EXHIBIT E

CONTRACT LABORATORY PROGRAM QUALITY ASSURANCE MONITORING PLAN

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1.0 OVERVIEW

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

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

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

1.1.1

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

1.2 Incentives/Sanctions

The Contractor may anticipate incentives by consistently providing the following: (1) high quality, technically sound data as stipulated by the ISM01.X contract; (2) on-time or early delivery of the Sample Delivery Group (SDG) Cover Sheet; (3) above average Quarterly Blind (QB) Performance Evaluation (PE) sample scores; (4) electronic deliverables that pass the initial Contract Compliance Screening (CCS) acceptance criteria; and (5) SDGs delivered on-time. Samples are distributed routinely to Contractors based on the quality of work performed, as measured by the Performance Scheduling Algorithm (PSA) (see Section G of the contract for details). A Contractor that consistently meets the contract performance requirements as highlighted above, will earn a higher PSA score, thereby increasing the likelihood of receiving samples for analyses. If the Contractor fails to meet the requirements set forth in this Statement of Work (SOW) or elsewhere in the contract, USEPA may take, but is not limited to, the following actions (see Section E of the contract for details): reduction in the number of samples sent under the contract; suspension of sample shipments; data package audit(s); Remedial QB Audit; electronic data audit(s); on-site laboratory evaluation(s); and/or remedial PE sample(s).

2.0 INTRODUCTION

Appropriate use of data generated under the large range of analytical conditions encountered in environmental analyses requires reliance on the Quality Control (QC) procedures and criteria incorporated into the ISM01.X Statement of Work (SOW).

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

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

2.1.1 The Contractor's QA/QC program shall include (1) internal QC criteria that demonstrate compliant levels of performance, as determined by QA review, as well as (2) external review of data and procedures accomplished by the monitoring activities of the USEPA OSRTI Analytical Services Branch (ASB), Regional Data Users, Sample Management Office (SMO), and the Quality Assurance Technical Support (QATS) Laboratory. Each external review accomplishes a different purpose. These reviews are described in specific sections of this exhibit. Laboratory evaluation samples, electronic data audits, and data packages provide an external QA reference for the program. A Contractor on-site evaluation system is also part of the external QA monitoring. A feedback loop provides the results of the various review functions to the Contractors through direct communications with the USEPA Regional Contract Laboratory Program Project Officer (CLP PO) and the USEPA OSRTI ASB Inorganic Program Manager (ASB PM).

2.1.2 This exhibit does not provide specific instructions for constructing QA Management Plans, QC systems, or a QA organization. It is, however, an explanation of the QA/QC requirements of CLP. It outlines minimum standards for QA/QC programs. It also includes specific items that are required in a Quality Assurance Management Plan (QAP) and by the QA/QC documentation detailed in this contract. Delivery of this documentation provides USEPA with a complete data package which will stand alone, and limits the need for contact with the Contractor or with an analyst, at a later date, if some aspect of the analysis is questioned.

2.1.3 In order to assure that the product delivered by the Contractor meets the requirements of the contract, and to improve interlaboratory data comparison, the Contractor shall:

- Prepare, and adhere to, a written approved QAP, as defined in Exhibit E, Section 5;
- Prepare and adhere to, Standard Operating Procedures (SOPs) as described in Exhibit E, Section 6;
- Adhere to the analytical methods in Exhibit D and associated QC requirements specified within Exhibit E;

- Verify and document analytical standards and retain documentation of the purity of neat materials, as well as, the purity and accuracy of solutions obtained from private chemical supply houses;
- Submit all requested raw data and required documentation for Regional review;
- Submit results of all analyzed laboratory evaluation samples, and adhere to corrective action procedures;
- Submit, upon request, instrument data tapes and applicable documentation for tape audits, including a copy of the Sample Data Package;
- Submit to on-site laboratory evaluations, and adhere to corrective action procedures; and
- Submit all original documentation generated during sample analyses for USEPA review.

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

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

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

4.1 Purpose

4.1.1 The purpose of this document is to provide (1) a uniform set of procedures for the analysis of inorganic constituents of samples, (2) documentation of methods and their performance, and (3) verification of the sample data generated. Although it is impossible to address every analytical situation in one document, this exhibit defines the minimum requirements for each major step relevant to any inorganic analysis.

4.1.2 The primary function of the Contract Laboratory Program (CLP) QA/QC program is the definition of procedures for the evaluation and documentation of analytical methodologies and the reduction and reporting of data. The location and summary of the QA/QC performance based contracting methods can be found in Exhibit E, Section 15, Table 1 - Contract Laboratory Program Quality Assurance Monitoring Plan. The objective is to provide a uniform basis for sample handling, instrument and methods maintenance, performance evaluation, and analytical data gathering and reporting. In many instances where methodologies are available, specific QC procedures are incorporated into the method documentation (see Exhibit D).

4.1.3 The QA/QC procedures defined herein shall be used by the Contractor when performing the methods specified in Exhibit D. When QA/QC procedures are specified in Exhibit D, the Contractor shall follow those procedures, in addition to procedures specified here.

4.2 Laboratory Audit and Intercomparison Study Program

The Contractor is required to participate in the Laboratory Audit and Intercomparison Study Program run by USEPA. The Contractor shall be required to analyze at least one Quarterly Blind (QB) sample per calendar quarter during the contract period for inorganics.

4.3 Quarterly Calculation of Critical Level (L_c) and Limits of Detections (L_d)

The Contractor shall update and report the quarterly calculation of L_cs and L_ds by the method specified in Exhibit D, by type, matrix, and model for each instrument used on this contract, to Sample Management Office (SMO), Quality Assurance Technical Support (QATS), and the USEPA Regional Contract Laboratory Program Project Officer (CLP PO) as specified in Exhibit B. All the L_cs, L_ds, and the Limits of Quantitation (L_q) shall meet the requirements specified in Exhibit C.

