EXHIBIT E

QUALITY SYSTEMS

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Exhibit E - Quality Systems

Table of Contents

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1.0 QUALITY SYSTEM

1.1 Overview

Since the purpose of this analytical service is to provide analytical data for the use by the U.S. Environmental Protection Agency (EPA) in support of the investigation and clean-up activities under Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Superfund Amendments and Reauthorization Act (SARA), the Contractor is responsible for developing and implementing a Quality System to enforce the requirements of the EPA CIO 2105.0 "*Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*". This will require the implementation of a quality system that meets the EPA's goal of providing data of documented quality.

1.1.1 The quality system provides the framework for planning, implementing, assessing, and improving work performed by the Contractor for performing quality assurance (QA) and quality control (QC) activities. Effective implementation of the quality system leads to several benefits including:

- Scientific Data Integrity – The Contractor will produce and submit data of known and documented quality;
- Effective Management of Internal and External Activities – The quality system requires documentation of activities and oversight for evaluation purposes which will reduce the potential for waste and abuse; and
- Continual Improvement – The continual improvement component of the quality system leads to the development of a better more responsive quality system and technical system which should result in better products and services.

1.1.2 Overall, successful implementation of the quality system will reduce the Agency's vulnerabilities in decision making and increase the EPA's credibility by providing the ability to make reliable, timely, cost effective, and defensible decisions. The consequences of not having a successfully implemented quality system include the potential to waste time, money, and resources, which increase uncertainty in the EPA's decision.

1.1.3 Under this program, the EPA requires two forms of documentation for the quality system:

- A Quality Management Plan (QMP) which documents the organization quality system; and
- A Quality Assurance Project Plan (QAPP) which documents the application of quality related activities to an activity-specific effort.

NOTE: The Contractor may combine these two documents into a single document that describes the organization's quality system and the application of this system to the work performed under this program.

2.0 QUALITY MANAGEMENT PLAN

During the contract solicitation process, the Contractor is required to submit the QMP or equivalent to the EPA Contracting Officer (CO). The QMP documents how an organization structures its quality system and describes its quality policies and procedures; criteria for and areas of application; and roles, responsibilities, and authorities. It also describes an organization's policies and procedures for implementing and assessing the effectiveness of the quality system. The Contractor shall follow the EPA Requirements for Quality Management Plans (QA/R-2) EPA/240/B-01/002 (or subsequent version) for guidance.

2.1 The QMP should describe the Quality System that is designed to support the objectives of the organization in providing the analytical services required in this document.

2.2 The QMP must be sufficiently inclusive, explicit, and readable to enable both management and staff to understand the priority which management places on QA and QC activities, established quality policies and procedures, and their respective quality related roles and responsibilities.

2.3 The QMP should document management practices, including QA and QC activities, used to ensure that the results of technical work are of the type and quality needed for their intended use.

2.4 The QMP should document the following: the mission and quality policy of the organization; the specific roles, authorities, and responsibilities of management and staff with respect to QA and QC activities; the means by which effective communications with personnel actually performing the work are assured; the processes used to plan, implement, and assess the work performed; the process by which measures of effectiveness for QA and QC activities will be established and how frequently effectiveness will be measured; and the continual improvement based on lessons learned from previous experience.

2.5 The elements to be addressed in a QMP include: management and organization; quality system description; personnel qualifications and training; procurement of items and services; documentation and records; computer hardware and software; planning; implementation of work processes; assessment and response; and quality improvement.

NOTE: It is not necessary for the Contractor to present the information in the same order as outlined above as long as each item is adequately addressed in the plan.

3.0 QUALITY ASSURANCE PROJECT PLAN

3.1 Introduction

The EPA requires that all environmental data used in decision making be supported by an approved QAPP. The QAPP integrates all technical and quality aspects of a project including planning, implementation, and assessment. The purpose of the QAPP is to document how QA and QC are applied to an environmental data operation to assure that the results obtained are of the type and quality needed and expected for this program. The Contractor shall follow the EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5 (EPA/240/B-01/003) (or subsequent version) for guidance.

3.1.1 The Contractor shall prepare a written QAPP 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.

3.1.2 The QAPP must present, in specific terms, the policies, organization, objectives, functional guidelines, and specific QA and 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 QAPP.

3.1.3 The QAPP shall be available during on-site laboratory evaluations.

3.1.4 The QAPP shall be submitted within 7 days of written request by the EPA Regional Laboratory Contracting Officer Representative (COR) or the Analytical Services Branch Contract Laboratory Program COR (ASB CLP COR).

3.2 Required Elements of a Quality Assurance Project Plan

The QAPP shall be paginated consecutively in ascending order. The required elements of a laboratory's QAPP are outlined in this section. This outline should be used as a framework for developing the QAPP.

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 ensured)
    d. QA Document Control Procedures

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 Relevant 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. Complete Sample Delivery Group (SDG) File (CSF) 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

3.3 Submission of the Quality Assurance Project Plan

3.3.1 Initial Submission

The Contractor is required to submit their QAPP to the EPA CO within the number of days provided in the associated laboratory contract document. The Contractor shall maintain a QAPP (fully compliant with the requirements of this contract) on file at their facility for the term of the contract.

3.3.2 Revision Submissions

The revised QAPP will become the official QAPP under the contract and may be used during legal proceedings.

3.3.2.1 During the term of the contract, the Contractor shall amend the QAPP when the following circumstances occur:

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

3.3.2.2 The Contractor shall amend and submit the QAPP to the recipient(s) identified in Exhibit B – Reporting and Deliverables Requirements, Table 1 – Deliverable Schedule, within 14 days of when the circumstances listed above result in a discrepancy between what was previously described in the QAPP, and what is presently occurring at the Contractor's facility.

3.3.2.2.1 All changes in the QAPP shall be clearly marked (e.g., a bar in the margin indicating 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 the amended section pages shall have the date on which the changes were implemented.

3.3.2.2.2 The Contractor shall archive all amendments to the QAPP document for future reference by the Government.

3.3.2.3 The Contractor shall send a copy of the latest version of the QAPP document within 7 days of a written request by the EPA Regional Laboratory COR or the ASB CLP COR, as directed. The EPA requestor will designate the recipients.

4.0 STANDARD OPERATING PROCEDURES

4.1 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 the EPA, 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 EPA Guidance for Preparing Standard Operating Procedures (SOPs) (QA/G-6).

4.1.1 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).

4.1.2 All SOPs shall reflect activities as they are currently performed in the laboratory. In addition, all SOPs shall be:

- Consistent with current EPA regulations, guidelines, and the 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 EPA Regional Laboratory COR or ASB CLP COR;
- 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;
- 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.

4.2 Format

The format for SOPs may vary depending upon the type of activity for which they are prepared. The SOPs shall be paginated consecutively in ascending order. 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;
- 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.

4.3 Required Standard Operating Procedures

The Contractor shall maintain the following SOPs:

4.3.1 Evidentiary SOPs for required chain of custody and document control.

4.3.2 Sample receipt and storage:

- Sample receipt and identification logbooks;
- Refrigerator temperature logbooks;
- Extract storage logbooks; and
- Security precautions.

4.3.3 Sample preparation:

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

4.3.4 Glassware cleaning

4.3.5 Calibration (balances, pipets, etc.):

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

4.3.6 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 sequence/injection logbooks; and
- Instrument error and editing flag descriptions and resulting corrective actions.

4.3.7 Maintenance activities (for each analytical system):

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

4.3.8 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.

4.3.9 Data reduction procedures:

- Data processing systems operation;
- Outlier identification methods;
- Identification of data requiring corrective action; and
- Procedures for format and/or forms for each operation.

4.3.10 Documentation policy/procedures:

- Contractor/analyst's notebook policy, including review policy;
- CSF contents;
- CSF organization and assembly procedures, including review policy; and
- Document inventory procedures, including review policy.

4.3.11 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 ensure that hardcopy and electronic deliverables are complete and compliant with the requirements in Exhibit B – Reporting and Deliverables Requirements and Exhibit H – Format for Electronic Data Deliverables;
- Procedures to ensure that hardcopy deliverables are in agreement with their comparable electronic deliverables;
- Demonstration of internal 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.

4.3.12 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 instrument files transferred to electronic media.

4.4 Submission of the Standard Operating Procedures

4.4.1 Initial Submission

The Contractor is required to submit their SOPs to the EPA CO within 60 days after contract award. The Contractor shall maintain on file a complete set of SOPs, fully compliant with the requirements of this contract for the term of the contract.

4.4.2 Revision Submissions

The revised SOPs will become the official SOPs under the contract and may be used during legal proceedings.

4.4.2.1 During the term of the contract, the Contractor shall amend the SOPs when the following circumstances occur:

- The EPA modifies the technical requirements of the SOW or the contract;
- The EPA notifies the Contractor of deficiencies in their SOP documentation;
- The EPA notifies the Contractor of deficiencies resulting from the EPA'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.

4.4.2.2 The Contractor shall amend and submit revised or write and submit new SOPs to the recipient(s) identified in Exhibit B – Reporting and Deliverables Requirements, Table 1 – Deliverable Schedule within 14 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.

4.4.2.2.1 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 the amended/new SOPs shall have the date on which the changes were implemented.

4.4.2.2.2 The Contractor shall document the reasons for the changes and archive all amended SOPs for future reference by the Government. Documentation of the reason(s) for changes to the SOPs shall also be submitted along with the SOPs.

4.4.2.3 The Contractor shall send a copy of the latest version of the SOPs within 7 days of written request by the EPA Regional Laboratory COR or the ASB CLP COR, as directed. The EPA requestor will designate the recipients.

5.0 CHAIN OF CUSTODY

5.1 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 EPA's sample data and records supporting sample related activities are admissible as evidence in litigation, Contractors are required to maintain EPA furnished samples under chain of custody and to account for all samples and supporting records of sample handling, preparation, and analysis.

The Contractor shall develop and implement the following SOPs for sample chain of custody (COC) under this contract. The Contractor shall provide the following SOPs: sample receiving, sample identification, sample security, sample storage, sample tracking and document control, electronic sample data control, and CSF organization and assembly to ensure accountability of sample chain of custody, as well as control of all sample-related records.

5.2 Sample Receiving

5.2.1 The Contractor shall designate a sample custodian responsible for receiving Government-furnished samples.

5.2.2 The Contractor shall designate a representative to receive Government-furnished samples in the event that the sample custodian is not available.

5.2.3 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.

5.2.4 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/COCs);
- Sample tags/numbers listed/not listed on TR/COCs;
- Presence or absence of shipping container temperature indicator bottle;
- Shipping container 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.

