to this implementation are described below.

2.1.1 Header Node

One Header node must be reported for each fraction.

2.1.2 SamplePlusMethod Node

Each Header node must contain one SamplePlusMethod node for each field sample, field blank (including rinse, equipment, and trip blanks), Performance Evaluation (PE) sample, method blank, Laboratory Control Sample (LCS), and non-client sample analyzed.

2.1.3 ReportedResult Node

Each SamplePlusMethod node must contain a ReportedResult node for each target compound.

2.1.4 ContactInformation Node

Each Header node must contain one ContactInformation node.

2.1.5 Analysis Node

Each SamplePlusMethod node must contain at least one Analysis node for the initial analysis, plus an additional Analysis node for each required dilution, reanalysis, or confirmation.

2.1.6 Analyte Node

Each Analysis node for the initial analysis under a SamplePlusMethod node must contain one Analyte node for each target compound, labeled compound, cleanup standard compound, and internal standard. Analysis nodes for dilutions, reanalyses, and confirmations must contain one Analyte node for each compound being monitored.

2.1.7 PreparationPlusCleanup Node

Each Analysis node under a SamplePlusMethod node must contain one PreparationPlusCleanup node for the preparation. Each Analysis node must contain one PreparationPlusCleanup node for each cleanup procedure used in preparing the sample extract for analysis.

2.1.8 Characteristic Node

Each SamplePlusMethod and PreparationPlusCleanup node may contain one or more Characteristic nodes, one for each sample characteristic that must be reported for a sample at time of receipt, or after preparation.

2.1.9 AnalyteGroup Node

Each Analysis node must contain one AnalyteGroup node for each Homologue. Detailed instructions for the content of each data element are provided in Table 1.

2.1.10 Node and Data Elements

This field reports each node in bold text, followed by its data elements. If an entire node is not required, then none of its data elements are listed.

2.1.11 Applicability

This field reports the samples, blanks, and standards for which each node and data element is required. An "X" in a column indicates that the node or element is required. Sample refers to field samples, field blanks, and PE samples unless otherwise noted. Abbreviations used in this field are defined in Table 2.

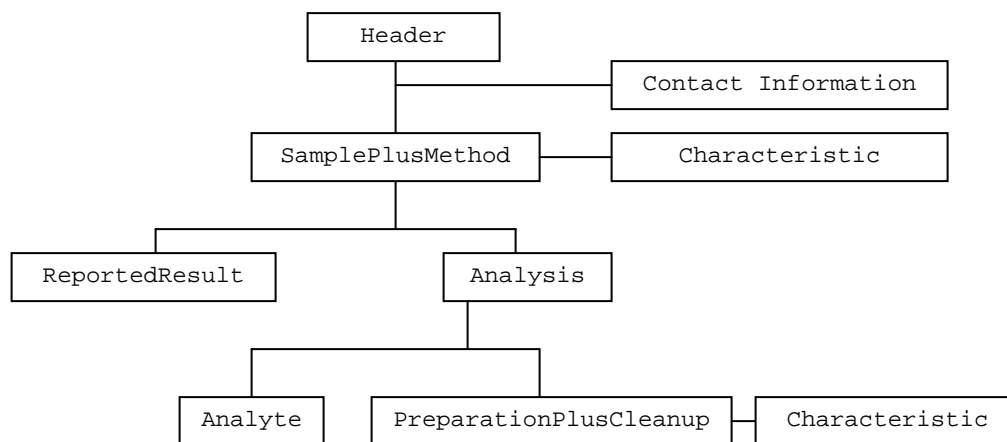


Figure 1: Data Node Hierarchy for
Level 2a Deliverable

2.1.12 Instructions

This field describes the required format and content of each data element. The content of each data element is specified as either literal (contained in quotes), or as a variable for which description and format is listed. Abbreviations used in this field are defined in Table 2.

3.0 BATCHES

3.1 This implementation requires the use of the following batches from the Staged Electronic Data Deliverable (SEDD) Specification:
"LabReportingBatch"; "PreparationBatch".

3.1.1 The "LabReportingBatch" links all samples reported in the same Sample Delivery Group (SDG). Report the SDG Number.

3.1.2 The "PreparationBatch" links all samples of the same matrix prepared at the same time by the same preparation method. All samples analyzed, including method blanks and Laboratory Control Samples (LCS) that are prepared together must have the same content for the "PreparationBatch" element.

4.0 DELIVERABLE

4.1 Each Sample Delivery Group (SDG) shall be submitted as a separate compressed (zipped) file

4.2 The Contractor will utilize a designated website (provided in its Laboratory Welcome Package) or Task Order to electronically submit their Electronic Data Deliverable (EDD) to the Sample Management Office (SMO). USEPA may approve alternative electronic means of file delivery. Written permission must be obtained from the USEPA Analytical Services Branch (ASB) prior to the use of any alternative means.

4.3 The Contractor must follow the delivery instructions in Exhibit B of this Statement of Work (SOW) and deliver their hardcopy and EDD to SMO concurrently. If one of these items is delivered on a later date, the Data Receipt Date (DRD) for the SDG will be the later of the two dates.

4.4 Information in the electronic deliverable must correspond to information submitted in the hardcopy raw data package and on Quality Control (QC) summary forms. If information in the raw data or on the forms is changed, the information in the electronic deliverable shall be changed accordingly. An electronic deliverable containing the changed information for the SDG shall be resubmitted along with the hardcopy at no additional cost to the USEPA.

4.5 The format for the file name shall be Case number_SDG number_contract number_submission number_DTD used_.zip. For example, the first submission of SDG number ABC12, Case number 12345, contract 68-W-0000 would be named 12345_ABC12_68-W-0000_1_SEDD_5-2_GENERAL_2a_2.zip.

4.6 The data package shall be provided electronically (pdf format is acceptable) on a compact disc (CD) which shall accompany the hardcopy deliverable. Hardcopy deliverables should be sent to the data delivery contact listed in the Task Order.

5.0 DOCUMENT TYPE DEFINITION (DTD)

5.1 Introduction

The deliverable will be validated against DTD SEDD_5-2_GENERAL_2a_2. The deliverable must not contain any tags not included in the DTD, and must conform to the hierarchical structure modeled in the DTD.