4.4 Annual Verification of Interelement Correction Factors

For Inductively Coupled Plasma - Atomic Emission Spectroscopy (ICP-AES) methods, the Contractor shall report, as specified in Exhibit B, all interelement correction factors.

4.5 Quality Assurance/Quality Control Measurements

4.5.1 In this Exhibit, as well as other places within this Statement of Work (SOW), the term "analytical sample" discusses the required frequency or placement of certain QA/QC measurements. The term "analytical sample" is defined in the glossary, Exhibit G.

4.5.2 In order for the QA/QC information to reflect the status of the samples analyzed, all samples and their associated QA/QC analysis shall be analyzed under the same operating and procedural conditions.

4.5.3 If any QC measurement fails to meet contract criteria, the analytical measurement must not be repeated prior to taking the appropriate corrective action as specified in Exhibit D.

4.5.4 The Contractor shall report all QC data in the exact format specified in Exhibits B and H.

4.5.5 L_cs, L_ds, precision, and interference effects shall be established for each analyte on a particular instrument. All reported measurements shall be within the instrumental calibrated ranges. The Contractor shall maintain QC data confirming instrument performance and analytical results.

5.0 QUALITY ASSURANCE MANAGEMENT PLAN (QAP)

5.1 Introduction

The Contractor shall establish a Quality Assurance (QA) program with the objective of providing sound analytical chemical measurements. This program shall incorporate the Quality Control (QC) procedures, any necessary corrective action, all documentation required during data collection, and the quality assessment measures performed by management to ensure acceptable data production. The Contractor shall follow the USEPA EPA Requirements for Quality Management Plans (EPA QA/R-2). An electronic version can be found at http://www.epa.gov/quality1/qa_docs.html.

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

- 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 in order to provide data which are technically sound and legally defensible.

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

5.2 Required Elements of a Quality Assurance Management Plan

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

A. Organization and Personnel

1. QA Policy and Objectives (the mission and quality policy of the organization)
2. QA Management (the specific roles, authorities, and responsibilities of management and staff with respect to QA and QC activities)
   a. Organization
   b. Assignment of QA/QC Responsibilities

c. Reporting Relationships (the means by which effective communications with personnel actually performing the work are assured)

d. QA Document Control Procedures

e. QA Program Assessment Procedures (the process used to plan, implement, and assess the work performed)

1. Personnel

a. Resumes

b. Education and Experience Pertinent to this Contract

c. Training Records and Progress

B. Facilities and Equipment

1. Instrumentation and Backup Alternatives

2. Maintenance Activities and Schedules

C. Document Control

1. Laboratory Notebook Policy

2. Sample Tracking/Custody Procedures

3. Logbook Maintenance and Archiving Procedures

4. Sample Delivery Group (SDG) File Organization, Preparation, and Review Procedures

5. Procedures for Preparation, Approval, Review, Revision, and Distribution of SOPs

6. Process for Revision of Technical or Documentation Procedures

D. Analytical Methodology

1. Calibration Procedures and Frequency

2. Sample Preparation 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. Quality Assurance (the process which measures the effectiveness of QA will be established and how frequently effectiveness will be measured)

1. Data Quality Assurance

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. Quality Control

1. Solvent, Reagent, and Adsorbent Check Analysis

2. Reference Material Analysis

3. Internal QC Checks

4. Corrective Action and Determination of QC Limit Procedures

5. Responsibility Designation

5.3 Updating and Submitting the Quality Assurance Management Plan

5.3.1 The revised QAP will become the official QAP under the contract and may be used during legal proceedings. The Contractor shall maintain the QAP on file at the Contractor's facility for the term of the contract. Both the initial submission and the revised QAP shall be paginated consecutively in ascending order. The revised QAP shall include:

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

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

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

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

5.3.2.1 The Contractor shall amend the QAP within 14 days of when the circumstances listed in Exhibit E, Section 5.3, result in a discrepancy between what was previously described in the QAP and what is presently occurring at the Contractor's facility. When the QAP is amended, all changes in the QAP shall be clearly marked (e.g., a bar in the margin indicating where the change is found in the document, highlighting the change by underlining the change, bold printing the change, or using a different print font) and a copy is sent to the USEPA Regional CLP PO and Quality Assurance Technical Support (QATS). The amended section pages shall have the date on which the changes were implemented. The Contractor shall incorporate all amendments to the latest version of the QAP document. The Contractor shall archive all amendments to the QAP document for future reference by USEPA.

5.4 Incentives/Sanctions

The Contractor shall amend the QAP as specified within this section. The QAP describes the policies and procedures for ensuring that work processes, products, or services satisfy expectations or specifications in ISM01.X. Failure to comply with the requirements of this section may result in sanctions as described in the contract.

6.0 STANDARD OPERATING PROCEDURES (SOPS)

6.1 Introduction

In order 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 Standard Operating Procedures (SOPs). As defined by USEPA, an SOP is a written document which provides directions for the step-by-step execution of an operation, analysis, or action which is commonly accepted as the method for performing certain routine or repetitive tasks. The Contractor shall follow the USEPA Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents (EPA QA/G-6). An electronic version can be found at http://www.epa.gov/quality1/qa_docs.html.

6.1.1 SOPs prepared by the Contractor shall be functional (i.e., clear, comprehensive, up-to-date, and sufficiently detailed to permit duplication of results by qualified analysts). The SOPs shall be paginated consecutively in ascending order.

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

- Consistent with current USEPA regulations, guidelines, and the Contract Laboratory Program (CLP) ISM01.X contract requirements.
- Consistent with instrument(s) manufacturer's specific instruction manuals.
- Available to USEPA 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 shall demonstrate the application of the SOPs if requested.