5.2.5 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.

5.2.6 The Contractor shall contact the Sample Management Office (SMO) to resolve problems and discrepancies including, but not limited to: absent documents; conflicting information and absent or broken custody seals.

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

5.3 Sample Identification

5.3.1 The Contractor shall maintain the identity of Government-furnished samples and prepared samples (including extracts) throughout the laboratory.

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

5.4 Sample Security

5.4.1 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.

5.4.2 The Contractor shall demonstrate security of designated secure areas.

5.5 Sample Storage

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

5.6 Sample Tracking and Document Control

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

5.6.2 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, sample analysis, CSF organization and assembly, and sample retention or disposal). When a document is a record of analysis, the instrument type and parameter group shall be included in the title.

5.6.3 When columns are used to organize information recorded on laboratory documents, the information recorded in the columns shall be identified in a column heading.

5.6.4 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.

5.6.5 Each laboratory document entry shall be dated in the format MM/DD/YYYY (e.g., 01/01/2013) and signed (or initialed) by the individual(s) responsible for performing the recorded activity at the time the activity is recorded.

5.6.6 Notations on laboratory documents shall be recorded in ink.

5.6.7 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.

5.6.8 Unused portions of laboratory documents shall be lined out, signed (or initialed) and dated.

5.6.9 Pages in bound and unbound logbooks shall be sequentially numbered.

5.6.10 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).

5.6.11 Instrument-specific analytical sequence logs shall be maintained to enable the reconstruction of analytical sequences.

5.6.12 Logbook entries shall be in chronological order.

5.6.13 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.

5.6.14 The Contractor shall document disposal or retention of Government-furnished samples, remaining portions of samples, and prepared samples.

5.7 Electronic Sample Data Control

5.7.1 Contractor personnel responsible for original data entry shall be identified at the time of data input.

5.7.2 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.

5.7.3 The Contractor shall routinely verify the accuracy of manually entered data, electronically entered data, and data acquired from instruments.

5.7.4 The Contractor shall routinely verify documents produced by the electronic data collection system to ensure accuracy of the information reported.

5.7.5 The Contractor shall ensure that the electronic data collection system is secure.

5.7.5.1 The electronic data collection system shall be maintained in a secure location.

5.7.5.2 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).

5.7.5.3 Electronic data collection systems shall be protected from the introduction of external programs or software (e.g., viruses).

5.7.6 The Contractor shall designate archive storage areas for electronic data and the software required to access the data.

5.7.7 The Contractor shall designate an individual responsible for maintaining archives of electronic data, including the software.

5.7.8 The Contractor shall maintain the archives of electronic data and necessary software in a secure location that shall be accessible only to authorized personnel.

5.8 Complete Sample Delivery Group File Organization and Assembly

5.8.1 The Contractor shall designate a Document Control Officer responsible for the organization and assembly of the CSF.

5.8.2 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.

5.8.3 The Contractor shall maintain documents relating to the CSF in a secure location.

5.8.4 All original laboratory forms and copies of SDG-related logbook pages shall be included in the CSF.

5.8.5 Copies of laboratory documents in the CSF shall be photocopied in a manner to provide complete and legible replicates.

5.8.6 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;
- PE sample instructions
- Chromatograms;

- Analytical records;
- Reanalysis/Re-extraction records;
- TR/COCs;
- Sample tracking records;
- Raw data summaries;
- Computer printouts;
- Records of failed or attempted analysis;
- Correspondence;
- FAX originals; and
- Other.

5.8.7 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.

5.8.8 CSF documents shall be organized and assembled on an SDG-specific basis.

5.8.9 Original documents which include information relating to more than one SDG (e.g., TR/COCs, calibration logs) shall be filed in the CSF with 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

5.8.10 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.

5.8.11 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.

5.8.12 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.

5.8.13 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.

5.8.14 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.

5.8.15 Custody seals shall be signed and dated by the Document Control Officer or a designated representative when sealing deliverable packages.

EXHIBIT F

PROGRAMMATIC QUALITY ASSURANCE/QUALITY CONTROL ELEMENTS

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Exhibit F – Programmatic Quality Assurance/Quality Control Elements

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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 (EPA's) Contract Laboratory Program (CLP). This integrated program is required to generate data of known and documented quality. The QA process consists of management reviews 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.

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

2.0 INTRODUCTION

Appropriate use of data generated under the large range of analytical conditions encountered in environmental analyses requires reliance on the QC procedures and criteria incorporated into the methods. 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 effects of, corrective action procedures. The parameters used to estimate information content include precision, accuracy, and other quantitative and qualitative indicators.

This Exhibit describes the overall programmatic QA/QC operations and 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 EPA 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.

3.0 GENERAL QUALITY ASSURANCE/QUALITY CONTROL PRACTICES

The necessary components of a complete QA/QC program include internal QC criteria that demonstrate compliant levels of performance, as determined by the Contractors' QA review and external QC review of data and procedures that is accomplished by the monitoring activities of the EPA.

Each external review accomplishes a different purpose. External reviews may include: Proficiency Testing, contract compliance screening, on-site laboratory audits, data package audits, electronic data audits, and the EPA regional data review. A feedback loop provides the results of these various review functions to the Contractor through communications with the EPA.

4.0 PROFICIENCY TESTING PROGRAM

As a means of measuring and evaluating both the Contractor's and the method's analytical performance, the Contractor shall participate in the EPA's Proficiency Testing (PT) Program. The EPA's PT Program involves the analysis of Case-specific Performance Evaluation (PE) samples and PT audits. The Contractor's PE and PT audit sample results will be used by the EPA 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.

4.1 Performance Evaluation Samples

4.1.1 PE sample(s) may be scheduled with the Contractor as frequently as on a Sample Delivery Group (SDG)-by-SDG basis.

4.1.2 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 or the concentrations in the PE samples.

4.1.3 The Contractor may receive the PE samples as either full volume samples or ampulated/bottled concentrates from the EPA or a designated EPA 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 – Analytical Methods. All contract required QC shall also be met.

4.1.4 The PE sample results are to be submitted in the SDG deliverable package per normal reporting procedures detailed in Exhibit B – Reporting and Deliverables Requirements. If these requirements are not met, the Region may reject all the data associated with the SDG.

4.1.5 The Contractor shall be responsible for correctly identifying and quantitating the analytes included in each PE sample. When PE sample results are received by the EPA, 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. The EPA will notify the Contractor of unacceptable performance.

4.2 Proficiency Testing Audits

4.2.1 A PT audit is a unique analytical Case containing only PT audit samples. The PT audit samples will be scheduled by the EPA Analytical Services Branch (ASB) through the Sample Management Office (SMO). PT audit samples assist the EPA in monitoring Contractor performance.

4.2.2 PT audit samples will be provided as single-blinds (recognizable as a PT audit sample but of unknown composition). The Contractor will not be informed of either the analytes or the concentrations in the PT audit samples.

4.2.3 The Contractor may receive the PT audit samples as either full volume samples or ampulated/bottled concentrates from the EPA or a designated EPA Contractor. The PT audit samples shall come with instructions concerning the unique preparation procedures, if any, required to reconstitute the PT audit samples (i.e., the required dilution of the PT audit sample concentrate). The Contractor shall prepare and analyze the PT audit samples using the procedure described in the sample preparation and method analysis sections of Exhibit D – Analytical Methods. All contract required QC shall be met, including Laboratory Control Samples (LCS) and Laboratory Control Sample Duplicates (LCSD).

4.2.4 The PT audit sample results are to be submitted in the SDG deliverable package per normal reporting procedures detailed in Exhibit B – Reporting and Deliverables Requirements.

4.2.5 The Contractor shall be responsible for correctly identifying and quantitating the analytes included in each PT audit sample. When PT audit sample results are received by the EPA, the PT audit sample results will be scored for correct analytical identification, quantitation, and timeliness. The PT audit sample scoring will be provided to the Contractor via coded evaluation sheets, by analyte.

4.2.6 The EPA will notify the Contractor of unacceptable performance. The Contractor's overall and fractional PT audit sample performance will be assessed into one of the following three categories:

4.2.6.1 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.

4.2.6.2 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.

4.2.6.3 Unacceptable Performance, Response Explaining Deficiencies Required: Score less than 75%. Corrective action response required.

4.2.7 In the case of Section 4.2.6.2 or 4.2.6.3, the Contractor shall describe the deficiency(ies) and the action(s) taken in a corrective action letter to the EPA Contracting Officer (CO), the EPA Regional Laboratory Contracting Officer Representative (COR), and the ASB CLP COR, within 14 days of receipt of notification from the EPA.

4.2.8 A remedial PT audit is a unique analytical Case containing only PT audit samples. A remedial PT audit may be scheduled by the EPA ASB with the Contractor(s) for any of the following reasons: unacceptable PE sample performance, and/or major change in the laboratory (e.g., relocation, new owner, or high turnover of key personnel). The Contractor may not receive samples under this contract until acceptable performance of a remedial PT audit sample is achieved. Sections 4.2.2 through 4.2.7 apply to the remedial PT audit process.

4.2.9 The Contractor shall be notified by the EPA CO concerning agreement or disagreement with the proposed remedy for unacceptable performance.

5.0 CONTRACT COMPLIANCE SCREENING

5.1 Overview

5.1.1 Contract Compliance Screening (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 SDG File (CSF) delivered to the EPA.

5.1.2 CCS is performed by SMO at the direction of the EPA. To ensure 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. The EPA reserves the right to add and/or delete individual checks.

5.2 Contract Compliance Screening Results

CCS results are distributed to the Contractor and all other data recipients. The Contractor shall correct deficiencies and submit corrections within 6 business days. The Contractor shall send all corrections to the EPA Regional Laboratory COR and SMO. CCS results are used in conjunction with other information to measure overall Contractor performance and to take appropriate actions to correct deficiencies in performance.

5.3 Contract Compliance Screening Trend Report

The EPA 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 CCS Trend Report during an on-site laboratory audit. In a detailed letter to the EPA Regional Laboratory COR, the EPA ASB CLP COR, and the EPA 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.

6.0 ON-SITE LABORATORY AUDITS

6.1 Overview

The EPA Regional Laboratory COR, the EPA ASB CLP COR, or the EPA CO's authorized representative will conduct an on-site laboratory audit. On-site laboratory audits are performed to monitor the Contractor's ability to meet selected terms and conditions specified in the contract.

6.2 On-Site Audit

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 QC procedures. Auditors conduct on-site laboratory audits to evaluate if laboratory policies and procedures are in place to satisfy evidence handling requirements.