5.2 SEDD Specification 5.2 General Stage 2a DTD

```
<?xml version="1.0" encoding="UTF-8"?>
<!--SEDD_5-2_GENERAL_2a_2.dtd 07/21/2008 Based on SEDD Specification 5.2 -->
<!-- Acronym Description -->
<!-- EDD - Electronic Data Deliverable -->
<!-- ID - Identity -->
<!-- Lab - Laboratory -->
<!-- QC - Quality Control -->
<!-- RPD - Relative Percent Difference -->
<!--ELEMENT Header (
    ClientID|
    ClientName|
    Comment|
    DateFormat|
    EDDID|
    EDDImplementationID|
    EDDImplementationVersion|
    EDDVersion|
    GeneratingSystemID|
    GeneratingSystemVersion|
    LabContract|
    LabContractModificationDescription|
    LabContractModificationID|
    LabDataPackageID|
    LabDataPackageName|
    LabDataPackageVersion|
    LabID|
    LabName|
    LabNarrative|
    LabQualifiersDefinition|
    LabReportedDate|
    ProjectID|
    ProjectName|
    SiteID|
    SiteName|
    ContactInformation|
    SamplePlusMethod
)*>
<!--ELEMENT Analysis (
    AliquotAmount|
    AliquotAmountUnits|
    AnalysisDuration|
    AnalysisDurationUnits|
    AnalysisGroupID|
    AnalysisType|
    Analyst|
    AnalyzedAmount|
    AnalyzedAmountUnits|
    AnalyzedDate|
```

Exhibit H -- Section 5

Document Type Definition (DTD) (Con't)

ClientAnalysisID|
ClientMethodCode|
ClientMethodID|
ClientMethodModificationDescription|
ClientMethodModificationID|
ClientMethodName|
ClientMethodSource|
ClientMethodVersion|
Column|
ColumnInternalDiameter|
ColumnInternalDiameterUnits|
ColumnLength|
ColumnLengthUnits|
Comment|
ConfirmationAnalysisID|
Counts|
CountsUncertainty|
CountsUncertaintyConfidenceLevel|
CountsUnceertaintyDetermination|
CountsUncertaintyIntervalType|
CountsUncertaintyLimitHigh|
CountsUncertaintyLimitLow|
CountsUncertaintyType|
CountsUnits|
DetectorID|
DetectorType|
DilutionFactor|
Efficiency|
HeatedPurge|
Inclusion|
InjectionVolume|
InjectionVolumeUnits|
InstrumentID|
LabAnalysisID|
LabFileID|
LabID|
LabMethodID|
LabMethodName|
LabName|
MethodCode|
MethodID|
MethodModificationDescription|
MethodModificationID|
MethodName|
MethodSource|
MethodVersion|
PreparationBatch|
ProcedureID|
ProcedureName|
ReferenceDate|
ResultBasis|
Temperature|
TemperatureUnits|
Wavelength|
WavelengthUnits|
Yield|
PreparationPlusCleanup|
Analyte|
AnalyteGroup

```
)*>
<!ELEMENT AnalysisGroup (
    AnalysisGroupID|
    AnalysisType|
    Comment|
    Analyte|
    AnalyteGroup
)*>
<!ELEMENT Analyte (
    AnalyteGroupID|
    AnalyteName|
    AnalyteNameContext|
    AnalyteType|
    BiasErrorRatio|
    CASRegistryNumber|
    ClientAnalyteID|
    ClientAnalyteName|
    Comment|
    Counts|
    CountsUncertainty|
    CountsUncertaintyConfidenceLevel|
    CountsUncertaintyDetermination|
    CountsUncertaintyIntervalType|
    CountsUncertaintyLimitHigh|
    CountsUncertaintyLimitLow|
    CountsUncertaintyType|
    CountsUnits|
    DetectionLimit|
    DetectionLimitType|
    DetectionLimitUnits|
    DifferenceErrorRatio|
    Efficiency|
    ExpectedResult|
    ExpectedResultUncertainty|
    ExpectedResultUncertaintyConfidenceLevel|
    ExpectedResultUncertaintyDetermination|
    ExpectedResultUncertaintyIntervalType|
    ExpectedResultUncertaintyLimitHigh|
    ExpectedResultUncertaintyLimitLow|
    ExpectedResultUncertaintyType|
    ExpectedResultUncertaintyUnits|
    ExpectedResultUnits|
    Inclusion|
    LabAnalyteID|
    LabQualifiers|
    LotNumber|
    PeakID|
    PercentRecovery|
    PercentRecoveryLimitHigh|
    PercentRecoveryLimitLow|
    PercentRecoveryLimitType|
    PercentRecoveryType|
    QuantitationLimit|
    QuantitationLimitType|
    QuantitationLimitUnits|
    ReportingLimit|
    ReportingLimitType|
    ReportingLimitUnits|
    Result|
```

Exhibit H -- Section 5
Document Type Definition (DTD) (Con't)

```

    ResultLimitHigh|
    ResultLimitLow|
    ResultLimitType|
    ResultType|
    ResultUncertainty|
    ResultUncertaintyConfidenceLevel|
    ResultUncertaintyDetermination|
    ResultUncertaintyIntervalType|
    ResultUncertaintyLimitHigh|
    ResultUncertaintyLimitLow|
    ResultUncertaintyType|
    ResultUncertaintyUnits|
    ResultUnits|
    StandardSource|
    Wavelength|
    WavelengthUnits
  )*>
<!ELEMENT AnalyteGroup (
  AnalyteGroupID|
  AnalyteName|
  AnalyteNameContext|
  AnalyteType|
  CASRegistryNumber|
  ClientAnalyteID|
  ClientAnalyteName|
  Comment|
  LabAnalyteID|
  LabQualifiers|
  Result|
  ResultType|
  ResultUncertainty|
  ResultUnits
  )*>
<!ELEMENT Characteristic (
  CharacteristicType|
  CharacteristicValue|
  CharacteristicUnits|
  Comment
  )*>
<!ELEMENT ContactInformation (
  LabAddress1|
  LabAddress2|
  LabCity|
  LabCountry|
  LabID|
  LabName|
  LabPointOfContact|
  LabPointOfContactElectronicAddress|
  LabPointOfContactTitle|
  LabPointOfContactType|
  LabState|
  LabTelephoneNumber|
  LabType|
  LabZipCode
  )*>
<!ELEMENT Handling (
  Analyst|
  ClientMethodCode|
  ClientMethodID|
  ClientMethodModificationDescription|
```

```
ClientMethodModificationID|
ClientMethodName|
ClientMethodSource|
ClientMethodVersion|
Comment|
HandledDate|
HandlingBatch|
HandlingType|
InitialAmount|
InitialAmountUnits|
LabID|
LabMethodID|
LabMethodName|
LabName|
MethodCode|
MethodID|
MethodModificationDescription|
MethodModificationID|
MethodName|
MethodSource|
MethodVersion|
ProcedureID|
ProcedureName|
SampleAmount|
SampleAmountUnits|
Characteristic
)*>
<!ELEMENT PreparationPlusCleanup (
    AliquotAmount|
    AliquotAmountUnits|
    Analyst|
    CleanedUpDate|
    CleanupBatch|
    CleanupType|
    ClientMethodCode|
    ClientMethodID|
    ClientMethodModificationDescription|
    ClientMethodModificationID|
    ClientMethodName|
    ClientMethodSource|
    ClientMethodVersion|
    Comment|
    FinalAmount|
    FinalAmountUnits|
    InitialAmount|
    InitialAmountUnits|
    LabID|
    LabMethodID|
    LabMethodName|
    LabName|
    LotNumber|
    MethodCode|
    MethodID|
    MethodModificationDescription|
    MethodModificationID|
    MethodName|
    MethodSource|
    MethodVersion|
    PreparationBatch|
```

```

        PreparationPlusCleanupType|
        PreparationType|
        PreparedDate|
        ProcedureID|
        ProcedureName|
        Solvent|
        Characteristic
    )*>
<!ELEMENT ReportedResult (
    AnalysisGroupID|
    AnalyteGroupID|
    AnalyteName|
    AnalyteNameContext|
    AnalyteType|
    BiasErrorRatio|
    CASRegistryNumber|
    ClientAnalyteID|
    ClientAnalyteName|
    ClientDetectionLimit|
    ClientDetectionLimitUnits|
    ClientQuantitationLimit|
    ClientQuantitationLimitUnits|
    Comment|
    DetectionLimit|
    DetectionLimitType|
    DetectionLimitUnits|
    DifferenceErrorRatio|
    ExpectedResult|
    ExpectedResultUncertainty|
    ExpectedResultUncertaintyConfidenceLevel|
    ExpectedResultUncertaintyDetermination|
    ExpectedResultUncertaintyIntervalType|
    ExpectedResultUncertaintyLimitHigh|
    ExpectedResultUncertaintyLimitLow|
    ExpectedResultUncertaintyType|
    ExpectedResultUncertaintyUnits|
    ExpectedResultUnits|
    LabAnalysisID|
    LabAnalyteID|
    LabQualifiers|
    LabResultStatus|
    PeakID|
    PercentDifference|
    PercentDifferenceLimitHigh|
    PercentDifferenceLimitLow|
    PercentDifferenceLimitType|
    PercentRecovery|
    PercentRecoveryLimitHigh|
    PercentRecoveryLimitLow|
    PercentRecoveryLimitType|
    PercentRecoveryType|
    QuantitationLimit|
    QuantitationLimitType|
    QuantitationLimitUnits|
    ReportingLimit|
    ReportingLimitType|
    ReportingLimitUnits|
    Result|
    ResultLimitHigh|