- Available to the designated recipients within 7 days, upon request by the USEPA Regional CLP Project Officer (CLP PO) or the USEPA OSRTI Analytical Services Branch Inorganic Program Manager (ASB PM).
- Capable of providing for the development of documentation that is sufficiently complete to record the performance of all tasks required by the protocol.
- Capable of demonstrating the validity of data reported by the Contractor and explain 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 work stations as appropriate.
- Subject to a document control procedure which precludes the use of outdated or inappropriate SOPs.
- Reviewed and signed by all Contractor personnel performing actions identified in the SOP.

6.2 Format

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

- Title page;
- Document Control;
- Scope and Applicability;
- Summary of Method;
- Definitions (acronyms, abbreviations, and specialized forms used in the SOP);
- Health & Safety;
- Personnel Qualifications;
- Interferences;
- Apparatus & Materials (list or specify; note also designated locations where found);
- Handling & Preservation;
- Instrument or Method Calibration;
- Sample Preparation and Analysis;

- Data Calculations;
- Quality Control (QC) limits;
- Corrective action procedures, including procedures for secondary review of information being generated;
- Data Management and Records Management;
- Miscellaneous notes and precautions; and
- References.

6.3 Required SOPs

The Contractor shall maintain the following SOPs:

6.3.1 Evidentiary SOPs for required chain-of-custody and document control are discussed in Exhibit F.

6.3.2 Sample Receipt and Storage

- Sample receipt and identification logbooks,
- Refrigerator temperature logbooks, and
- Security precautions.

6.3.3 Sample Preparation

6.3.3.1 Metals

6.3.3.2 Cyanide

6.3.4 Glassware Cleaning

6.3.5 Calibration (Balances, etc.)

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

6.3.6 Analytical Procedures (for each analytical system)

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

- Critical Level (L_c), Limit of Detection (L_d), and Limit of Quantitation (L_q) calculations and Interelement Correction (IEC) determinations.

6.3.7 Maintenance Activities (for each analytical system)

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

6.3.8 Analytical Standards

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

6.3.9 Data Reduction Procedures

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

6.3.10 Documentation Policy/Procedures

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

6.3.11 Data Validation/Self-Inspection Procedures

- Data flow and chain-of-command for data review;
- Procedures for measuring precision and accuracy;
- Evaluation parameters for identifying systematic errors;
- Procedures to assure that hardcopy and electronic deliverables are complete and compliant with the requirements in the Statement of Work (SOW) Exhibits B and H;
- Procedures to assure that hardcopy deliverables are in agreement with their comparable electronic deliverables;

- Demonstration of internal Quality Assurance (QA) inspection procedure (demonstrated by supervisory sign-off on personal notebooks, internal laboratory evaluation samples, etc.);
- Frequency and type of internal audits (e.g., random, quarterly, spot checks, perceived trouble areas);
- Demonstration of problem identification, corrective actions, and resumption of analytical processing. Sequence resulting from internal audit (i.e., QA feedback); and
- Documentation of audit reports (internal and external), response, corrective action, etc.

6.3.12 Data Management and Handling

- Procedures for controlling and estimating data entry errors;
- Procedures for reviewing changes to data and deliverables and ensuring traceability of updates;
- Lifecycle management procedures for testing, modifying, and implementing changes to existing computing systems including hardware, software, and documentation or installing 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; and
- Specifications for staff training procedures.

6.4 Updating and Submitting SOP Requirements

6.4.1 The revised SOPs will become the official SOPs under the contract and may be used during legal proceedings. The Contractor shall maintain the complete set of SOPs on file at the Contractor's facility for the term of the contract. Both the initial submission and the revised SOPs shall be paginated consecutively in ascending order. The revised SOPs shall include:

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

6.4.1.1 The Contractor shall send a complete set of the latest version of SOPs or individually requested SOPs within 7 days of a request from an USEPA Regional CLP PO or the USEPA OSRTI ASB PM. The request will designate the recipients.

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

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

6.4.2.1 Existing SOPs shall be amended or new SOPs shall be written within 14 days of when the circumstances listed in Exhibit E, Section 6.4, result in a discrepancy between what was previously described in the SOPs and what is presently occurring at the Contractor's facility. All changes in the SOPs shall be clearly marked (e.g., a bar in the margin indicating where the change is in the document, highlighting the change by underlining the change, bold printing the change, or using a different print font) and a copy is sent to the USEPA Regional CLP PO and Quality Assurance Technical Support (QATS). The amended/new SOPs shall have the date on which the changes were implemented.

6.4.2.2 When existing SOPs are amended or new SOPs are written, the Contractor shall document the reasons for the changes and maintain the amended SOPs or new SOPs on file. Documentation of the reasons for the changes shall be maintained on file with the amended SOPs or new SOPs.

6.4.2.3 Documentation of the reason(s) for changes to the SOPs shall also be submitted along with the SOPs.

6.5 Incentives/Sanctions

The Contractor shall amend SOPs as specified within this section. The SOPs specify analytical procedures in greater detail than appear in Exhibit D. Adherence to these requirements will ensure that the procedure is conducted in a standard, reliable, and reproducible process described in ISM01.X. Failure to comply with the requirements specified herein may result in sanctions as described in the contract.

7.0 CONTRACT COMPLIANCE SCREENING (CCS) PERFORMANCE STANDARDS

7.1 Overview

7.1.1 CCS is one aspect of the Government's contractual right of inspection of analytical data. CCS examines the Contractor's adherence to the contract requirements based on the Sample Data Package delivered to USEPA.

7.1.2 CCS is performed by the Sample Management Office (SMO) under the direction of USEPA. To assure a uniform review, a set of standardized procedures has been developed to evaluate the Sample Data Package submitted by a Contractor against the technical and completeness requirements of the contract. USEPA reserves the right to add and/or delete individual checks.

7.2 CCS Results

CCS results are distributed to the Contractor and other data recipients. The Contractor has 4 business days to correct deficiencies and shall send all corrections to the Regional client 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.