6.2.1 The items to be monitored during an on-site audit may include, but not be limited to, the following:

- Size and appearance (e.g., cleanliness, organization) of the facility;
- Quantity, age, availability, scheduled maintenance, and performance of instrumentation;
- Availability, review, appropriateness, and utilization of the Quality Assurance Project Plan (QAPP) and Standard Operating Procedures (SOPs);
- Staff qualifications, experience, and personnel training programs;
- Analysis of PE samples (may be in the presence of the EPA-designated team);
- Reagents, standards, and sample storage facilities;
- All logbooks (e.g., extraction logs, standards and reagent preparation logs, analysis logs, instrument maintenance logs);
- All raw analytical data; and
- Review of the Contractor's sample analysis, data package assembly, inspection, completion, and data management procedures.

6.2.2 Prior to an on-site audit, various documentation pertaining to performance of the Contractor is reviewed by the audit team and may be discussed during the audit. Items that may be discussed include, but not limited to, the following:

- Previous on-site audit reports;
- PE or PT audit sample scores;
- EPA Regional review of data;
- Contractor performance information;
- Data and Electronic audit reports;
- Results of CCS; and
- Data trend reports.

6.3 Discussion of the On-Site Audit Findings

The auditors shall present their findings and recommendations for corrective actions necessary to the Contractor personnel during a debriefing meeting at the conclusion of the audit. A report which discusses deficiencies found during the on-site audit will be sent to the Contractor to provide further clarification of findings.

6.3.1 In a detailed letter to the EPA Regional Laboratory COR, the EPA ASB CLP COR, and the EPA CO, 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.

7.0 DATA PACKAGE AUDITS

7.1 Overview

Audits provide the EPA with an in-depth inspection and evaluation of the Case data package with regard to achieving QA/QC acceptability. Data package audits enable the EPA to evaluate the implementation, precision, and accuracy of the analytical methods. The audits are performed by the EPA to support the following activities:

- Program overview;
- Contractual requirements and data consistency;
- Identification/Investigation of data quality problems;
- Support for on-site laboratory audits; and
- Specific EPA Regional requests.

7.2 Required Information

Data packages are periodically selected from recently received Cases and evaluated for the technical quality of hardcopy raw data, QA, and the adherence to contractual requirements. A thorough review of the raw data is completed, including all instrument readouts used for the sample results, instrument printouts, and other documentation for deviations from the contractual requirements; a check for transcription and calculation errors; a review of the qualifications of the laboratory personnel involved with the Case; and a review of the latest version of all SOPs on file. This function provides external monitoring of program QC requirements. Data package audits are used to assess the technical quality of the data and evaluate overall laboratory performance.

7.3 Submission Request

The data package from a recent Case, a specific Case or a PE sample may be requested. Upon request from the EPA Regional Laboratory COR, the EPA ASB CLP COR, or the EPA CO, the Contractor shall send the required data package and all necessary documentation to the EPA designated recipient within 7 days of notification in accordance with Exhibit B – Reporting and Deliverables Requirements, Table 1 – Deliverable Schedule.

7.4 Response to the Data Package Audit Report

After completion of the data package audit, the EPA shall make the data package audit report available to the Contractor. In a detailed letter to the designated recipients, 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.

8.0 ELECTRONIC DATA AUDITS

8.1 Overview

Audits provide the EPA with an in-depth inspection and evaluation of the electronic data with regard to achieving QA/QC acceptability. Electronic data audits enable the EPA to evaluate the implementation, precision, and accuracy of the analytical methods. The audits are performed by the EPA to support the following activities:

- Program overview;
- Contractual requirements and data consistency;
- Identification/Investigation of data quality problems;
- Support for on-site laboratory audits; and
- Specific EPA Regional requests.

8.2 Required Information

Data packages are periodically selected from recently received Cases and evaluated for the technical quality of hardcopy raw data, QA, and the adherence to contractual requirements. A thorough review of the raw data is completed, including all instrument readouts used for the sample results, instrument printouts, and other documentation for deviations from the contractual requirements; a check for transcription and calculation errors; a review of the qualifications of the laboratory personnel involved with the Case; and a review of the latest version of all SOPs on file. This function provides external monitoring of program QC requirements. Electronic data audits are used to assess the technical quality of the data and evaluate overall laboratory performance.

8.2.1 The Contractor shall store all raw and processed analytical data in appropriate instrument manufacturer's proprietary software format uncompressed and with no security codes. This data shall include all necessary data files for a complete reconstruction of the previously submitted hardcopy and electronic deliverable data package. The Contractor is required to retain the instrument electronic data for 3 years after submission of the reconciled CSF.

8.2.2 All associated raw data files in the instrument manufacturer proprietary software format must be submitted if those files contain data or instrumental parameters regarding any analysis and or correction applied to an instrument or analytical result. This electronic data shall include data for all samples, blanks, Laboratory Control Samples/Laboratory Control Samples Duplicates (LCSs/LCSDs), and all instrument QC, as applicable, initial calibrations/verifications, and continuing calibration verifications.

8.2.3 The Contractor shall maintain a written reference logbook of data files of the EPA Sample Number, calibration data, standards, LCSs/LCSDs, and blanks. The logbook shall include the EPA Sample Numbers and standard and blank IDs, identified by Case.

8.2.4 The Contractor shall supply upon request raw data for the Method Detection Limit (MDL) studies which are used to set the MDL values for the SDG.

8.2.5 Electronic data shipped to the EPA-designated recipient must be fully usable by the recipient. When submitting instrument electronic data to the EPA, the following materials shall be delivered in response to the request:

8.2.5.1 All associated raw data files for all analytical samples, calibration and QC data.

8.2.5.2 All processed data files and quantitation output files associated with the raw data files described in Section 8.2.5.1.

8.2.5.3 All associated identification and calculation files used to generate the data submitted in the data package. This includes, but is not limited to, result files, acquisition files, calibration files, and method files.

8.2.5.4 References relating data files to EPA Sample Numbers, calibration data, standards, blanks, and LCSs/LCSDs. The logbook shall include the EPA Sample Numbers and Lab File Identifiers for all samples, blanks, and standards, identified by Case and SDG.

8.2.5.5 A printout of the directory of all files in each directory, including all subdirectories and the files contained therein.

8.2.5.6 A copy of the CSF, if an audit request is made within the period during which the Contractor must retain a copy.

8.2.5.7 A statement attesting to the completeness of the instrument electronic data submission, signed and dated by the Contractor's Laboratory Manager or Manager's designee. 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 file submission:

- Contractor name;
- Date of submission;
- Case Number;
- SDG Number;
- Instrument manufacturer and model number;
- Instrument operating software and version number;
- Data system computer;
- System operating software;
- Data system network;
- Data backup software/service;
- 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.

8.3 Submission of Request

The instrument electronic data from a recent Case, a specific Case, or a PE sample may be requested. Upon request from the EPA Regional Laboratory COR, the EPA ASB CLP COR, or the EPA CO, the Contractor shall send the required instrument electronic data and all necessary documentation to the EPA designated recipient within 7 days of notification in accordance with Exhibit B – Reporting and Deliverables Requirements, Table 1 – Deliverable Schedule.

8.4 Response to the Electronic Data Audit Report

After completion of the electronic data audit, the EPA will make the electronic data audit report available to the Contractor. In a detailed letter to the designated recipients, the Contractor shall discuss the corrective actions implemented to resolve the deficiencies listed in the electronic data audit report within 14 days of receipt of the report.

9.0 REGIONAL DATA REVIEW

9.1 Overview

Contractor data are generated to meet the specific needs of the EPA Regions. In order to verify the usability of data for the intended purpose, each EPA Region reviews data from the perspective of the end user, based on functional guidelines for data review, which have been developed jointly by the Regions and the EPA ASB. Each EPA Region uses the guidelines as the basis for data evaluation. Individual EPA Regions may augment the basic guideline review process with additional review based on the EPA Region-specific or site-specific concerns. The EPA Regional reviews, like the sites under investigation, vary based on the nature of the problem under investigation and the EPA Regional response appropriate to the specific circumstances.

The EPA Regional data reviews, relating usability of the data to a specific site, are part of the collective assessment process. They complement the review done by SMO, which is designed to identify contractual discrepancies, and the review done by the EPA ASB, which is designed to evaluate Contractor and method performance.

9.2 Submission Request

As part of the CLP contractual requirements, CLP laboratories shall deliver their CSF for each SDG to the EPA Region where the samples have been collected. The EPA Regional recipients are identified at the time of scheduling. The data shall be shipped in accordance to the procedures described in Exhibit B – Reporting and Deliverables Requirements of this Statement of Work (SOW). The EPA Regions use the hardcopy data to perform their data review. The EPA Region may contact the laboratory after they initiate or complete their review requesting additional information or clarification. The Contractor shall respond to the request within 5 business days.

10.0 TABLES

TABLE 1. Contract Laboratory Program Quality Assurance Monitoring Plan

SOW Reference	Performance Requirements	Performance Standards	QA Monitoring Plan
Exhibit A: Summary of Requirements	Summary of Program Requirements	Performance standards are summarized in Exhibit A, Sections 1.0 through 4.0.	QA monitoring plan is outlined in Exhibit F.
Exhibit B: Reporting and Deliverables Requirements	Reporting and Deliverable Requirements	Performance standards are outlined in Exhibit B, Sections 1.0 through 4.0.	CCS in Exhibit F, Section 5.0, and SMO data review will be used to monitor reporting electronic deliverables.
Exhibit C: Chlorinated Dibenzo-*p*-Dioxins and Chlorinated Dibenzofurans and Chlorinated Biphenyl Congeners Target Analyte List and Contract Required Quantitation Limits	Target Analyte List and Contract Required Quantitation Limits	Performance standards are outlined in Exhibit C.	QA monitoring plan is outlined in Exhibit F.
Exhibit D: Chlorinated Dibenzo-*p*-Dioxins and Chlorinated Dibenzofurans and Chlorinated Biphenyl Congeners Analytical Methods	CDDs and CDFs requirements are outlined in Exhibit D, Sections 1.0 through 8.0, 14.0, and 15.0.	Performance standards are outlined in Exhibit D, Sections 9.0 through 12.0.	QA monitoring plan is outlined in Exhibit D, Section 12.0, and Exhibit F.
	CBCs requirements are outlined in Exhibit D, Sections 1.0 through 8.0, 14.0, and 15.0.	Performance standards are outlined in Exhibit D, Sections 9.0 through 12.0.	QA monitoring plan is outlined in Exhibit D, Section 12.0, and Exhibit F.