```



```
ResultLimitLow|
ResultLimitType|
ResultType|
ResultUncertainty|
ResultUncertaintyConfidenceLevel|
ResultUncertaintyDetermination|
ResultUncertaintyIntervalType|
ResultUncertaintyLimitHigh|
ResultUncertaintyLimitLow|
ResultUncertaintyType
ResultUncertaintyUnits|
ResultUnits|
RetentionTime|
RetentionTimeUnits|
RPD|
RPDLimitHigh|
RPDLimitType|
RPDType
    )*>
<!ELEMENT SamplePlusMethod (
    ClientID|
    ClientMethodCategory|
    ClientMethodCode|
    ClientMethodID|
    ClientMethodModificationDescription|
    ClientMethodModificationID|
    ClientMethodName|
    ClientMethodSource|
    ClientMethodType|
    ClientMethodVersion|
    ClientName|
    ClientSampleID|
    CollectedDate|
    CollectedEndDate|
    Comment|
    Composite|
    CoolerID|
    CustodyID|
    EquipmentBatch|
    Filtered|
    LabContract|
    LabContractModificationDescription|
    LabContractModificationID|
    LabID|
    LabMethodID|
    LabMethodName|
    LabName|
    LabReceiptDate|
    LabReportingBatch|
    LabSampleID|
    LocationID|
    LocationName|
    MatrixID|
    MatrixMedium|
    MethodBatch|
    MethodCategory|
    MethodCode|
    MethodID|
    MethodLevel|
```

Exhibit H -- Section 5

Document Type Definition (DTD) (Con't)

```

        MethodModificationDescription|
        MethodModificationID|
        MethodName|
        MethodSource|
        MethodType|
        MethodVersion|
        OriginalClientSampleID|
        OriginalLabSampleID|
        PhaseAnalyzed|
        Preservative|
        ProjectID|
        ProjectName|
        QCCategory|
        QCLinkage|
        QCType|
        Quarantine|
        SamplingBatch|
        ShippingBatch|
        SiteID|
        SiteName|
        StorageBatch|
        Analysis|
        Characteristic|
        ReportedResult|
        Handling|
        AnalysisGroup
    )*>

<!ELEMENT AliquotAmount (#PCDATA)>
<!ELEMENT AliquotAmountUnits (#PCDATA)>
<!ELEMENT AnalysisDuration (#PCDATA)>
<!ELEMENT AnalysisDurationUnits (#PCDATA)>
<!ELEMENT AnalysisGroupID (#PCDATA)>
<!ELEMENT AnalysisType (#PCDATA)>
<!ELEMENT Analyst (#PCDATA)>
<!ELEMENT AnalyteGroupID (#PCDATA)>
<!ELEMENT AnalyteName (#PCDATA)>
<!ELEMENT AnalyteNameContext (#PCDATA)>
<!ELEMENT AnalyteType (#PCDATA)>
<!ELEMENT AnalyzedAmount (#PCDATA)>
<!ELEMENT AnalyzedAmountUnits (#PCDATA)>
<!ELEMENT AnalyzedDate (#PCDATA)>
<!ELEMENT BiasErrorRatio (#PCDATA)>
<!ELEMENT CASRegistryNumber (#PCDATA)>
<!ELEMENT CharacteristicType (#PCDATA)>
<!ELEMENT CharacteristicUnits (#PCDATA)>
<!ELEMENT CharacteristicValue (#PCDATA)>
<!ELEMENT CleanedUpDate (#PCDATA)>
<!ELEMENT CleanupBatch (#PCDATA)>
<!ELEMENT CleanupType (#PCDATA)>
<!ELEMENT ClientAnalysisID (#PCDATA)>
<!ELEMENT ClientAnalyteID (#PCDATA)>
<!ELEMENT ClientAnalyteName (#PCDATA)>
<!ELEMENT ClientDetectionLimit (#PCDATA)>
<!ELEMENT ClientDetectionLimitUnits (#PCDATA)>
<!ELEMENT ClientID (#PCDATA)>
<!ELEMENT ClientMethodCategory (#PCDATA)>
<!ELEMENT ClientMethodCode (#PCDATA)>
<!ELEMENT ClientMethodID (#PCDATA)>