7.3 CCS Trend Report

USEPA will periodically generate a CCS trend report which summarizes CCS results over a given period of time. USEPA will send the CCS trend report or discuss the CCS trend report during an on-site laboratory evaluation. In a detailed letter to the USEPA Regional Contract Laboratory Program Project Officer (CLP PO) and USEPA Contracting Officer, the Contractor shall address the deficiencies and the subsequent corrective action implemented by the Contractor to correct the deficiencies within 14 days of receipt of the report or the on-site laboratory evaluation.

7.4 Incentives/Sanctions

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

7.4.2 The Contractor shall correct deficiencies and resubmit the data within 4 business days, as specified within this section. Resubmission and correction of the data will ensure that the end user is reviewing contractually compliant data described in ISM01.X. Correct resubmission of the data may also result in a reduction in overall sanctions. Specific details on incentives can be found in the contract. If the Contractor fails to adhere to the requirements listed in this section, the Contractor will be in noncompliance with the contract and may be subjected to sanctions as described in the contract.

8.0 ANALYTICAL PERFORMANCE STANDARDS REQUIREMENTS AND REAGENTS

8.1 Overview

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

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

8.2.1 If the laboratory cannot obtain analytical reference standards, the laboratory may prepare their own chemical standards. Laboratories shall obtain the highest purity possible when purchasing chemical standards; standards purchased at less than 97% purity shall be documented as to why a higher purity could not be obtained.

8.2.2 The chemical standards shall be kept at manufacturer recommended conditions when not being used in the preparation of standard solutions. Proper storage of chemicals is essential in order to safeguard them from decomposition.

8.2.3 The Contractor shall be responsible for having analytical documentation proving the purity of each compound as stated. Purity confirmation, when performed, shall use appropriate techniques. Use of two or more independent methods is recommended. The correction factor for impurity when weighing neat materials in the preparation of solution standards is:

EQ. 1 Weight of Impure Compound

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

WHERE, "weight of pure compound" is that required to prepare a specific volume of a solution standard of a specified concentration.

8.2.4 The Contractor is responsible for obtaining analytical documentation proving that all compounds used in the preparation of solution standards are correctly identified.

8.2.5 Logbooks shall be kept for all weighing and dilutions of standards and reagents. All subsequent dilutions from the primary standard and the calculations for determining their concentrations shall be recorded and verified by a second person. All solution standards shall be refrigerated, if required, when not in use. All solution standards shall be clearly labeled as to the identity of the analyte or analytes, the standard ID number of the solution, concentration, date prepared, solvent, expiration date of the solution, special storage requirements (if any), and initials of the preparer.

8.3 Purchase of Chemical Standards Already in Solution

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

8.3.1 Reference standards shall be accompanied by documentation of the purity confirmation of the material to verify the integrity of the standard solutions.

8.3.2 The quality of reference standards purchased shall be demonstrated statistically and analytically by a method of the supplier’s choice. One way this can be demonstrated is to prepare and analyze three solutions: a high standard, a low standard, and a standard at the target concentration (see Sections 8.3.2.1 and 8.3.2.2). The supplier must then demonstrate that the analytical results for the high standard and low standard are consistent with the difference in theoretical concentrations. This is done by the Student’s t-test in Section 8.3.2.4. If this is achieved, the supplier must then demonstrate that the concentration of the target standard lies midway between the concentrations of the low and high standards. This is done by the Student’s t-test in Section 8.3.2.5. Thus, the standard is certified to be within 10% of the target concentration using the equations in Section 8.3.2.6. If the procedure above is used, the supplier must document that the following have been achieved.

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

8.3.2.2 Six replicate analyses of each standard (a total of 18 analyses) shall be performed in the following sequence: low standard; target standard; high standard; low standard; target standard; high standard; etc.

8.3.2.3 The mean and variance of the six results for each solution shall be calculated:

EQ. 2 Mean

$$\text{MEAN} = \frac{Y_1 + Y_2 + Y_3 + Y_4 + Y_5 + Y_6}{6}$$

EQ. 3 Variance

$$\text{VARIANCE} = \frac{Y_1^2 + Y_2^2 + Y_3^2 + Y_4^2 + Y_5^2 + Y_6^2 - 6(\text{MEAN})^2}{6}$$

The values Y_1, Y_2, Y_3, ..., represent the results of the six analyses of each standard. The means of the low, target, and high standards are designated M_1, M_2, and M_3, respectively. The variances of the low, target, and high standards are designated V_1, V_2, and V_3, respectively. Additionally, a pooled variance, V_p, is calculated.

EQ. 4 Pooled Variance

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

If the square root of V_P is less than one percent of M_2, then $M_2^2/10{,}000$ is to be used as the value of V_P in all subsequent calculations.

8.3.2.4 The test statistic shall be calculated:

EQ. 5 Low and High Standard Test Statistic

$$\text{TEST STATISTIC} = \frac{\left| \frac{M_3}{1.1} - \frac{M_1}{0.9} \right|}{\left(\frac{V_P}{3} \right)^{0.5}}$$

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

8.3.2.5 The test statistic shall be calculated:

EQ. 6 Target Standard Test Statistic

$$\text{TEST STATISTIC} = \frac{\left| M_2 - \left(\frac{M_1}{1.8}\right) - \left(\frac{M_3}{2.2}\right) \right|}{\left(\frac{V_P}{4}\right)^{0.5}}$$

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

8.3.2.6 The 95% confidence intervals for the mean result of each standard shall be calculated:

EQ. 7 Low Standard Interval

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

EQ. 8 Target Standard Interval

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

EQ. 9 High Standard Interval

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

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

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

8.4 Requesting Standards from the USEPA Standards Repository

Solutions of analytical reference materials can be ordered from the USEPA Chemical Standards Repository, depending on availability. The Contractor may place an order for standards only after demonstrating that these standards are not available from commercial vendors, either in solution or as a neat material.