SOW Reference	Performance Requirements	Performance Standards	QA Monitoring Plan
Exhibit E: Quality Systems	General QA/QC Requirements	As outlined in each Exhibit D, Section 12.0.	QA Management Plan is outlined in Exhibit E, Section 2.0.
	Quality Assurance Project Plan	As outlined in Exhibit E, Section 3.0, a written QAPP shall be used to ensure acceptable data production of known and documented quality.	The EPA will review and approve the QAPP after contract award and throughout the contract term as needed. *[The Quality Management Plan (QMP) will be reviewed and approved by the EPA pre contract award.]*
	Standard Operating Procedures	Performance standards are outlined in Exhibit E, Section 4.0, and must be performed as stated.	SOPs will be reviewed by the EPA during on-site audits, after modifications are made, and randomly, as deemed appropriate.
	Data Management	Performance standards are outlined in Exhibit E, Section 4.3.12.	The EPA will monitor data management practices during quality assurance and evidentiary on-site audits.
Exhibit F: Programmatic Quality Assurance/ Quality Control Elements	Proficiency Audit Testing	Performance standards are outlined in Exhibit F, Section 4.0, and must be performed as stated.	Acceptable PT audit scores will assist in monitoring Contractor performance as defined in Exhibit F, Section 4.2.5.
	Contract Compliance Screening	Performance standards are outlined in the IFB and must be performed as stated.	CSF will be evaluated against the technical and completeness requirements of the contract.
	On-Site Laboratory Audits	Performance standards are outlined in Exhibit F, Section 6.2.	The EPA will evaluate the results from quality assurance and evidentiary on-site audits as defined in Exhibit F, Section 6.3, to assist in monitoring the Contractor.

SOW Reference	Performance Requirements	Performance Standards	QA Monitoring Plan
Exhibit F: Programmatic Quality Assurance/ Quality Control Elements (Cont'd)	Data Package Audits	Performance standards are outlined in Exhibit F, Section 7.0.	Data package audits are performed by the EPA to evaluate technical quality of the hardcopy raw data, QA, and adherence to contractual requirements.
	Electronic Data Evaluation and Audits	Performance standards are outlined in Exhibit F, Section 8.0.	The EPA uses Exhibit F, Section 8.0, to monitor laboratory electronic deliverables.
	Regional Data Review	Analytical data is reviewed by each Region from the perspective of the end user to determine the usability of the data, as outlined in Exhibit F, Section 9.0.	The EPA Regional validation and/or SMO data review reports are generated for all data packages.
Exhibit G: Glossary of Terms	Glossary of Terms	Contractors shall adhere to interpretation of SOW terms as defined within Exhibit G.	N/A
Exhibit H: Format for Electronic Data Deliverables	Data Dictionary and Format	Performance standards are outlined in Exhibit H.	CCS in Exhibit F, Section 5.0, will be used to monitor electronic deliverables.

EXHIBIT G

GLOSSARY OF TERMS

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ALIQUOT – A measured portion of a field sample, standard, 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).

ANALYTE - The specific compound an analysis seeks to determine.

ANALYTICAL METHOD - Specifies the procedures for sample preparation, instrument calibration, sample analysis, and result calculations.

ANALYTICAL REFERENCE STANDARD – Standards purchased from private chemical supply companies used to prepare calibration standards and Continuing Calibration Verification (CCV) standards.

ANALYTICAL SAMPLE - Any solution or media introduced into an instrument on which an analysis is performed; excluding instrument calibration, Continuing Calibration Verification (CCV), and tunes. Note the following are all defined as analytical samples: undiluted and diluted samples (EPA and non-EPA), Laboratory Control Samples (LCSs), LCS Duplicates (LCSDs), Performance Evaluation (PE) samples, and Preparation Blanks.

ANALYTICAL SEQUENCE – The actual instrumental analysis of the samples, from the time of instrument calibration through the analysis of the final sample. All sample analyses during the analytical sequence are subject to the Quality Control (QC) protocols set forth in Exhibit D – Analytical Methods and Exhibit F – Programmatic Quality Assurance/Quality Control Elements of the contract, unless otherwise specified in the individual methods.

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

ASTM/ASTM INTERNATIONAL - A developer and provider of voluntary consensus standards.

BATCH – A group of samples prepared at the same time in the same location using the same method.

BLANK - An analytical sample that has negligible or unmeasurable amounts of a substance of interest. The blank is designed to assess specific sources of contamination. Types of blanks may include calibration blanks, instrument blanks, method blanks, and field blanks. See the individual definitions for types of blanks.

CALIBRATION - A set of operations that establish under specific conditions, the relationship between values indicated by a measuring instrument and the corresponding known values.

CALIBRATION STANDARDS - A series of known standard solutions used by the analyst for calibration of the instrument (i.e., preparation of the analytical curve). The solutions may or may not be subjected to the preparation method but contain the same matrix (i.e., the same amount of reagents and/or preservatives) as the sample preparations to be analyzed.

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).

CHLORINATED BIPHENYL CONGENER (CBC) - One of the 209 individual chlorinated biphenyl congeners determined using this Method. The 209 CBCs are listed in Exhibit C – Chlorinated Dibenzo-*p*-Dioxins and Chlorinated Dibenzofurans and Chlorinated Biphenyl Congeners Target Analyte List and Contract Required Quantitation Limits.

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.

CLEANUP STANDARD - A standard containing either $^{37}Cl_4$-2,3,7,8-TCDD or PCB-28L, PCB-111L, and PCB-178L that is added to all extracts prior to cleanup. The purpose of this standard is to measure the efficiency of the cleanup process.

CLOSING CONTINUING CALIBRATION VERIFICATION - Last analytical standard analyzed every 12 hours to verify the initial calibration accuracy of the system.

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.

CONTINUING CALIBRATION VERIFICATION (CCV) – A single parameter or multi-parameter standard solution prepared by the analyst and used to verify the stability of the instrument calibration with time, and the instrument performance during the analysis of samples. The CCV can be one of the calibration standards.

CONTRACT COMPLIANCE SCREENING (CCS) – A screening of electronic and hardcopy data deliverables for completeness and compliance with the contract. This screening is done under EPA direction by the SMO Contractor.

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

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

CONTROL LIMITS - A range within which specified measurement results must fall to be compliant. Control limits may be mandatory, requiring corrective action if exceeded, or advisory, requiring that noncompliant data be flagged.

DATE - The date format for all reporting forms is MM/DD/YYYY - Where MM = 01 for January, 02 for February, ... 12 for December; DD = 01 to 31; YYYY = 2012, 2013, 2014, etc.

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

DRY WEIGHT – The weight of a sample based on percent solids. The weight after drying in an oven.

EPA ASB HIGH RESOLUTION CLP CONTRACTING OFFICER REPRESENTATIVE (ASB CLP COR) - The EPA ASB official who manages the High Resolution CLP Program.

EPA CONTRACTING OFFICER (CO) - The EPA official who has the authority to enter into, administer, terminate contracts, and/or make related determinations and findings.

EPA REGIONAL CLP LEAD - The Regional EPA official responsible for monitoring laboratory performance and/or requesting analytical data or services from a CLP laboratory.

EPA REGIONAL LABORATORY CONTRACTING OFFICER REPRESENTATIVE (REGIONAL LABORATORY COR) – The EPA official who monitors assigned CLP laboratories (either inside or outside of the Regional Laboratory COR's respective Region), responds to and identifies problems in laboratory operations, and participants in on-site laboratory programs.

EPA SAMPLE NUMBER - A unique identification number designated by the EPA for each sample. The EPA Sample Number appears on the Sample Traffic Report/Chain of Custody Record which documents information on that sample.

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

ESTIMATED MAXIMUM POSSIBLE CONCENTRATION (EMPC) - The EMPC is calculated for analytes for which the quantitation and/or confirmation ion(s) has signal to noise in excess of 3, but does not meet all 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 identified as a blank. A field blank is used to check for cross-contamination during sample collection, sample shipment, and in the laboratory. A field blank includes trip blanks, rinsate blanks, bottle blanks, equipment blanks, preservative blanks, decontamination 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 received to be analyzed that is contained in single or multiple containers and identified by a unique EPA Sample Number.

FORM – A hardcopy and/or electronic information/data entry sheet with locked preformatted structure that guides and/or controls user entry/input.

GAS CHROMATOGRAPH (GC) – The instrument used to separate analytes on a stationary phase within a chromatographic column.

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 – Contractual holding time is the elapsed time expressed in days from the date of receipt of the sample by the Contractor until the date of its extraction and analysis.

> Holding time = (sample extraction date or analysis date - sample receipt date)

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

HYDROMATRIX™ - Diatomaceous earth-based material that is capable of adsorbing and retaining up to twice its weight of an aqueous media.

INDEPENDENT STANDARD – A Contractor-prepared standard solution that is composed of analytes from a different source than those used in the standards for the calibration.

IN-HOUSE - At the Contractor’s facility.

INITIAL CALIBRATION - Analysis of analytical standards for a series of different concentrations; used to define the quantitative response, linearity, and dynamic range of the instrument to target analytes.

INJECTION – Introduction of the analytical samples into the instrument excitation system to measure concentration of an analyte.

INSTRUMENT BLANK – A blank designed to determine the level of contamination associated with the analytical instruments.

INTEGRATION SCAN RANGE - 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.

INTERFERANTS - Substances which affect the analysis for the element of interest.

INTERNAL STANDARD – For chlorinated biphenyl congeners (CBC), a labeled compound used as a reference for quantitation of other labeled compounds and for quantitation of native CBCs other than the congener of which it is a labeled analogue. For chlorinated dibenzo-*p*-dioxin/chlorinated dibenzofuran (CDD/CDF), $^{13}C_{12}$-1,2,3,4-TCDD and $^{13}C_{12}$-1,2,3,7,8,9-HxCDD. The internal standards are added to every blank, Quality Control (QC) sample, and sample extract aliquot just prior to analysis.

INTERNAL STANDARD QUANTITATION - A means of determining the concentration of: (1) a naturally occurring (native) analyte by reference to a compound other than its labeled analogue; and (2) a labeled compound by reference to another labeled compound.

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.

ISOTOPE DILUTION QUANTITATION - A means of determining a naturally occurring (native) analyte by reference to the same compound in which one or more atoms has been isotopically enriched.

K-D - Kuderna-Danish concentrator; a device used to concentrate the analytes in a solvent.