```

```
<!ELEMENT ClientMethodModificationDescription (#PCDATA)>
<!ELEMENT ClientMethodModificationID (#PCDATA)>
<!ELEMENT ClientMethodName (#PCDATA)>
<!ELEMENT ClientMethodSource (#PCDATA)>
<!ELEMENT ClientMethodType (#PCDATA)>
<!ELEMENT ClientMethodVersion (#PCDATA)>
<!ELEMENT ClientName (#PCDATA)>
<!ELEMENT ClientQuantitationLimit (#PCDATA)>
<!ELEMENT ClientQuantitationLimitUnits (#PCDATA)>
<!ELEMENT ClientSampleID (#PCDATA)>
<!ELEMENT CollectedDate (#PCDATA)>
<!ELEMENT CollectedEndDate (#PCDATA)>
<!ELEMENT Column (#PCDATA)>
<!ELEMENT ColumnInternalDiameter (#PCDATA)>
<!ELEMENT ColumnInternalDiameterUnits (#PCDATA)>
<!ELEMENT ColumnLength (#PCDATA)>
<!ELEMENT ColumnLengthUnits (#PCDATA)>
<!ELEMENT Comment (#PCDATA)>
<!ELEMENT Composite (#PCDATA)>
<!ELEMENT ConfirmationAnalysisID (#PCDATA)>
<!ELEMENT CoolerID (#PCDATA)>
<!ELEMENT Counts (#PCDATA)>
<!ELEMENT CountsUncertainty (#PCDATA)>
<!ELEMENT CountsUncertaintyConfidenceLevel (#PCDATA)>
<!ELEMENT CountsUncertaintyDetermination (#PCDATA)>
<!ELEMENT CountsUncertaintyIntervalType (#PCDATA)>
<!ELEMENT CountsUncertaintyLimitHigh (#PCDATA)>
<!ELEMENT CountsUncertaintyLimitLow (#PCDATA)>
<!ELEMENT CountsUncertaintyType (#PCDATA)>
<!ELEMENT CountsUnits (#PCDATA)>
<!ELEMENT CustodyID (#PCDATA)>
<!ELEMENT DateFormat (#PCDATA)>
<!ELEMENT DetectionLimit (#PCDATA)>
<!ELEMENT DetectionLimitType (#PCDATA)>
<!ELEMENT DetectionLimitUnits (#PCDATA)>
<!ELEMENT DetectorID (#PCDATA)>
<!ELEMENT DetectorType (#PCDATA)>
<!ELEMENT DifferenceErrorRatio (#PCDATA)>
<!ELEMENT DilutionFactor (#PCDATA)>
<!ELEMENT EDDID (#PCDATA)>
<!ELEMENT EDDImplementationID (#PCDATA)>
<!ELEMENT EDDImplementationVersion (#PCDATA)>
<!ELEMENT EDDVersion (#PCDATA)>
<!ELEMENT Efficiency (#PCDATA)>
<!ELEMENT EquipmentBatch (#PCDATA)>
<!ELEMENT ExpectedResult (#PCDATA)>
<!ELEMENT ExpectedResultUncertainty (#PCDATA)>
<!ELEMENT ExpectedResultUncertaintyConfidenceLevel (#PCDATA)>
<!ELEMENT ExpectedResultUncertaintyDetermination (#PCDATA)>
<!ELEMENT ExpectedResultUncertaintyIntervalType (#PCDATA)>
<!ELEMENT ExpectedResultUncertaintyLimitHigh (#PCDATA)>
<!ELEMENT ExpectedResultUncertaintyLimitLow (#PCDATA)>
<!ELEMENT ExpectedResultuncertaintyType (#PCDATA)>
<!ELEMENT ExpectedResultUncertaintyUnits (#PCDATA)>
<!ELEMENT ExpectedResultUnits (#PCDATA)>
<!ELEMENT Filtered (#PCDATA)>
<!ELEMENT FinalAmount (#PCDATA)>
<!ELEMENT FinalAmountUnits (#PCDATA)>
<!ELEMENT GeneratingSystemID (#PCDATA)>
```

```
<!ELEMENT GeneratingSystemVersion (#PCDATA)>
<!ELEMENT HandledDate (#PCDATA)>
<!ELEMENT HandlingBatch (#PCDATA)>
<!ELEMENT HandlingType (#PCDATA)>
<!ELEMENT HeatedPurge (#PCDATA)>
<!ELEMENT Inclusion (#PCDATA)>
<!ELEMENT InitialAmount (#PCDATA)>
<!ELEMENT InitialAmountUnits (#PCDATA)>
<!ELEMENT InjectionVolume (#PCDATA)>
<!ELEMENT InjectionVolumeUnits (#PCDATA)>
<!ELEMENT InstrumentID (#PCDATA)>
<!ELEMENT LabAddress1 (#PCDATA)>
<!ELEMENT LabAddress2 (#PCDATA)>
<!ELEMENT LabAnalysisID (#PCDATA)>
<!ELEMENT LabAnalyteID (#PCDATA)>
<!ELEMENT LabCity (#PCDATA)>
<!ELEMENT LabContract (#PCDATA)>
<!ELEMENT LabContractModificationDescription (#PCDATA)>
<!ELEMENT LabContractModificationID (#PCDATA)>
<!ELEMENT LabCountry (#PCDATA)>
<!ELEMENT LabDataPackageID (#PCDATA)>
<!ELEMENT LabDataPackageName (#PCDATA)>
<!ELEMENT LabDataPackageVersion (#PCDATA)>
<!ELEMENT LabFileID (#PCDATA)>
<!ELEMENT LabID (#PCDATA)>
<!ELEMENT LabMethodID (#PCDATA)>
<!ELEMENT LabMethodName (#PCDATA)>
<!ELEMENT LabName (#PCDATA)>
<!ELEMENT LabNarrative (#PCDATA)>
<!ELEMENT LabPointOfContact (#PCDATA)>
<!ELEMENT LabPointOfContactElectronicAddress (#PCDATA)>
<!ELEMENT LabPointOfContactTitle (#PCDATA)>
<!ELEMENT LabPointOfContactType (#PCDATA)>
<!ELEMENT LabQualifiers (#PCDATA)>
<!ELEMENT LabQualifiersDefinition (#PCDATA)>
<!ELEMENT LabReceiptDate (#PCDATA)>
<!ELEMENT LabReportedDate (#PCDATA)>
<!ELEMENT LabReportingBatch (#PCDATA)>
<!ELEMENT LabResultStatus (#PCDATA)>
<!ELEMENT LabSampleID (#PCDATA)>
<!ELEMENT LabState (#PCDATA)>
<!ELEMENT LabTelephoneNumber (#PCDATA)>
<!ELEMENT LabType (#PCDATA)>
<!ELEMENT LabZipCode (#PCDATA)>
<!ELEMENT LocationID (#PCDATA)>
<!ELEMENT LocationName (#PCDATA)>
<!ELEMENT LotNumber (#PCDATA)>
<!ELEMENT MatrixID (#PCDATA)>
<!ELEMENT MatrixMedium (#PCDATA)>
<!ELEMENT MethodBatch (#PCDATA)>
<!ELEMENT MethodCategory (#PCDATA)>
<!ELEMENT MethodCode (#PCDATA)>
<!ELEMENT MethodID (#PCDATA)>
<!ELEMENT MethodLevel (#PCDATA)>
<!ELEMENT MethodModificationDescription (#PCDATA)>
<!ELEMENT MethodModificationID (#PCDATA)>
<!ELEMENT MethodName (#PCDATA)>
<!ELEMENT MethodSource (#PCDATA)>
<!ELEMENT MethodType (#PCDATA)>
```

```
<!ELEMENT MethodVersion (#PCDATA)>
<!ELEMENT OriginalClientSampleID (#PCDATA)>
<!ELEMENT OriginalLabSampleID (#PCDATA)>
<!ELEMENT PeakID (#PCDATA)>
<!ELEMENT PercentDifference (#PCDATA)>
<!ELEMENT PercentDifferenceLimitHigh (#PCDATA)>
<!ELEMENT PercentDifferenceLimitLow (#PCDATA)>
<!ELEMENT PercentDifferenceLimitType (#PCDATA)>
<!ELEMENT PercentRecovery (#PCDATA)>
<!ELEMENT PercentRecoveryLimitHigh (#PCDATA)>
<!ELEMENT PercentRecoveryLimitLow (#PCDATA)>
<!ELEMENT PercentRecoveryLimitType (#PCDATA)>
<!ELEMENT PercentRecoveryType (#PCDATA)>
<!ELEMENT PhaseAnalyzed (#PCDATA)>
<!ELEMENT PreparationBatch (#PCDATA)>
<!ELEMENT PreparationPlusCleanupType (#PCDATA)>
<!ELEMENT PreparationType (#PCDATA)>
<!ELEMENT PreparedDate (#PCDATA)>
<!ELEMENT Preservative (#PCDATA)>
<!ELEMENT ProcedureID (#PCDATA)>
<!ELEMENT ProcedureName (#PCDATA)>
<!ELEMENT ProjectID (#PCDATA)>
<!ELEMENT ProjectName (#PCDATA)>
<!ELEMENT QCCategory (#PCDATA)>
<!ELEMENT QCLinkage (#PCDATA)>
<!ELEMENT QCType (#PCDATA)>
<!ELEMENT QuantitationLimit (#PCDATA)>
<!ELEMENT QuantitationLimitType (#PCDATA)>
<!ELEMENT QuantitationLimitUnits (#PCDATA)>
<!ELEMENT Quarantine (#PCDATA)>
<!ELEMENT ReferenceDate (#PCDATA)>
<!ELEMENT ReportingLimit (#PCDATA)>
<!ELEMENT ReportingLimitType (#PCDATA)>
<!ELEMENT ReportingLimitUnits (#PCDATA)>
<!ELEMENT Result (#PCDATA)>
<!ELEMENT ResultBasis (#PCDATA)>
<!ELEMENT ResultLimitHigh (#PCDATA)>
<!ELEMENT ResultLimitLow (#PCDATA)>
<!ELEMENT ResultLimitType (#PCDATA)>
<!ELEMENT ResultType (#PCDATA)>
<!ELEMENT ResultUncertainty (#PCDATA)>
<!ELEMENT ResultUncertaintyConfidenceLevel (#PCDATA)>
<!ELEMENT ResultUncertaintyDetermination (#PCDATA)>
<!ELEMENT ResultUncertaintyIntervalType (#PCDATA)>
<!ELEMENT ResultUncertaintyLimitHigh (#PCDATA)>
<!ELEMENT ResultUncertaintyLimitLow (#PCDATA)>
<!ELEMENT ResultUncertaintyType (#PCDATA)>
<!ELEMENT ResultUncertaintyUnits (#PCDATA)>
<!ELEMENT ResultUnits (#PCDATA)>
<!ELEMENT RetentionTime (#PCDATA)>
<!ELEMENT RetentionTimeUnits (#PCDATA)>
<!ELEMENT RPD (#PCDATA)>
<!ELEMENT RPDLimitHigh (#PCDATA)>
<!ELEMENT RPDLimitType (#PCDATA)>
<!ELEMENT RPDType (#PCDATA)>
<!ELEMENT SampleAmount (#PCDATA)>
<!ELEMENT SampleAmountUnits (#PCDATA)>
<!ELEMENT SamplingBatch (#PCDATA)>
<!ELEMENT ShippingBatch (#PCDATA)>
```