8.5 Documentation of the Verification and Preparation of Chemical Standards

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

8.5.1 Weighing logbooks, calculations, raw data, etc., whether produced by the Contractor or purchased from chemical supply houses, shall be maintained by the Contractor and may be subject to review during on-site inspection visits. In those cases where the documentation is supportive of the analytical results of data packages sent to USEPA, such documentation is to be kept on file by the Contractor for a period of one year.

8.5.2 Upon request by the USEPA Regional CLP Project Officer (CLP PO), the Contractor shall submit their most recent previous year's documentation (12 months) for the verification and preparation of chemical standards within 14 days of the receipt of request to the designated recipients.

8.5.3 USEPA will periodically generate a report discussing deficiencies in the Contractor's documentation for the verification and preparation of chemical standards. USEPA will send the report or discuss the deficiencies during an on-site laboratory evaluation. In a detailed letter to the USEPA Regional CLP PO and CLP Quality Assurance Coordinator, the Contractor shall address the deficiencies and the subsequent corrective action implemented by the Contractor to correct the deficiencies within 14 days of receipt of the report or the on-site laboratory evaluation.

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

8.6 Incentives/Sanctions

The Contractor shall obtain the highest purity possible when purchasing chemical standards specified within this section. The use of high purity standards will ensure a more accurate identification and quantitation of analytes described in the ISM01.X Statement of Work (SOW). Failure to meet the requirements set forth in this section may result in sanctions as described in the contract.

9.0 DATA PACKAGE MONITORING AUDITS

9.1 Overview

Data package audits are performed by USEPA for program overview and specific Regional concerns. Standardized procedures have been established to assure uniformity of the auditing process. Data packages are periodically selected from recently received Cases. They are evaluated for the technical quality of hardcopy raw data, Quality Assurance (QA), and adherence to contractual requirements. This function provides external monitoring of program Quality Control (QC) requirements. Data package audits are used to assess the technical quality of the data and evaluate overall laboratory performance. Audits provide USEPA with an in-depth inspection and evaluation of the Case data package with regard to achieving QA/QC acceptability. 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 Standard Operating Procedures (SOPs) on file.

9.2 Responding to the Data Package Audit Report

9.2.1 After completion of the data package audit, USEPA will send a copy of the data package audit report to the Contractor or discuss the data package audit report on an on-site laboratory evaluation. In a detailed letter to the USEPA Regional Contract Laboratory Program Project Officer (CLP PO) and the USEPA designated recipient, the Contractor shall discuss the corrective actions implemented to resolve the deficiencies listed in the data package audit report within 14 days of receipt of the report.

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

9.3 Incentives/Sanctions

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

10.0 REGIONAL DATA REVIEW MONITORING

10.1 Overview

Contractor data are generated to meet the specific needs of USEPA Regions. In order to verify the usability of data for the intended purpose, each 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 USEPA OSRTI Analytical Services Branch (ASB). Each Region uses these guidelines as the basis for data evaluation. Individual Regions may augment the basic guideline review process with additional review based on Region-specific or site-specific concerns. Regional reviews, like the sites under investigation, vary based on the nature of the problem under investigation and the Regional response appropriate to the specific circumstances.

10.1.1 Regional data reviews, relating usability of the data to a specific site, are part of the collective assessment process. They complement the review done at the Sample Management Office (SMO), which is designed to identify contractual discrepancies, and the review done by the USEPA OSRTI ASB, which is designed to evaluate Contractor and method performance.

11.0 QUALITY ASSURANCE (QA) PROFICIENCY MONITORING

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

11.1 Performance Evaluation (PE) Samples

11.1.1 The PE sample(s) may be scheduled with the Contractor as frequently as on a Sample Delivery Group (SDG)-by-SDG basis. The PE samples may be sent either by the Regional client or the USEPA OSRTI Analytical Services Branch (ASB). PE samples assist USEPA in monitoring Contractor performance.

11.1.2 PE samples will be provided as either single-blinds (recognizable as a PE sample but of unknown composition), or as double-blinds (not recognizable as a PE sample and of unknown composition). The Contractor will not be informed of either the analytes/parameters or the concentrations in the PE samples.

11.1.3 The Contractor may receive the PE samples as either full volume samples or ampulated/bottled concentrates from USEPA or a designated USEPA Contractor. The PE samples shall come with instructions concerning the unique preparation procedures, if any, required to reconstitute the PE samples (i.e., the required dilution of the PE sample concentrate). PE samples are to be digested and analyzed with the rest of the routine samples in the SDG. The Contractor shall prepare and analyze the PE sample using the procedure described in the sample preparation and method analysis sections of Exhibit D. All contract required Quality Control (QC) shall be met. The PE sample results are to be submitted in the SDG deliverable package per normal reporting procedures detailed in Exhibit B.

11.1.4 In addition to PE sample preparation and analysis, the Contractor shall be responsible for correctly identifying and quantitating the analytes included in each PE sample. When PE sample results are received by USEPA, the PE sample results will be evaluated for correct analytical identification and quantitation. The PE sample evaluation will be provided to the Contractor via coded evaluation sheets, by analyte. USEPA will notify the Contractor of unacceptable performance.

11.2 Quarterly Blind (QB) Audits

11.2.1 A QB Audit is a unique analytical Case containing only PE samples (i.e., referred to as QB samples). The QB samples will be scheduled by the USEPA OSRTI ASB through the Sample Management Office (SMO). QB samples assist USEPA in monitoring Contractor performance.