LABELED COMPOUNDS – Isotopically-labeled compounds that are added to every sample and are present at the same concentration in every blank, LCS, LCSDs, sample, and calibration solution. The labeled compounds 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) - A matrix spiked at a known concentration. LCSs are analyzed using the same sample preparation, reagents, and analytical methods employed for the EPA samples received.

LABORATORY CONTROL SAMPLE DUPLICATE (LCSD) – A second LCS prepared and analyzed to measure laboratory precision.

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. Also referred to as Validated Time of Sample Receipt (VTSR).

MASS RESOLUTION – A measure of the ability of the mass spectrometer to distinguish the mass-to-charge ratios (m/z) of two mass fragments from one another. For a single peak made up of singly charged ions at mass m in a mass spectrum, the resolution may be expressed as $m/\Delta m$ where Δm is the width of the peak at a height which is a specified fraction of the maximum peak height. In reference methods for this Statement of Work (SOW), the value 5% is always used. For an isolated symmetrical peak recorded with a system which is linear in the range between 5% and 10% levels of the peak, the 5% peak width definition is technically equivalent to the 10% valley definition. Using this definition, a resolution of 10,000 means that $m/\Delta m = 10{,}000$. For example, using only singly charged mass fragments, the mass fragment of TCDD at 319.8965 can be distinguished from one at mass 319.9285 and from one at mass 319.8645 (+/- 0.032 amu).

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 aqueous/water, soil/sediment, or a wipe. Matrix is <u>not</u> synonymous with phase (liquid or solid).

MATRIX EFFECT - The enhancement or suppression of minor element spectral lines due to a particular matrix constituent.

METHOD BLANK - An aliquot of reagent water, silica sand, or corn oil that is treated exactly as a sample including exposure to all glassware, equipment, solvents, reagents, internal standards, and surrogates that are used with samples. The Method Blank is used to determine if analytes or interferences are present in the laboratory environment, the reagents, or the apparatus.

METHOD DETECTION LIMIT (MDL) - The concentration of a target parameter that, when a sample is processed through the complete method, produces a signal with 99 percent probability that it is different from the blank. For 7 replicates of the sample, the mean value must be 3.14s above the blank, where "s" is the standard deviation of the 7 replicates.

m/z – Mass to Charge ratio; synonymous with m/e.

OPENING CONTINUING CALIBRATION VERIFICATION - First analytical standard analyzed every 12 hours to verify the initial calibration of the system.

PERCENT DIFFERENCE (%D) - The difference between the two values divided by one of the values multiplied by 100.

PERCENT RECOVERY (%R) – The percentage of an analyte or compound added to a sample that is recovered.

PERCENT SOLIDS (%S) - The proportion of solid in a soil/sediment sample determined by drying an aliquot of the sample.

PERFLUOROKEROSENE (PFK) - A tune or reference compound used to calibrate the exact m/z scale in the High Resolution Mass Spectrometer (HRMS).

PERFORMANCE EVALUATION (PE) SAMPLE - A sample of known composition to the EPA; however, unknown to the Contractor, that is provided to evaluate Contractor performance.

PREPARATION BLANK - See Method Blank.

PREPARATION LOG – An official record of the sample preparation.

PROFICIENCY TESTING (PT) AUDIT SAMPLE – A sample of known composition provided by the EPA for Contractor analysis. Used by the EPA to evaluate Contractor performance on a program-wide basis.

QUALITY ASSURANCE TECHNICAL SUPPORT (QATS) LABORATORY – A Contractor-operated facility operated under the QATS contract, awarded and administered by the EPA.

RAW DATA - The originally recorded and unprocessed measurements from any measuring device such as analytical instruments, balances, pipettes, thermometers, etc.

REAGENT WATER - The purity of this water must be equivalent to ASTM Type II reagent water of Specification D1193-06, "Standard Specification for Reagent Water".

RELATIVE PERCENT DIFFERENCE (RPD) - The relative percent difference 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 analyte compared to its labeled compound analog. RRs are determined using the area responses of both the primary and secondary exact m/z 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 for each compound in each calibration standard.

RELATIVE RETENTION TIME (RRT) - The ratio of the retention time of a compound to that of a standard (such as an internal standard).

REPORTED DATA – Reported data are processed from the raw measurement values that may have been reformatted from the original measurement to meet specific reporting requirements, such as significant figures and decimal precision.

RESOLUTION – Also termed Separation or Percent Resolution, the separation between peaks on a chromatogram, calculated by dividing the depth of the valley between the peaks by the peak height of the smaller peak being resolved, multiplied by 100.

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 analyte's retention time falling within the specified retention time window established for that analyte. The RT is dependent on the nature of the column's stationary phase, column diameter, temperature, flow rate, and other parameters.

ROUNDING RULES – If the figure following those to be retained is greater than or equal to 5, round up, otherwise round down. As an example, 11.443 is rounded down to 11 and 11.5 is rounded up to 12. If a series of multiple operations is to be performed (add, subtract, divide, multiply), all figures are carried through the calculations. Then the final answer is rounded to the proper number of significant figures. See specific form instructions (Exhibit B – Reporting and Deliverables Requirements) for exceptions.

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 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).
- All samples scheduled with the same level of deliverables.
- In addition, all samples assigned to an SDG must have been scheduled under the same contractual turnaround time.

Samples may be assigned to SDGs by matrix (i.e., all soil/sediment samples in one SDG, all aqueous/water samples in another) at the discretion of the laboratory. Laboratories shall take all precautions to meet the 20 sample per SDG criteria.

SAMPLE MANAGEMENT OFFICE (SMO) – A Contractor-operated facility operated under the SMO contract, awarded and administered by the EPA.

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 – Reporting and Deliverables Requirements.

SELECTED ION CURRENT PROFILE (SICP) - The line described by the signal at an exact m/z.

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 RATIO (S/N) - The height of the signal as measured from the mean (average) of the noise to the peak maximum divided by the width of the noise.

SOIL - Synonymous with soil/sediment, sediment, and sludge as used herein.

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

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.

STOCK SOLUTION - A standard solution which can be diluted to derive other standards.

SUPPORTING DATA – Any data that substantiates the Reported Data (see definition above), including initial instrument measurements, instrument result calculations, standards concentrations, standard concentration calculations, sample preparation data (e.g., initial/final sample volume measurements, reagent quantities, etc.), MDLs, and IECs. Supporting Data include standard preparation logs, sample preparation logs, instrument analysis logs, MDL and IEC studies, balance logs, pipette logs, percent solids logs, etc.

TARGET ANALYTE LIST - A list of analytes as designated by the Statement of Work (SOW) for analysis. See Exhibit C - Chlorinated Dibenzo-*p*-Dioxins and Chlorinated Dibenzofurans and Chlorinated Biphenyl Congeners Target Analyte List and Contract Required Quantitation Limits.

TOTAL TOXIC EQUIVALENT – The sum of the Toxic Equivalents (TEQs) of all individual WHO toxic CBCs or each individual 2,3,7,8-substituted dibenzo-*p*-dioxin and dibenzofuran.

TOXIC EQUIVALENCY FACTOR (TEF) - An estimate of the toxicity of a specific congener relative to 2,3,7,8-tetrachlorodibenzo-*p*-dioxin.

TOXIC EQUIVALENT (TEQ) - The product of the concentration of each individual WHO toxic CBC or each individual 2,3,7,8-substituted dibenzo-*p*-dioxin and dibenzofuran multiplied by their respective TEFs.

TIME - hh:mm:ss - When required to record time on any deliverable item, time shall be expressed as Military Time [i.e., a 24-hour clock (0000-2359)].

TRAFFIC REPORT/CHAIN OF CUSTODY RECORD (TR/COC) – An EPA sample identification form completed by the sampler, which 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.

TWELVE-HOUR TIME PERIOD - For chlorinated dibenzo-*p*-dioxin and chlorinated dibenzofuran (CDD/CDF) 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.

UNIQUE GC RESOLUTION or UNIQUELY RESOLVED - Two adjacent chromatographic peaks in which the height of the valley is less than 40 percent of the height of the shorter peak (See Exhibit D – Analytical Methods, for unique resolution specific to the SPB-octyl column).

VALIDATED TIME OF SAMPLE RECEIPT (VTSR) - 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.

WET WEIGHT - The weight of a sample aliquot including moisture (undried).

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 congeners and evaluate descriptor switching times.

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EXHIBIT H

FORMAT FOR ELECTRONIC DATA DELIVERABLES

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Table of Contents

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1.0 INTRODUCTION

The high-resolution gas chromatography/high-resolution mass spectrometry (HRGC/HRMS) analytical service provides analytical data for use by the U.S. Environmental Protection Agency (EPA), in support of the investigation and clean-up activities under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) and the Superfund Amendments and Reauthorization Act of 1986 (SARA). The electronic data deliverable (EDD) requirements in this section are designed to allow the EPA and other federal agencies or programs to rapidly assess the accuracy, completeness, and usefulness of the analytical results and the data.

2.0 FORMAT CHARACTERISTICS

2.1 This constitutes an implementation of the Staged Electronic Data Deliverable (SEDD) based on analytical results and other associated 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/fem/seddspec52.htm

2.1.1 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.

2.1.2 The Contractor shall create the deliverable using the UTF-8 (Unicode Transformation Format - 8 bit) character set.

2.1.3 The initial line of the deliverable shall be: <?xml version="1.0" encoding="UTF-8"?>.

2.1.4 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.

2.1.5 The use of XML comment lines is permitted at any position in the file after the first two lines.

2.2 This implementation includes detailed specifications for the required format of the content of each data element for each analytical method. 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 3.0 describes the requirements for each data element.

2.2.1 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.

2.2.2 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.

2.2.3 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) Record. The Laboratory Code, Case Number, Contract Number, Sample Delivery Group (SDG) Number, Modified Analysis (MA) Number (if applicable), sample number, and analytical method shall be identical in the EDD and the TR/COC Record and the SDG coversheet submitted by the Contractor for the SDG.

2.2.4 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.

3.0 DATA ELEMENTS

3.1 The 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 DTD against which the deliverable will be validated (see Exhibit H, Section 6.0). The frequency requirements for each of the data nodes applicable to this implementation are described below.

3.1.1 Header Node

One Header node must be reported for each analytical method.

3.1.2 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, Proficiency Testing (PT) audit sample, method blank, instrument blank, Laboratory Control Sample (LCS), LCS Duplicate (LCSD), and non-client sample.

3.1.3 ReportedResult Node

Each SamplePlusMethod node must contain one and only one ReportedResult node for each target analyte.

3.1.4 Contact Information Node

Each Header node must contain one ContactInformation node.