Exhibit H -- Section 5
Document Type Definition (DTD) (Con't)

```
<!ELEMENT SiteID (#PCDATA)>
<!ELEMENT SiteName (#PCDATA)>
<!ELEMENT Solvent (#PCDATA)>
<!ELEMENT StandardSource (#PCDATA)>
<!ELEMENT StorageBatch (#PCDATA)>
<!ELEMENT Temperature (#PCDATA)>
<!ELEMENT TemperatureUnits (#PCDATA)>
<!ELEMENT Wavelength (#PCDATA)>
<!ELEMENT WavelengthUnits (#PCDATA)>
<!ELEMENT Yield (#PCDATA)>
```

6.0 DATA ELEMENT INSTRUCTION TABLES

6.1 Specification 5.2 Stage 2a

Table 1
Dioxin Data Element Instructions

Node and Data Elements	Sample	ICS	MB	NCS	Instructions
Header	X	X	X	X	
ClientID	X	X	X	X	Report "1" for Region 1, "2" for Region 2, etc. For samples received from QATS, report "91".
ClientName					Not required.
Comment					Not required.
DateFormat	X	X	X	X	Report MMDDYYThh:mm:ss. All dates and times reported in the EDD must follow this format. If any part of the time is unknown, report "00" for the unknown hours, minutes, and seconds.
EDDID	X	X	X	X	Report "SEDD".
EDDImplementationID	X	X	X	X	Report "SEDD_5-2_GENERAL_2a" (This is the DTD used).
EDDImplementationVersion	X	X	X	X	Report "2" (This is the version of the DTD used).
EDDVersion	X	X	X	X	Report "5.2".
GeneratingSystemID	X	X	X	X	Report name of generating software or vendor.
GeneratingSystemVersion	X	X	X	X	Report software version number.
Lab Contract	X	X	X	X	Report the Task Order number.
LabContractModificationDescription					Not required.
LabContractModificationID					Not required.
LabDataPackageID	X	X	X	X	Report the Sample Delivery Group (SDG).
LabDataPackageName	X	X	X	X	Report "Dioxin".
LabDataPackageVersion	X	X	X	X	Report "1", then increment with each resubmission.
LabID					Report the Agency-assigned Lab Code.
Lab Name	X	X	X	X	Report the Lab Name.
LabNarrative					Not required.
LabQualifiersDefinition	X	X	X	X	Use the format 'Qualifier:Definition' to report each qualifier used. Use a ';' to separate the definitions of multiple qualifiers.
LabReportedDate	X	X	X	X	Report the date this data was reported to the client.
ProjectID	X	X	X	X	Report the Case Number.
ProjectName					Not required.
SiteID					Not required.
SiteName					Not required.
SamplePlusMethod	X	X	X	X	
ClientID	X				Report "1" for Region 1, "2" for Region 2, etc. For samples received from QATS, report "91".
ClientMethodCategory					Not required.
ClientMethodCode					Not required.