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

11.2.3 The Contractor may receive the QB samples as either full volume samples or ampulated/bottled concentrates from USEPA or a designated USEPA Contractor. The QB samples shall come with instructions concerning the unique preparation procedures, if any, required to reconstitute the QB samples (i.e., the required dilution of the QB sample concentrate). The Contractor shall prepare and analyze the QB samples using the procedure described in the sample preparation and method analysis sections of Exhibit D. All contract required QC shall be met, including spike and duplicate analyses. The QB sample results are to be submitted in the SDG deliverable package per normal reporting procedures detailed in Exhibit B.

11.2.4 In addition to QB sample preparation and analysis, the Contractor shall be responsible for correctly identifying and quantitating the analytes included in each QB sample. When QB sample results are received by USEPA, the QB sample results will be scored for correct analytical identification, quantitation, and timeliness. The QB sample scoring will be provided to the Contractor via coded evaluation sheets, by analyte. USEPA will notify the Contractor of unacceptable performance. The Contractor’s QB sample performance will be assessed into one of the following three categories:

11.2.4.1 Acceptable, No Response Required: Score greater than or equal to 90%. The data meets most or all of the scoring criteria. No response is required.

11.2.4.2 Acceptable, Response Explaining Deficiencies Required: Score greater than or equal to 75%, but less than 90%. Deficiencies exist in the Contractor's performance. Corrective action response required.

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

11.2.5 In the case of Section 11.2.4.2 or 11.2.4.3, the Contractor shall describe the deficiency(ies) and the action(s) taken in a corrective action letter to the USEPA Contracting Officer, USEPA Regional Contract Laboratory Program Project Officer (CLP PO), the Analytical Services Branch Inorganic Program Manager (ASB PM), and the CLP Quality Assurance (QA) Coordinator within 14 days of receipt of notification from USEPA.

11.2.6 In the case of Section 11.2.4.2 or 11.2.4.3, if new Standard Operating Procedures (SOPs) are required to be written, or if existing SOPs are required to be rewritten or amended because of deficiencies and subsequent corrective action implemented by the Contractor, the Contractor shall write/amend the SOPs per the requirements listed in Exhibit E, Section 6.

11.2.7 A Remedial QB Audit is a unique analytical Case containing only QB samples. A Remedial QB Audit may be scheduled by the USEPA OSRTI ASB with the Contractor(s) for any of the following reasons: unacceptable PE sample performance, unacceptable QB sample performance, and/or major change in the laboratory (e.g., relocation, new owner, or high turn-over of key personnel). The Contractor shall be on Contracting Officer (CO) Hold until the Remedial QB Audit package is submitted. Sections 11.2.2 through 11.2.7 apply to the Remedial QB Audit process.

11.2.8 The Contractor shall be notified by the USEPA Contracting Officer concerning agreement or disagreement with the proposed remedy for unacceptable performance.

11.3 Incentives/Sanctions

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

12.0 ON-SITE LABORATORY QUALITY ASSURANCE (QA) MONITORING EVALUATIONS

12.1 Overview

The USEPA Regional Contract Laboratory Program Project Officer (CLP PO), the USEPA Office of Superfund Remediation and Technology Innovation (OSRTI) Analytical Services Branch Inorganic Program Manager (ASB PM), or the USEPA Contracting Officer's authorized representative will conduct an on-site laboratory evaluation. On-site laboratory evaluations are carried out to monitor the Contractor's ability to meet selected terms and conditions specified in the contract. The evaluation process incorporates two separate categories: Quality Assurance (QA) Evaluation and Evidentiary Audit.

12.2 Quality Assurance On-Site Evaluation

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

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

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

12.2.2 Prior to an on-site evaluation, various documentation pertaining to performance of the specific Contractor is integrated into a profile package for discussion during the evaluation. Items that may be included are: previous on-site reports; Quarterly Blind (QB) and/or PE sample scores results; Regional review of data; Contractor performance information provided by the Region; data audit reports; results of Contract Compliance Screening (CCS); and data trend reports.

12.3 Evidentiary Audit

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

12.3.1 Procedural Audit. The Contractor shall perform analysis of PE sample(s) in the presence of the USEPA designated team during the procedural audit. The procedural audit will be comprised of everything from sample receipt to data package assembly and completion. This includes the review and examination of actual SOPs and accompanying documentation for the following laboratory operations: sample receiving, sample storage, sample identification, sample security, sample tracking (from receipt to completion of analysis), analytical project file organization and assembly, and proper disposal of samples and cogenerated wastes.

12.3.2 Written SOPs Audit. The written SOPs audit consists of review and examination of the written SOPs to determine if they are accurate and complete for the following laboratory operations: sample receiving, sample storage, sample identification, sample security, sample tracking (from receipt to completion of analysis), and analytical project file organization and assembly.

12.3.3 Analytical Project File Evidence Audit. The analytical project file evidence audit consists of review and examination of the analytical project file documentation. The auditors review the files to determine:

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

12.4 Discussion of the On-Site Team's Findings

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

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

12.5 Incentives/Sanctions

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

13.0 ELECTRONIC DATA QUALITY ASSURANCE (QA) MONITORING AUDITS

13.1 Overview

Periodically, USEPA requests the instrument electronic data from Contractors for a specific Case in order to accomplish electronic data audits. Generally, electronic data submissions and audits are requested for the following reasons.

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

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

13.1.2 The Contractor shall store all raw and processed electronic analytical data in the appropriate instrument manufacturer's format, uncompressed, and with no security codes. The data shall include all necessary data files for a complete reconstruction of the previously submitted hardcopy and electronic deliverable data package. 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 instrument electronic data shall include data for all samples and all QC samples, including but not limited to: blanks, matrix spikes, post-digestion spikes, analytical spikes, duplicates, serial dilutions, Laboratory Control Samples (LCSs), Interference Check Samples (ICSs), tunes, initial calibrations and verifications, and Continuing Calibration Verifications (CCVs). In addition, the Contractor shall supply raw data for the Critical Level (L_c) and Limit of Detection (L_d) calculations which are used to set the L_c and L_d values for the quarter in which the Sample Delivery Group (SDG) was analyzed. The Contractor shall maintain a reference logbook of data files of EPA sample number, calibration data, standards, blanks, spikes, and duplicates. The logbook shall include EPA sample numbers, identified by Case and SDG.