3.1.5 Analysis Node

Each SamplePlusMethod node must contain at least one Analysis node. A separate Analysis node is required for each dilution, reanalysis, reextraction, or confirmation.

3.1.6 Analyte Node

Each Analysis node under the initial analysis under a SamplePlusMethod node must contain one Analyte node for each target analyte (excluding Homologues, TEQs, and total results), labeled compound, cleanup standard compound, and internal standard. Analysis nodes for dilutions and reanalyses must contain one Analyte node for each analyte/compound being monitored.

3.1.7 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.

3.1.8 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.

3.1.9 AnalyteGroup Node

Each Analysis node must contain one AnalyteGroup Node for each Homologue, TEQ, and total result. Do not report OCDD and OCDF as Homologues for CDD/CDF analysis, or decachlorobiphenyl as Homologue for CBC analysis.

3.2 Detailed instructions for the content of each data element are provided in Section 7.0, Table 1 – High Resolution Superfund Methods Data Element Instructions. The following is an explanation of the data fields in the table.

3.2.1 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.

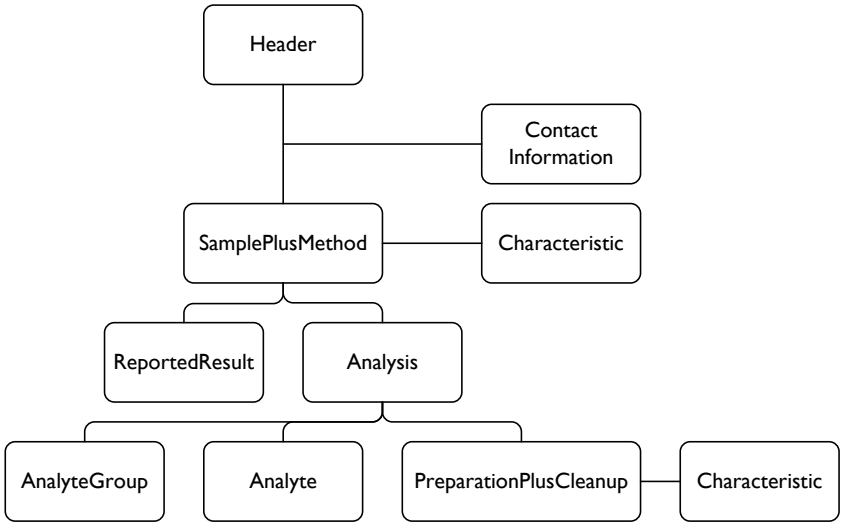
3.2.2 Applicability

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 Section 7.0, Table 2 - Abbreviations.

3.2.3 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 Section 7.0, Table 2 - Abbreviations.

Figure 1: Data Node Hierarchy for
Level 2a Deliverable



4.0 BATCHES

4.1 This implementation requires the use of the following batches from the SEDD Specification: "LabReportingBatch"; "PreparationBatch"; and "CleanBatch".

4.1.1 The "LabReportingBatch" links all samples reported in the same SDG. Report the SDG Number.

4.1.2 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 LCS/LCSD that are prepared together must have the same content for the "PreparationBatch" element.

4.1.3 The "CleanBatch" links all samples processed through a cleanup procedure at the same time. All samples analyzed, including method blanks, and LCS/LCSD must have the same content for the "CleanupBatch" element.

5.0 DELIVERABLE

5.1 Each analytical method in an SDG shall be submitted as a separate file. The Contractor may choose to deliver their file as a ZIP of an XML file. For reporting requirements, the analytical methods are: Dioxin and CBCs. All analytical methods within an SDG shall be submitted at the same time (i.e., the file for the second analytical method in an SDG shall be submitted in a single file upload with the first analytical method).

5.2 The Contractor will utilize the Electronic Data Exchange and Evaluation System (EXES) at http://epasmoweb.fedcsc.com to electronically submit their EDD to the Sample Management Office (SMO). The EPA may approve alternative electronic means of file delivery. Written permission must be obtained from the EPA Analytical Services Branch (ASB) prior to the use of any alternative means.

5.3 The Contractor must follow the delivery instructions in Exhibit B - Reporting and Deliverables Requirements, of this Statement of Work (SOW), and deliver their hardcopy and EDD and Portable Document Format (PDF) of the Complete SDG File (CSF) 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.

5.4 Information in the electronic deliverable must correspond to information submitted in the hardcopy raw data package and on 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 EPA.

5.5 The format for the file name shall be Case number_SDG number_contract number_submission number_DTD used_Method. For example, the first submission of the CBC Analytical Method from 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_CBC.zip.

6.0 DOCUMENT TYPE DEFINITION

6.1 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.

6.2 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|
          ClientAnalysisID|
```

```
                ClientMethodCode|
                ClientMethodID|
                ClientMethodModificationDescription|
                ClientMethodModificationID|
                ClientMethodName|
                ClientMethodSource|
                ClientMethodVersion|
                Column|
                ColumnInternalDiameter|
                ColumnInternalDiameterUnits|
                ColumnLength|
                ColumnLengthUnits|
                Comment|
                ConfirmationAnalysisID|
                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|
                CASRegistryNumber|
                ClientAnalyteID|
                ClientAnalyteName|
                Comment|
                DetectionLimit|
                DetectionLimitType|
                DetectionLimitUnits|
                DifferenceErrorRatio|
                Efficiency|
                ExpectedResult|
                ExpectedResultUnits|
                Inclusion|
                LabAnalyteID|
                LabQualifiers|
                LotNumber|
                PeakID|
                PercentRecovery|
                PercentRecoveryLimitHigh|
                PercentRecoveryLimitLow|
                PercentRecoveryLimitType|
                PercentRecoveryType|
                QuantitationLimit|
                QuantitationLimitType|
                QuantitationLimitUnits|
                ReportingLimit|
                ReportingLimitType|
                ReportingLimitUnits|
                Result|
                ResultLimitHigh|
                ResultLimitLow|
                ResultLimitType|
                ResultType|
                ResultUncertainty|
                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|
          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|
                CASRegistryNumber|
                ClientAnalyteID|
                ClientAnalyteName|
                ClientDetectionLimit|
                ClientDetectionLimitUnits|
                ClientQuantitationLimit|
                ClientQuantitationLimitUnits|
                Comment|
                DetectionLimit|
                DetectionLimitType|
                DetectionLimitUnits|
                DifferenceErrorRatio|
                ExpectedResult|
                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|
          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|
          MethodModificationDescription|
          MethodModificationID|
```

```
                MethodName|
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                MethodType|
                MethodVersion|
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                Preservative|
                ProjectID|
                ProjectName|
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                QCLinkage|
                QCType|
                Quarantine|
                SamplingBatch|
                ShippingBatch|
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                ReportedResult|
                Handling|
                AnalysisGroup
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7.0 DATA ELEMENT INSTRUCTION TABLES

Column abbreviations: Laboratory Control Sample (LCS), Laboratory Control Sample Duplicate (LCSD), Method Blank (MB), Instrument Blank (IB), and Non-Client Sample (NCS).

7.1 Specification 5.2 Stage 2a

TABLE 1. HIGH RESOLUTION SUPERFUND METHODS DATA ELEMENT INSTRUCTIONS

	Applicability				
Node and Data Elements	Sample	LCS/LCSD	MB/IB	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 MMDDYYYYThh: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 the name of generating software or vendor.
GeneratingSystemVersion	X	X	X	X	Report the software version number.
LabContract	X	X	X	X	Report the Contract Number.
LabContractModificationDescription					Not required.
LabContractModificationID					Not required.
LabDataPackageID	X	X	X	X	Report the SDG.
LabDataPackageName	X	X	X	X	Report "Dioxin" or "CB_Congeners".
LabDataPackageVersion	X	X	X	X	Report "1", then increment with each resubmission.
LabID	X	X	X		Report the Agency-assigned Lab Code.
LabName	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.

TABLE 1. HIGH RESOLUTION SUPERFUND METHODS DATA ELEMENT INSTRUCTIONS (CON'T)

Node and Data Elements	Applicability: Sample	LCS/LCSD	MB/IB	NCS	Instructions
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	X	X	X		If only the WHO Toxic Congeners are analyzed, report "Toxic_Congeners". Otherwise, report "All_Congeners". Not required for Dioxin.
ClientMethodCode					Not required.
ClientMethodID	X	X	X	X	Report "HRSM01.2".
ClientMethodModificationDescription					Not required.
ClientMethodModificationID	X	X	X		Report the Modified Analysis Number if applicable.
ClientMethodName					Not required.
ClientMethodSource	X	X	X	X	Report "EPA_CLP".
ClientMethodType	X	X	X	X	Report "HRGC/HRMS".
ClientMethodVersion	X	X	X	X	Report the month and year the SOW was issued.
ClientName					Not required.
ClientSampleID	X	X	X	X	Report the EPA 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 Record Form number.
EquipmentBatch					Not required.
Filtered					Not required.
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", "Sludge", "Tissue", "Biosolids", "Ash", or "Oil" as applicable.
MatrixMedium	X	X	X	X	Report "Aqueous" or "Solid" as applicable. Use "Solid" for Soil/Sediment, Sludge, Tissue (non-human), Biosolids, Ash, and Oil.

TABLE 1. HIGH RESOLUTION SUPERFUND METHODS DATA ELEMENT INSTRUCTIONS (CON'T)

Node and Data Elements	Applicability: Sample	LCS/LCSD	MB/IB	NCS	Instructions
MethodBatch					Not required.
MethodCategory					Not required.
MethodCode					Not required.
MethodID	X	X	X	X	Report "HRSM01.2".
MethodLevel					Not required.
MethodModificationDescription					Not required.
MethodModificationID					Not required.
MethodName					Not required.
MethodSource	X	X	X	X	Report "EPA_CLP".
MethodType	X	X	X	X	Report "HRGC/HRMS".
MethodVersion	X	X	X	X	Report the month and year the SOW was issued.
OriginalClientSampleID					Not required.
OriginalLabSampleID					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 or IB; "Blank_Spike" for LCS; or "Blank_Spike_Duplicate" for LCSD.
QCLinkage		X	X		Report "PreparationBatch" for MB and LCS/LCSD.
QCType	X	X	X	X	Report "Field_Sample" for field samples; "Field_Blank" for field, equipment, rinse, or trip blanks; "PT_Sample" for Performance Evaluation Samples and Proficiency Testing audit samples; "Method_Blank" for MB; "Instrument_Blank" for IB; "Laboratory_Control_Sample" for LCS; "Laboratory_Control_Sample_Duplicate" for LCSD; or Non_Client_Sample for NCS.
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; or "Temperature" for each SamplePlusMethod.
CharacteristicValue	X	X	X		Report percent solids and percent lipids to three significant figures. Report the temperature at receipt to the nearest degree.
CharacteristicUnits	X	X	X		Report "C" for "Temperature".
Comment					Not required.