Exhibit H -- Section 6
Data Element Instruction Tables (Con't)

Table 1
Dioxin Data Element Instructions (Con't)

Node and Data Elements	Sample	LCS	MB	NCS	Instructions
ClientMethodID	X	X	X	X	Report "DLM02.2".
ClientMethodModificationDescription					Not required.
ClientMethodModificationID	X	X	X		Report the Modified Analysis number or the Task Order number.
ClientMethodName					Not required.
ClientMethodSource	X	X	X	X	Report "USEPA_CLP".
ClientMethodType	X	X	X	X	Report "HRGC/HRMS".
ClientMethodVersion	X	X	X	X	Report month and year the SOW was issued.
ClientName					Not required.
ClientSampleID	X	X	X	X	Report the Sample Number.
CollectedDate	X				Report the date and time the sample was collected.
CollectedEndDate					Not required.
Comment					Not required.
Composite					Not required.
CoolerID					Not required.
CustodyID	X				Report the Traffic Report/Chain of Custody Form number.
EquipmentBatch					Not required.
Filtered	X				Report "Yes" for field-filtered samples, otherwise report "No".
LabContract	X	X	X		Report the Contract number.
LabContractModificationDescription					Not required.
LabContractModificationID					Not required.
LabID	X	X	X	X	Report the Agency-assigned Lab Code.
LabMethodID					Not required.
LabMethodName					Not required.
LabName	X	X	X	X	Report the Lab Name.
LabReceiptDate	X				Report the date and time the sample was received.
LabReportingBatch	X	X	X	X	Links all samples analyzed to this deliverable. Report the SDG number.
LabSampleID	X	X	X	X	Report the Lab Sample ID as assigned by the lab.
LocationID					Not required.
LocationName					Not required.
MatrixID	X	X	X	X	Report "Water", "Soil", "Ash", "Tissue", or "Oil" as applicable.
MatrixMedium	X	X	X	X	Report "Aqueous" or "Solid" as applicable. Use "Solid" for Ash, Tissue, and Oil.
MethodBatch					Not required.
MethodCategory					Not required.
MethodCode					Not required.
MethodID	X	X	X	X	Report "DLM02.2".

Exhibit H -- Section 6
Data Element Instruction Tables (Con't)

Table 1

Dioxin Data Element Instructions (Con't)

Node and Data Elements	Sample	LCS	MB	NCS	Instructions
MethodLevel					Not required.
MethodModificationDescription					Not required.
MethodModificationID					Not required.
MethodName					Not required.
MethodSource	X	X	X	X	Report "USEPA_CLP".
MethodType	X	X	X	X	Report "HRGC/HRMS".
MethodVersion	X	X	X	X	Report month and year the SOW was issued.
OriginalClientSampleID					Not required.
OriginalLabSampleID					Not required.
PhaseAnalyzed					Not required.
Preservative	X				Report any chemical or physical preservative used.
ProjectID	X	X	X		Report the Case Number.
ProjectName					Not required.
QCCategory		X	X		Report "Blank" for MB; "Blank_Spike" for LCS;
QCLinkage		X	X		Report "PreparationBatch" for MB and LCS.
QCType	X	X	X		Report "Field_Sample" for field samples; "Field_Blank" for field, equipment, rinse, or trip blanks; "PT_Sample" for PE samples; "Method_Blank" for MB; "Laboratory_Control_Sample" for LCS.
Quarantine	X				Report "Yes" or "No" based on sampling information.
SamplingBatch					Not required.
ShippingBatch					Not required.
SiteID					Not required.
SiteName					Not required.
StorageBatch					Not required.
Characteristic	X	X	X		
CharacteristicType	X	X	X		Report "Percent_Lipids" for Tissue samples; "Percent_Solids" for Soil samples; "Temperature" for each SamplePlusMethod.
CharacteristicValue	X	X	X		Report percent solids and percent lipids to two significant figures if less than 10, and three significant figures if greater than or equal to 10; and report the temperature at receipt to the nearest degree.
CharacteristicUnits	X	X	X		Report "C" for "Temperature".
Comment					Not required.
ContactInformation	X	X	X	X	
LabAddress1	X	X	X	X	Report the street address of the laboratory.

Exhibit H -- Section 6
Data Element Instruction Tables (Con't)

Table 1
Dioxin Data Element Instructions (Con't)

Node and Data Elements	Sam ple	LCS	MB	NCS	Instructions
LabAddress2	X	X	X	X	If applicable, report any additional address information (e.g., suite, maildrop). Otherwise leave blank.
LabCity	X	X	X	X	Report the city in which the laboratory is located.
LabCountry	X	X	X	X	Report the country in which the laboratory is located.
LabID	X	X	X	X	Report the Agency-assigned Lab Code.
LabName	X	X	X	X	Report the Lab Name.
LabPointOfContact	X	X	X	X	Report the name of the person at the laboratory serving as the point of contact.
LabPointOfContactElectronicAddress	X	X	X	X	Report the email address of the point of contact.
LabPointOfContactTitle	X	X	X	X	Report the title of the point of contact
LabPointOfContactType					Not required.
LabState	X	X	X	X	Report the state or province in which the laboratory is located.
LabTelephoneNumber	X	X	X	X	Report the 10-digit phone number for the laboratory.
LabType					Not required.
LabZipCode	X	X	X	X	Report the ZIP or postal code.
Analysis	X	X	X	X	
AliquotAmount					Not required.
AliquotAmountUnits					Not required.
AnalysisDuration					Not required.
AnalysisDurationUnits					Not required.
AnalysisGroupID					Not required.
AnalysisType	X	X	X		Report "Initial", "Confirmation", "Dilution-01", or "Reanalysis-01", then increment as necessary.
Analyst	X	X	X		Report the Analyst's initials.
AnalyzedAmount					Not required.
AnalyzedAmountUnits					Not required.
AnalyzedDate	X	X	X	X	Report the date and time the sample was analyzed.
ClientAnalysisID					Not required.
ClientMethodCode					Not required.
ClientMethodID	X	X	X	X	Report "DLM02.2".
ClientMethodModificationDescription					Not required.
ClientMethodModificationID					Not required.
ClientMethodName					Not required.
ClientMethodSource	X	X	X	X	Report "USEPA_CLP".
ClientMethodVersion	X	X	X	X	Report month and year the SOW was issued.
Column	X	X	X		Report the column used for analysis.
ColumnInternalDiameter	X	X	X		Report the internal diameter in mm.
ColumnInternalDiameterUnits	X	X	X		Report "mm".
ColumnLength	X	X	X		Report the length in meters.

Table 1

Dioxin Data Element Instructions (Con't)

Node and Data Elements	Sample	LCS	MB	NCS	Instructions
ColumnLengthUnits	X	X	X		Report "m".
Comment					Not required.
ConfirmationAnalysisID					Not required.
Counts					Not required.
CountsUncertainty					Not required.
CountsUncertaintyConfidenceLevel					Not required.
CountsUncertaintyDetermination					Not required.
CountsUncertaintyIntervalType					Not required.
CountsUncertaintyLimitHigh					Not required.
CountsUncertaintyLimitLow					Not required.
CountsUncertaintyType					Not required.
CountsUnits					Not required.
DetectorID					Not required.
DetectorType					Not required.
DilutionFactor	X	X	X		Report the Dilution Factor used to the nearest tenth. Report "1.0" when no dilutions are used.
Efficiency					Not required.
HeatedPurge					Not required.
Inclusion					Not required.
InjectionVolume	X	X	X		Report the injection volume in uL.
InjectionVolumeUnits	X	X	X		Report "uL".
InstrumentID	X	X	X	X	Report the laboratory identifier for the instrument used for this analysis.
LabAnalysisID	X	X	X	X	Report a unique identifier.
LabFileID	X	X	X	X	Report the lab file ID.
LabID					Not required.
LabMethodID					Not required.
LabMethodName					Not required.
LabName					Not required.
MethodCode					Not required.
MethodID	X	X	X	X	Report "DLM02.2".
MethodModificationDescription					Not required.
MethodModificationID					Not required.
MethodName					Not required.
MethodSource	X	X	X	X	Report "USEPA_CLP".
MethodVersion	X	X	X	X	Report month and year the SOW was issued.
PreparationBatch					Not required.
ProcedureID					Not required.
ProcedureName					Not required.
ReferenceDate					Not required.