13.1.3 The Contractor is required to retain the instrument electronic data for three years after submission of the reconciled Complete SDG File. Electronic media shipped to the USEPA designated recipient must be fully usable by the recipient. Compact Discs (CDs) or DVDs may be used. Alternative means for delivery of electronic data may be utilized by the Contractor upon prior written approval by USEPA. When submitting electronic instrument data to USEPA, the following materials shall be delivered in response to the request.

13.1.3.1 All associated raw data files for all analytical samples and all QC samples. For example, files for ICP should include raw or background corrected intensities and mercury and cyanide files should include raw absorbances or integrated areas.

13.1.3.2 All processed data files and quantitation output files associated with the raw data files described in Section 13.1.3.1.

13.1.3.3 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.

13.1.3.4 All Contractor-generated Inductively Coupled Plasma - Atomic Emission Spectrometer (ICP-AES)/ICP - Mass Spectrometer (ICP-MS) interference correction files must be submitted.

13.1.3.5 A copy of the Contractor's reference logbook relating data files to EPA sample number, calibration data, standards, blanks, spikes, and duplicates. The logbook shall include EPA sample numbers and laboratory file identifiers for all samples, blanks, and standards, identified by Case and SDG.

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

13.1.3.7 A copy (hardcopy) of the completed Sample Data Package.

13.1.3.8 A statement attesting to the completeness of the electronic instrument data submission signed and dated by the Contractor's laboratory manager. The Contractor shall also provide a statement attesting that the data reported have not been altered in any way. These statements shall be part of a Cover Sheet that includes the following information relevant to the data submission:

- Contractor name;
- Date of submission;
- Case number;
- SDG number;
- Instrument make and model number for each instrument;
- Instrument operating software name and version number;
- Data software name and version used for acquisition, re-quantitation, and hardcopy/report generation;
- Data system computer;
- System operating software;
- Data system network;
- Data backup software;
- Data backup hardware;
- Media type and volume of data (in MB) backed up; and
- Names and telephone numbers of two Contractor contacts for further information regarding the submission.

13.2 Submission of the Instrument Electronic Data

Upon request of the USEPA Regional Contract Laboratory Program Project Officer (CLP PO), the Contractor shall send the required instrument electronic data and all necessary documentation to the USEPA designated recipient [e.g., Quality Assurance Technical Support (QATS)] within 7 days of notification.

NOTE: The instrument electronic data shall be shipped according to the procedures in Exhibit F.

13.3 Responding to the Electronic Data Audit Report

After completion of the electronic data audit, USEPA will send a copy of the electronic data audit report to the Contractor or may discuss the electronic data audit report at an on-site laboratory evaluation. In a detailed letter to the USEPA Regional CLP PO, 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 or the on-site laboratory evaluation.

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

13.4 Incentives/Sanctions

The Contractor shall submit to electronic data audits and adhere to the requirements specified in this section. Resubmission and correction of electronic data will ensure that the end user is reviewing contractually compliant data described in the ISM01.X contract. If the Contractor fails to adhere to the requirements listed in this section, the Contractor will be in noncompliance with the contract and may be subjected to sanctions as described in the contract.

14.0 DATA MANAGEMENT PERFORMANCE REQUIREMENTS

14.1 Overview

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

14.1.2 Data manually entered from hardcopy shall be subject to QC checks and the error rates estimated. Systems should prevent entry of incorrect or out-of-range data and alert data entry personnel of errors. In addition, data entry error rates shall be estimated and recorded on a monthly basis by re-entering a statistical sample of the data entered and calculating discrepancy rates by data element.

14.2 Documenting Data Changes

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

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

14.3 Lifecycle Management Procedures

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

14.3.1 A software test and acceptance plan including test requirements, test results and acceptance criteria shall be developed, followed, and available in written form.

14.3.2 System changes shall not be made directly to production systems generating deliverables. Changes shall be made first to a development system and tested prior to implementation.

14.3.3 Each version of the production system will be given an identification number, date of installation, and date of last operation and will be archived.

14.3.4 System and operations documentation shall be developed and maintained for each system. Documentation shall include a user’s manual and an operations and maintenance manual.

14.3.5 This documentation shall be available for on-site review and/or upon written request by the USEPA Regional Contract Laboratory Program Project Officer (CLP PO) or the USEPA OSRTI Analytical Services Branch (ASB) Inorganic Program Manager (ASB PM).

14.4 Personnel Responsibilities

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

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

15.0 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 E.
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 E, Section 7.0, and SMO data review will be used to monitor reporting electronic deliverables.
Exhibit C: Inorganic Target Analyte List with Contract Required Quantitation Limits	Target Analyte List with Contract Required Quantitation Limits	Performance standards are outlined in Exhibit C, Section 1.0.	QA monitoring plan is outlined in Exhibit E.
Exhibit D: Analytical Methods	ICP-AES requirements are outlined in Exhibit D, Part A, Sections 1.0 through 8.0, 14.0, and 15.0.	Performance standards are outlined in Exhibit D, Part A, Sections 9.0 through 11.0.	QA monitoring plan is outlined in Exhibit D, Part A, Section 12.0, and Exhibit E.
	ICP-MS requirements are outlined in Exhibit D, Part B, Sections 1.0 through 8.0, 14.0, and 15.0.	Performance standards are outlined in Exhibit D, Part B, Sections 9.0 through 11.0.	QA monitoring plan is outlined in Exhibit D, Part B, Section 12.0, and Exhibit E.
	Mercury requirements are outlined in Exhibit D, Part C, Sections 1.0 through 8.0, 14.0 and 15.0.	Performance standards are outlined in Exhibit D, Part C, Sections 9.0 through 11.0.	QA monitoring plan is outlined in Exhibit D, Part C, Section 12.0, and Exhibit E.
	Cyanide requirements are outlined in Exhibit D, Part D, Sections 1.0 through 8.0, 14.0, and 15.0.	Performance standards are outlined in Exhibit D, Part D, Sections 9.0 through 11.0.	QA monitoring plan is outlined in Exhibit D, Part D, Section 12.0, and Exhibit E.