TABLE 1. HIGH RESOLUTION SUPERFUND METHODS DATA ELEMENT INSTRUCTIONS (CON'T)

Node and Data Elements	Applicability: Sample	LCS/LCSD	MB/IB	NCS	Instructions
ContactInformation	X	X	X	X	
LabAddress1	X	X	X	X	Report the street address of the laboratory.
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.
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", "Reextraction-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	X	X	X	X	Report the EPA Sample Number as given in Exhibit B – Reporting and Deliverables Requirements, Section 3.3.7.
ClientMethodCode					Not required.
ClientMethodID	X	X	X	X	Report "HRSM01.2".
ClientMethodModificationDescription					Not required.
ClientMethodModificationID					Not required.
ClientMethodName					Not required.
ClientMethodSource	X	X	X	X	Report "EPA_CLP".
ClientMethodVersion	X	X	X	X	Report the month and year the SOW was issued.

TABLE 1. HIGH RESOLUTION SUPERFUND METHODS DATA ELEMENT INSTRUCTIONS (CON'T)

Node and Data Elements	Applicability: Sample	LCS/LCSD	MB/IB	NCS	Instructions
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.
ColumnLengthUnits	X	X	X		Report "m".
Comment					Not required.
ConfirmationAnalysisID	X	X	X		Links on analysis to a confirmation analysis. Report the Lab Analysis ID of the confirmation analysis.
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 "HRSM01.2".
MethodModificationDescription					Not required.
MethodModificationID					Not required.
MethodName					Not required.
MethodSource	X	X	X	X	Report "EPA_CLP".
MethodVersion	X	X	X	X	Report the month and year the SOW was issued.
PreparationBatch					Not required.
ProcedureID					Not required.
ProcedureName					Not required.
ReferenceDate					Not required.
ResultBasis	X	X	X		Report "Dry" for Soil samples. Report "Wet" for Tissue, Biosolids, Sludge, and Oil samples.
Temperature					Not required.
TemperatureUnits					Not required.
Wavelength					Not required.

TABLE 1. HIGH RESOLUTION SUPERFUND METHODS DATA ELEMENT INSTRUCTIONS (CON'T)

Node and Data Elements	Applicability: Sample	LCS/LCSD	MB/IB	NCS	Instructions
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 unique identifier from the AnalyteGroup the Homologue, TEQ, or total result is derived from.
AnalyteName	X	X	X		Report analytes as they appear in the CAS Registry. For co-eluting analytes, concatenate names using "/" as the separator. For Homologues, TEQs, and total results, report names as they appear in Exhibit C - Chlorinated Dibenzo-*p*-Dioxins and Chlorinated Dibenzofurans and Chlorinated Biphenyl Congeners Target Analyte List and Contract Required Quantitation Limits.
AnalyteNameContext	X	X	X		Report "CAS".
AnalyteType	X	X	X		Report "Target" for all target analytes and "Spike" for target analytes designated as spike analytes for LCS/LCSD analysis.
CASRegistryNumber	X	X	X		Report CAS Numbers as they appear in Exhibit C - Chlorinated Dibenzo-*p*-Dioxins and Chlorinated Dibenzofurans and Chlorinated Biphenyl Congeners Target Analyte List and Contract Required Quantitation Limits. For co-eluting analytes, report the CAS Numbers for each analyte, separated by "/".
ClientAnalyteID	X	X	X		Report CAS Numbers as they appear in Exhibit C - Chlorinated Dibenzo-*p*-Dioxins and Chlorinated Dibenzofurans and Chlorinated Biphenyl Congeners Target Analyte List and Contract Required Quantitation Limits. For co-eluting analytes, report the CAS Numbers for each analyte, separated by "/". For TEQs and total results, report the SMO Assigned No. as it appears in Exhibit C - Chlorinated Dibenzo-*p*-Dioxins and Chlorinated Dibenzofurans and Chlorinated Biphenyl Congeners Target Analyte List and Contract Required Quantitation Limits.
ClientAnalyteName	X	X	X		Report analytes as they appear in the Analyte Name column in Exhibit C - Chlorinated Dibenzo-*p*-Dioxins and Chlorinated Dibenzofurans and Chlorinated Biphenyl Congeners Target Analyte List and Contract Required Quantitation Limits. For co-eluting analytes, concatenate names using "/" as the separator.
ClientDetectionLimit	X	X	X		Report the CRQL as found in Exhibit C - Chlorinated Dibenzo-*p*-Dioxins and Chlorinated Dibenzofurans and Chlorinated Biphenyl Congeners Target Analyte List and Contract Required Quantitation Limits.
ClientDetectionLimitUnits	X	X	X		Report "ng/kg" for Soil, Sludge, Tissue, Biosolids, Ash, and Oil. Report "pg/L" for Water.

TABLE 1. HIGH RESOLUTION SUPERFUND METHODS DATA ELEMENT INSTRUCTIONS (CON'T)

Node and Data Elements	Applicability: Sample	LCS/LCSD	MB/IB	NCS	Instructions
ClientQuantitationLimit	X	X	X		Report the CRQL.
ClientQuantitationLimitUnits	X	X	X		Report "ng/kg" for Soil, Sludge, Tissue, Biosolids, Ash, and Oil. Report "pg/L" for Water.
Comment					Not required.
DetectionLimit	X	X	X		Report the adjusted MDL, to at least two significant figures for Dioxins, Furans, and WHO Toxic Congeners.
DetectionLimitType	X	X	X		Report "MDL_sa".
DetectionLimitUnits	X	X	X		Report "ng/kg" for Soil, Sludge, Tissue, Biosolids, Ash, and Oil. Report "pg/L" for Water.
DifferenceErrorRatio					Not required.
ExpectedResult		X			Report the true value for LCS/LCSD.
ExpectedResultUnits		X			Report "ng/kg" for Soil, Sludge, Tissue, Biosolids, Ash, and Oil. Report "pg/L" for Water.
LabAnalysisID	X	X	X		Report the unique identifier from the analysis this reported result was derived from. Not required for Homologues, TEQs, and total results.
LabAnalyteID					Not required.
LabQualifiers	X	X	X		Report flags as specified in Exhibit B – Reporting and Deliverables Requirements.
LabResultStatus					Not required.
PeakID					Not required.
PercentDifference					Not required.
PercentDifferenceLimitHigh					Not required.
PercentDifferenceLimitLow					Not required.
PercentDifferenceLimitType					Not required.
PercentRecovery		X			Report the Percent Recovery to the nearest whole number.
PercentRecoveryLimitHigh		X			Report the upper limit for the Percent Recovery to the nearest whole percent.
PercentRecoveryLimitLow		X			Report the lower limit for the Percent Recovery to the nearest whole percent.
PercentRecoveryLimitType		X			Report "Method".
PercentRecoveryType					Not required.
QuantitationLimit	X	X	X		Report the CRQL for those analytes with SOW specified CRQLs, adjusted for sample weight and volume, percent solids, and dilution factor, to at least two significant figures.
QuantitationLimitType	X	X	X		Report "CRQL_sa".
QuantitationLimitUnits	X	X	X		Report "ng/kg" for Soil, Sludge, Tissue, Biosolids, Ash, and Oil. Report "pg/L" for Water.
ReportingLimit	X	X	X		Report the adjusted EDL to at least two significant figures for Dioxins, Furans, and WHO Toxic Congeners.
ReportingLimitType	X	X	X		Report "EDL_sa".

TABLE 1. HIGH RESOLUTION SUPERFUND METHODS DATA ELEMENT INSTRUCTIONS (CON'T)

Node and Data Elements	Applicability: Sample	LCS/LCSD	MB/IB	NCS	Instructions
ReportingLimitUnits	X	X	X		Report "ng/kg" for Soil, Sludge, Tissue, Biosolids, Ash, and Oil. Report "pg/L" for Water.
Result	X	X	X		Report the final calculated result for detects and Homologues that meet all technical acceptance criteria, for TEQs, and for EMPCs, to two significant figures. 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.
ResultUnits	X	X	X		Report "ng/kg" for Soil, Sludge, Tissue, Biosolids, Ash, 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		X			Report the RPD between LCS and LCSD.
RPDLimitHigh		X			Report the upper limit for the RPD.
RPDLimitType		X			Report "Method".
RPDType					Not required.
PreparationPlusCleanup	X	X	X		
AliquotAmount	X	X	X		Report the sample amount in grams for Soil, Sludge, Tissue, Biosolids, Ash, or Oil; or in mL for Water.
AliquotAmountUnits	X	X	X		Report "g" for Soil, Sludge, Tissue, Biosolids, Ash, and Oil. Report "mL" for Water.
Analyst	X	X	X		Report the Analyst's initials.
CleanedUpDate	X	X	X		Report the date and time the sample 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", or "Silica_Gel" as appropriate.
ClientMethodCode					Not required.
ClientMethodID					Not required.
ClientMethodModificationDescription					Not required.
ClientMethodModificationID					Not required.
ClientMethodName					Not required.
ClientMethodSource	X	X	X		Report "EPA_CLP".
ClientMethodVersion	X	X	X		Report the month and year the SOW was issued.

TABLE 1. HIGH RESOLUTION SUPERFUND METHODS DATA ELEMENT INSTRUCTIONS (CON'T)

Node and Data Elements	Applicability: Sample	LCS/LCSD	MB/IB	NCS	Instructions
Comment					Not required.
FinalAmount	X	X	X		Report the final preparation or cleanup volume produced by this process in uL.
FinalAmountUnits	X	X	X		Report "uL".
InitialAmount	X	X	X		Report the initial amount of extracted sample used for this cleanup method in microliters.
InitialAmountUnits	X	X	X		Report "uL".
LabID					Not required.
LabMethodID					Not required.
LabMethodName					Not required.
LabName					Not required.
LotNumber					Not required.
MethodCode					Not required.
MethodID	X	X	X		Report "HRSM01.2".
MethodModificationDescription					Not required.
MethodModificationID					Not required.
MethodName					Not required.
MethodSource	X	X	X		Report "EPA_CLP".
MethodVersion	X	X	X		Report the 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", "CLLE", "CONH", "HCl", "SPE", "SOXH", "SDS", or "PFEX" as appropriate.
PreparedDate	X	X	X		Report the date and time the sample extraction procedure began.
ProcedureID					Not required.
ProcedureName					Not required.
Solvent					Not required.
Analyte	X	X	X		
AnalyteGroupID	X	X	X		Report the unique identifier from the AnalyteGroup the Homologue or TEQ is derived from.
AnalyteName	X	X	X		Report analytes as they appear in the CAS registry. For co-eluting compounds, concatenate names using "/" as the separator.
AnalyteNameContext	X	X	X		Report "CAS".
AnalyteType	X	X	X		Report "Target" for all target analytes, "Spike" for all target analytes designated as spike compounds for LCS/LCSD analysis, "Internal_Standard" for internal standards, "Monitor" for the labeled cleanup standard compounds, and "Surrogate" for all other labeled compounds.