Exhibit H -- Section 6
Data Element Instruction Tables (Con't)

Table 1
Dioxin Data Element Instructions (Con't)

Node and Data Elements	Sample	LCS	MB	NCS	Instructions
ResultBasis	X		X		Report "Dry" for Soil samples.
Temperature					Not required.
TemperatureUnits					Not required.
WaveLength					Not required.
WaveLengthUnits					Not required.
Yield					Not required.
AnalysisGroup					Not required.
Handling					Not required.
ReportedResult	X	X	X		
AnalysisGroupID					Not required.
AnalyteGroupID	X	X	X		Report the AnalyteGroupID for the homologues.
AnalyteName	X	X	X		Report analytes as they appear in the CAS Registry.
AnalyteNameContext	X	X	X		Report "CAS".
AnalyteType	X	X	X		Report "Target" for all target compounds, and "Spike" for all target analytes designated as spike compounds for LCS analysis.
BiasErrorRatio					Not required.
CASRegistryNumber	X	X	X		Report CAS Numbers as they appear in the SOW.
ClientAnalyteID	X	X	X		Report CAS number.
ClientAnalyteName	X	X	X		Report analytes as they appear in the SOW.
ClientDetectionLimit					Not required.
ClientDetectionLimitUnits					Not required.
ClientQuantitationLimit	X	X	X		Report the CRQL.
ClientQuantitationLimitUnits	X	X	X		Report "ng/kg" for Soil, Ash, Tissue, and Oil. Report "pg/L" for Water.
Comment					Not required.
DetectionLimit	X	X	X		Report the Estimated Detection Limit (EDL), to two significant figures.
DetectionLimitType	X	X	X		Report "EDL".
DetectionLimitUnits	X	X	X		Report "ng/kg" for Soil, Ash, Tissue, and Oil. Report "pg/L" for Water.
DifferenceErrorRatio					Not required.
ExpectedResult		X			Report the true value for LCS.
ExpectedResultUncertainty					Not required.
ExpectedResultUncertaintyConfidenceLevel					Not required.
ExpectedResultUncertaintyDetermination					Not required.
ExpectedResultUncertaintyIntervalType					Not required.
ExpectedResultUncertaintyLimitHigh					Not required.
ExpectedResultUncertaintyLimitLow					Not required.

Table 1

Dioxin Data Element Instructions (Con't)

Node and Data Elements	Sample	LCS	MB	NCS	Instructions
ExpectedResultUncertaintyType					Not required.
ExpectedResultUncertaintyUnits					Not required.
ExpectedResultUnits		X			Report "ng/kg" for Soil, Ash, Tissue, and Oil. Report "pg/L" for Water.
LabAnalysisID	X	X	X		Report the unique identifier from the analysis this reported result was derived from.
LabAnalyteID					Not required.
LabQualifiers	X	X	X		Report flags as specified in the SOW.
LabResultStatus					Not required.
PeakID					Not required.
PercentDifference					Not required.
PercentDifferenceLimitHigh					Not required.
PercentDifferenceLimitLow					Not required.
PercentDifferenceLimitType					Not required.
PercentRecovery		X			Report the Percent Recovery.
PercentRecoveryLimitHigh		X			Report the upper limit for the Percent Recovery.
PercentRecoveryLimitLow		X			Report the lower limit for the Percent Recovery.
PercentRecoveryLimitType		X			Report "Method".
PercentRecoveryType					Not required.
QuantitationLimit	X	X	X		Report the CRQL adjusted for sample weight and volume, percent solids and dilution factor to two significant figures.
QuantitationLimitType	X	X	X		Report "CRQL_sa".
QuantitationLimitUnits	X	X	X		Report "ng/kg" for Soil, Ash, Tissue, and Oil. Report "pg/L" for Water.
ReportingLimit					Not required.
ReportingLimitType					Not required.
ReportingLimitUnits					Not required.
Result	X	X	X		Report the final calculated result for detects that meet all technical acceptance criteria. Report the Estimated Maximum Possible Concentration (EMPC) for detects that do not meet all technical acceptance criteria. Leave blank if not detected.
ResultLimitHigh					Not required.
ResultLimitLow					Not required.
ResultLimitType					Not required.
ResultType	X	X	X		Report "=" for all detected analytes that meet technical acceptance criteria. Report "Less_Than" for EMPCs. Report "Not_Detected" for non-detects.
ResultUncertainty					Not required.
ResultUncertaintyConfidenceLevel					Not required.
ResultUncertaintyDetermination					Not required.
ResultUncertaintyIntervalType					Not required.

Exhibit H -- Section 6
Data Element Instruction Tables (Con't)

Table 1
Dioxin Data Element Instructions (Con't)

Node and Data Elements	Sample	LCS	MB	NCS	Instructions
ResultUncertaintyLimitHigh					Not required.
ResultUncertaintyLimitLow					Not required.
ResultUncertaintyType					Not required.
ResultUncertaintyUnits					Not required.
ResultUnits	X	X	X		Report "ng/kg" for Soil, Ash, Tissue, and Oil. Report "pg/L" for Water.
RetentionTime	X	X	X		Report the retention time in decimal minutes for all detects that meet all technical acceptance criteria.
RetentionTimeUnits	X	X	X		Report "Minutes".
RPD					Not required.
RPDLimitHigh					Not required.
RPDLimitType					Not required.
RPDType					Not required.
PreparationPlusCleanup	X	X	X		
AliquotAmount	X	X	X		Report the sample amount in grams for Soil, Ash, Tissue, or Oil, or in mL for Water.
AliquotAmountUnits	X	X	X		Report "g" for Soil, Ash, Tissue, and Oil. Report "mL" for Water.
Analyst	X	X	X		Report the Analyst's initials.
CleanedUpDate	X	X	X		Report the date the cleanup procedure began.
CleanUpBatch	X	X	X		Links all the samples that were cleaned up together. Report a unique identifier for each batch.
CleanUpType	X	X	X		Report "Alumina", "Anthropogenic", "Carbon", "Florisil", "GPC", "HPLC", "Silica_Gel", or "Sulfuric_Acid" as appropriate.
ClientMethodCode					Not required.
ClientMethodID					Not required.
ClientMethodModificationDescription					Not required.
ClientMethodModificationID					Not required.
ClientMethodName					Not required.
ClientMethodSource	X	X	X		Report "USEPA_CLP".
ClientMethodVersion	X	X	X		Report month and year the SOW was issued.
Comment					Not required.
FinalAmount	X	X	X		Report the final extract volume produced by the extraction method in uL.
FinalAmountUnits	X	X	X		Report "uL".
InitialAmount					Not required.
InitialAmountUnits					Not required.
LabID					Not required.
LabMethodID					Not required.
LabMethodName					Not required.
LabName					Not required.

Table 1

Dioxin Data Element Instructions (Con't)

Node and Data Elements	Sample	LCS	MB	NCS	Instructions
LotNumber					Not required.
MethodCode					Not required.
MethodID	X	X	X		Report "DLM02.2".
MethodModificationDescription					Not required.
MethodModificationID					Not required.
MethodName					Not required.
MethodSource	X	X	X		Report "USEPA_CLP".
MethodVersion	X	X	X		Report month and year the SOW was issued.
PreparationBatch	X	X	X		Links all samples that were prepared together. Report a unique identifier for each batch.
PreparationPlusCleanupType	X	X	X		Report "Preparation" or "Cleanup".
PreparationType	X	X	X		Report "SEPF" separatory funnel, "SPE" for solid phase extraction, "SDS" for Soxhlet/Dean-Stark, or "HCL" for HCL digestion/extraction.
PreparedDate	X	X	X		Report the date and time the sample was extracted.
ProcedureID					Not required.
ProcedureName					Not required.
Solvent					Not required.
Analyte	X	X	X		
AnalyteGroupID	X	X	X		For detects that meet all technical acceptance criteria, report the AnalyteGroupID for the Homologue.
AnalyteName	X	X	X		Report analytes as they appear in the SOW.
AnalyteNameContext	X	X	X		Report "CAS".
AnalyteType	X	X	X		Report "Target" for all target compounds, "Spike" for all target analytes designated as spike compounds for LCS analysis, "Surrogate" for all labeled compounds, "Internal_Standard" for internal standards, and "Monitor" for the cleanup standard compound.
BiasErrorRatio					Not required.
CASRegistryNumber	X	X	X		Report the CAS Number as it appears in the SOW.
ClientAnalyteID	X	X	X		Report CAS number.
ClientAnalyteName	X	X	X		Report the analytes as they appear in the SOW.
Comment					Not required.
Counts					Not required.
CountsUncertainty					Not required.
CountsUncertaintyConfidenceLevel					Not required.
CountsUncertaintyDetermination					Not required.
CountsUncertaintyIntervalType					Not required.
CountsUncertaintyLimitHigh					Not required.
CountsUncertaintyLimitLow					Not required.
CountsUncertaintyType					Not required.
CountsUnits					Not required.

Exhibit H -- Section 6
Data Element Instruction Tables (Con't)

Table 1
Dioxin Data Element Instructions (Con't)

Node and Data Elements	Sample	LCS	MB	NCS	Instructions
DetectionLimit	X	X	X		Report the Estimated Detection Limit (EDL).
DetectionLimitType	X	X	X		Report "EDL".
DetectionLimitUnits	X	X	X		Report "ng/kg" for Soil, Ash, Tissue, and Oil. Report "pg/L" for Water.
DifferenceErrorRatio					Not required.
Efficiency					Not required.
ExpectedResult	X	X	X		Report the concentration of labeled compounds, internal standards, and cleanup standard in the final extract.
ExpectedResultUncertainty					Not required.
ExpectedResultUncertaintyConfidenceLevel					Not required.
ExpectedResultUncertaintyDetermination					Not required.
ExpectedResultUncertaintyIntervalType					Not required.
ExpectedResultUncertaintyLimitHigh					Not required.
ExpectedResultUncertaintyLimitLow					Not required.
ExpectedResultUncertaintyType					Not required.
ExpectedResultUncertaintyUnits					Not required.
ExpectedResultUnits	X	X	X		Report "ng/mL".
Inclusion					Not required.
LabAnalyteID					Not required.
LabQualifiers	X	X	X		Report qualifiers as specified in the SOW.
LotNumber	X	X	X		Report the vendor/manufacturer assigned lot number for this standard (labeled compounds, Internal Standards and Cleanup standard).
PeakID					Not required.
PercentRecovery	X	X	X		Report the percent recovery of the labeled compounds.
PercentRecoveryLimitHigh	X	X	X		Report the upper limit of the percent recovery.
PercentRecoveryLimitLow	X	X	X		Report the lower limit of the percent recovery.
PercentRecoveryLimitType	X	X	X		Report "Method".
PercentRecoveryType					Not required.
QuantitationLimit	X	X	X		Report the CRQL.
QuantitationLimitType	X	X	X		Report "CRQL_sa".
QuantitationLimitUnits	X	X	X		Report "ng/kg" for Soil, Ash, Tissue, and Oil. Report "pg/L" for Water.
ReportingLimit					Not required.
ReportingLimitType					Not required.
ReportingLimitUnits					Not required.
Result	X	X	X		For targets and labeled compounds, report the final calculated result. Leave blank if not detected.
ResultLimitHigh					Not required.

Exhibit H -- Section 6
Data Element Instruction Tables (Con't)

Table 1

Dioxin Data Element Instructions (Con't)

Node and Data Elements	Sample	LCS	MB	NCS	Instructions
ResultLimitLow					Not required.
ResultLimitType					Not required.
ResultType	X	X	X		Report "=" for all detected analytes that meet technical acceptance criteria, "Less_Than" for EMPCs, "Not_Detected" for non-detects.
ResultUncertainty					Not required.
ResultUncertaintyConfidenceLevel					Not required.
ResultUncertaintyDetermination					Not required.
ResultUncertaintyIntervalType					Not required.
ResultUncertaintyLimitHigh					Not required.
ResultUncertaintyLimitLow					Not required.
ResultUncertaintyType					Not required.
ResultUncertaintyUnits					Not required.
ResultUnits	X	X	X		Report "ng/kg" for Soil, Ash, Tissue, and Oil. Report "pg/L" Water.
StandardSource	X	X	X		Report the vendor/manufacturer for this standard.
Wavelength					Not required.
WavelengthUnits					Not required.
AnalyteGroup	X	X	X		
AnalyteGroupID	X				Report the AnalyteGroupID for the Homologue.
AnalyteName	X				Report Homologues as they appear in the SOW.
AnalyteNameContext	X				Report "CAS".
AnalyteType	X				Report "Target".
CASRegistryNumber	X				Report the CAS Number as it appears in the SOW.
ClientAnalyteID	X				Report the CAS Number as it appears in the SOW.
ClientAnalyteName	X				Report Homologues as they appear in the SOW.
Comment					Not required.
LabAnalyteID					Not required.
LabQualifiers	X				Report qualifiers as specified in the SOW.
Result	X				Report the total result for the Homolog. Leave blank if not detected
ResultType	X				Report "="
ResultUncertainty					Not required
ResultUnits	X				Report "ng/kg" for Soil, Ash, Tissue, and Oil. Report "pg/L" Water.

Exhibit H -- Section 6
Data Element Instruction Tables (Con't)

Table 1
Dioxin Data Element Instructions (Con't)

Abbreviation	Definition
C	Celsius
CAS	Chemical Abstracts Service
CRQL	Contract Required Quantitation Limit
DTD	Document Type Definition
EDD	Electronic Data Deliverable
EDL	Estimated Detection Limit
EMPC	Estimated Maximum Possible Concentration
ID	Identifier
Lab	Laboratory
LCS	Laboratory Control Sample
MB	Method Blank
NCS	Non-Client (ZZZZZZ) Sample
PE	Performance Evaluation
QC	Quality Control