TABLE 1. HIGH RESOLUTION SUPERFUND METHODS DATA ELEMENT INSTRUCTIONS (CON'T)

Node and Data Elements	Applicability: Sample	LCS/LCSD	MB/IB	NCS	Instructions
CASRegistryNumber	X	X	X		Report the CAS Number as it appears in Exhibit C - Chlorinated Dibenzo-*p*-Dioxins and Chlorinated Dibenzofurans and Chlorinated Biphenyl Congeners Target Analyte List and Contract Required Quantitation Limits. For co-eluting compounds, report the CAS Numbers for each compound, separated by "/".
ClientAnalyteID	X	X	X		Report the CAS Number as it appears in Exhibit C - Chlorinated Dibenzo-*p*-Dioxins and Chlorinated Dibenzofurans and Chlorinated Biphenyl Congeners Target Analyte List and Contract Required Quantitation Limits. For co-eluting compounds, report the CAS Numbers for each compound, separated by "/".
ClientAnalyteName	X	X	X		Report the Analyte Names as they appear in the Analyte Name column in Exhibit C - Chlorinated Dibenzo-*p*-Dioxins and Chlorinated Dibenzofurans and Chlorinated Biphenyl Congeners Target Analyte List and Contract Required Quantitation Limits. For co-eluting compounds, concatenate names using "/" as the separator.
Comment					Not required.
DetectionLimit	X	X	X		Report the MDL to at least two significant figures for target Dioxins, Furans, and WHO Toxic Congeners.
DetectionLimitType	X	X	X		Report "MDL".
DetectionLimitUnits	X	X	X		Report "ng/kg" for Soil, Sludge, Tissue, Biosolids, Ash, 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 standards in the final extract.
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 standards).
PeakID					Not required.
PercentRecovery	X	X	X		Report the percent recovery of the labeled compounds to the nearest whole percent.
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.

TABLE 1. HIGH RESOLUTION SUPERFUND METHODS DATA ELEMENT INSTRUCTIONS (CON'T)

Node and Data Elements	Applicability: Sample	LCS/LCSD	MB/IB	NCS	Instructions
QuantitationLimit	X	X	X		For target analytes with SOW specified CRQLs, report the adjusted CRQL to at least two significant figures.
QuantitationLimitType	X	X	X		Report "CRQL_sa".
QuantitationLimitUnits	X	X	X		Report "ng/kg" for Soil, Sludge, Tissue, Biosolids, Ash, and Oil. Report "pg/L" for Water.
ReportingLimit	X	X	X		Report the adjusted EDL as applicable to at least two significant figures for target Dioxins, Furans, and WHO Toxic Congeners.
ReportingLimitType	X	X	X		Report "EDL_sa".
ReportingLimitUnits	X	X	X		Report "ng/kg" for Soil, Sludge, Tissue, Biosolids, Ash, and Oil. Report "pg/L" for Water.
Result	X	X	X		For targets, spikes, internal standards, labeled compounds, cleanup standards, and surrogates report the final calculated result, or EMPC, to two significant figures. 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 all EMPCs. Report "Not_Detected" for non-detects.
ResultUncertainty					Not required.
ResultUnits	X	X	X		Report "ng/kg" for Soil, Sludge, Tissue, Biosolids, Ash, 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	X	X		Report a unique identifier for each AnalyteGroup.
AnalyteName	X	X	X		Report names of the Homologues, TEQs, or total results as they appear in the Analyte Name column in Exhibit C - Chlorinated Dibenzo-*p*-Dioxins and Chlorinated Dibenzofurans and Chlorinated Biphenyl Congeners Target Analyte List and Contract Required Quantitation Limits.
AnalyteNameContext	X	X	X		Report "CAS".
AnalyteType	X	X	X		Report "Derived".
CASRegistryNumber					Not required.
ClientAnalyteID	X	X	X		Report the SMO assigned number as it appears in Exhibit C - Chlorinated Dibenzo-*p*-Dioxins and Chlorinated Dibenzofurans and Chlorinated Biphenyl Congeners Target Analyte List and Contract Required Quantitation Limits.

TABLE 1. HIGH RESOLUTION SUPERFUND METHODS DATA ELEMENT INSTRUCTIONS (CON'T)

	Applicability				
Node and Data Elements	Sample	LCS/LCSD	MB/IB	NCS	Instructions
ClientAnalyteName	X	X	X		Report the Analyte Names as they appear in the Analyte Name column in Exhibit C - Chlorinated Dibenzo-*p*-Dioxins and Chlorinated Dibenzofurans and Chlorinated Biphenyl Congeners Target Analyte List and Contract Required Quantitation Limits.
Comment					Not required.
LabAnalyteID					Not required.
LabQualifiers					Not required.
Result	X	X	X		Report the final calculated value per the SOW. Leave blank if not detected.
ResultType					Report"=" for detects. Report "Not_Detected" for non-detects.
ResultUncertainty					Not required.
ResultUnits					Report "ng/kg" for Soil, Sludge, Tissue, Biosolids, Ash, and Oil. Report "pg/L" for Water.

TABLE 2. ABBREVIATIONS

Abbreviation	Definition
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
IB	Instrument Blank
ID	Identifier
Lab	Laboratory
LCS	Laboratory Control Sample
LCSD	Laboratory Control Sample Duplicate
MB	Method Blank
MDL	Method Detection limit
NCS	Non-Client (ZZZZZZ) Sample
QATS	Quality Assurance Technical Support
RPD	Relative Percent Difference
SDG	Sample Delivery Group
SOW	Statement of Work
TEQ	Toxic Equivalent
WHO	World Health Organization

APPENDIX A - FORMAT CHARACTERISTICS FOR METHOD DETECTION LIMIT STUDY DATA

1.0 FORMAT CHARACTERISTICS FOR METHOD DETECTION LIMIT STUDY DATA

The Method Detection Limit (MDL) study data deliverable consists of a Microsoft® Excel spreadsheet containing the following columns (Table A-1) in the order specified.

The Contractor shall provide one spreadsheet for each combination of instrument ID, analytical method, and preparation method used to report results under this contract.

The Contractor shall deliver the spreadsheets to the recipients specified in Table 1 of Exhibit B – Reporting and Deliverables Requirements.

The format for the Microsoft® Excel file name shall be MDL_SOW Number_Analytical Method_Preparation Method_Instrument ID.xls.

TABLE A-1. MDL STUDY DATA DELIVERABLE

Column	Instruction
LabID	Report the agency assigned Lab Code.
LabContract	Report the Lab Contract Number per the instructions for Header/LabContract.
SOW	Report the SOW per the instructions for SamplePlusMethod/ClientMethodID.
ClientMethodType	Report the analytical method per the instructions for SamplePlusMethod/ClientMethodType.
ClientMethodCode	Report the preparation method per the instructions for PreparationPlusCleanup/ClientMethodID.
ClientMethodCategory	Leave null.
ClientMethodModificationID	Report the MA number per the instructions for SamplePlusMethod/ClientMethodModificationID if applicable. Otherwise leave null.
Level	Report the sample level per the instructions for SamplePlusMethod/MethodLevel.
Matrix	Report the sample matrix per the instructions for SamplePlusMethod/MatrixID.
InstrumentID	Report the instrument ID per the instructions for Analysis/InstrumentID.
ColumnID	Report the GC column ID per the instructions for Analysis/Column if applicable. Otherwise leave null.
ClientAnalyteID	Report the analyte per the instructions for ReportedResult/ClientAnalyteID.
Peak	Leave null.
ResultUnits	Report the units for the replicate concentrations reported per the instructions for ReportedResult/ResultUnits.
Replicate##	The Laboratory shall include as many columns as there are replicates reported. Usually this would be seven, but more than seven replicates can be reported. The Laboratory shall report the results of the analysis of each replicate for each analyte. Each column shall be labeled "Replicate##", where the ## shall be replaced with the numeric designation of the replicate (e.g., Replicate01 for the first, Replicate02 for the second, Replicate03 for the third, etc.).

Column	Instruction
LabAnalysisID##	Following each Replicate## column, the Laboratory shall report a LabAnalysisID## column, reporting the LabAnalysisID of that replicate for that analyte per the instructions for Analysis/LabAnalysisID. The LabAnalysisID## columns shall be labeled in the same manner as the Replicate## columns.
AnalyzedDate##	Following each LabAnalysisID## column, the Laboratory shall report a AnalyzedDate## column, reporting the analysis date and time for that replicate for that analyte per the instructions for the Analysis/AnalyzedDate data element. The AnalyzedDate## columns shall be labeled in the same manner as the Replicate## columns.
StandardDeviation	Report the calculated standard deviation of the replicates for each analyte to at least three significant figures.
StudentsTValue	Report the appropriate Student’s T value for the degrees of freedom based on the number of replicates and 99% for the one-sided test.
DetectionLimit	Report the calculated Detection Limit for each analyte per the instructions for ReportedResult/DetectionLimit.
DetectionLimitUnits	Report the appropriate units for the preparation method per the instructions for ReportedResult/DetectionLimitUnits.
MDLAcceptable	Enter "Y" if the calculated MDL is less than one-half the CRQL for the analyte and matrix. Otherwise enter "N".
ExpectedResult	Report the concentration for each analyte in the MDL standards per the instructions for ReportedResult/ExpectedResult.
ExpectedResultUnits	Report the concentration units for each analyte in the MDL standards per the instructions for ReportedResult/ExpectedResultUnits.
ConcentrationAcceptable	Enter "Y" if the concentration of the analyte in the MDL standards was less than or equal to 10 times the calculated MDL for that analyte. Otherwise enter "N".
EffectiveDate	Report the date on which the Laboratory began to use the calculated MDL for reporting sample results for that analyte, instrument, and method formatted per the instructions for Header/DateFormat. This date cannot precede the analysis date of the MDL replicates.