SOW Reference	Performance Requirements	Performance Standards	QA Monitoring Plan
Exhibit E: Contract Laboratory Program Quality Assurance Monitoring Plan	General QA/QC Requirements	As outlined in Exhibit D, Quality Control sections.	QA Management Plan is outlined in Exhibit E, Section 5.0.
	Quality Assurance Management Plan	As outlined in Exhibit E, Sections 5.1.1 and 5.1.2, a written QA Management Plan shall be used to ensure acceptable data production of known and documented quality.	USEPA will review and approve the QA Management Plan.
	Standard Operating Procedures	Performance standards are outlined in Exhibit E, Sections 6.0 through 6.4, and must be performed as stated.	SOPs will be reviewed by USEPA during Pre-Award, on-site audits, after modifications are made and randomly, as deemed appropriate.
	Contract Compliance Screening	Performance standards are outlined in Section E.2 of the ISM01.X IFB and must be performed as stated.	The sample data package will be evaluated against the technical and completeness requirements of the contract.
	Analytical Standards	Performance standards are outlined in Exhibit E, Sections 8.0 through 8.5, and must be performed as stated.	Randomly, USEPA will review analytical standards verification and preparation documentation, as deemed appropriate.
	Data Package Audits	Performance standards are outlined in Exhibit E, Sections 9.0 through 9.2.	Data package audits are performed by USEPA to evaluate technical quality of the hardcopy raw data, QA, and adherence to contractual requirements.
	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 E, Section 10.0	Regional validation and/or SMO data review reports are generated for all data packages.

SOW Reference	Performance Requirements	Performance Standards	QA Monitoring Plan
Exhibit E: Contract Laboratory Program Quality Assurance Monitoring Plan (Con't)	Proficiency Testing	Performance standards are outlined in Exhibit E, Sections 11.0 through 11.2, and must be performed as stated.	Acceptable QB scores will assist in monitoring contractor performance as defined in Exhibit E, Sections 11.2.4.1 through 11.2.4.3, and 11.2.8.
	On-Site Laboratory Evaluations	Performance standards are outlined in Exhibit E, Sections 12.0 through 12.4.	USEPA will evaluate the results from quality assurance and evidentiary on-site audits as defined in Exhibit E, Sections 12.2.1 through 12.3.3, to assist in monitoring the contractor.
	Electronic Data Audits	Performance standards are outlined in Exhibit E, Sections 13.0 through 13.3.	CCS in Exhibit E, Section 7.0, will be used to monitor electronic deliverables.
	Data Management	Performance standards are outlined in Exhibit E, Sections 14.0 through 14.4, and must be performed as stated.	USEPA will monitor data management practices during quality assurance and evidentiary on-site audits.
Exhibit F: Chain-of-Custody, Document Control and Written Standard Operating Procedures	Standard Operating Procedures	Performance standards are outlined in Exhibit F, Sections 2.0 through 2.7.	SOPs will be reviewed by USEPA during Pre-Award, on-site audits, after modifications are made, and randomly as deemed appropriate.
	Written Standard Operating Procedures	Performance standards are outlined in Exhibit F, Sections 3.0 through 3.7.	SOPs will be reviewed by USEPA during Pre-Award, on-site audits, after modifications are made, and randomly as deemed appropriate.
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 E, Section 7.0, will be used to monitor electronic deliverables.

EXHIBIT F

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

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Exhibit F – Chain-of-Custody, Document Control and
Written Standard Operating Procedures

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1.0 INTRODUCTION

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

1.1 Purpose of Evidence Requirements

The purpose of the evidence requirements include:

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

2.0 STANDARD OPERATING PROCEDURES

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

2.1 Sample Receiving

2.1.1 The Contractor shall designate a sample custodian responsible for receiving USEPA samples.

2.1.2 The Contractor shall designate a representative to receive USEPA samples in the event that the sample custodian is not available.

2.1.3 Upon receipt, the condition of shipping containers and sample containers shall be inspected and recorded on Form DC-1 by the sample custodian or a designated representative.

2.1.4 Upon receipt, the condition of the custody seals (intact/broken) shall be inspected and recorded on Form DC-1 by the sample custodian or a designated representative.

2.1.5 The sample custodian or a designated representative shall verify and record on Form DC-1 the agreement or disagreement of information recorded on all documents received with samples and information recorded on sample containers.

2.1.6 The sample custodian or a designated representative shall verify and record the following information on Form DC-1 as samples are received and inspected:

- Presence or absence and condition of custody seals on shipping and/or sample containers;
- Custody seal numbers when present;
- Presence or absence of Traffic Reports/Chain of Custody Records or Packing Lists;
- Presence or absence of airbills or airbill stickers;
- Airbill or airbill sticker numbers;
- Presence or absence of sample tags;
- Sample tags listed/not listed on Traffic Reports/Chain of Custody Records;
- Condition of the sample bottles;
- Presence or absence of cooler temperature indicator bottle;
- Cooler temperature;
- Date of receipt;
- Time of receipt;
- EPA sample numbers;
- pH of all aqueous/water samples;
- Sample tag numbers;
- Assigned laboratory numbers;
- Remarks regarding condition of sample shipment, etc.;
- Samples delivered by hand; and
- Problems and discrepancies.

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

NOTE: Initials are not acceptable.

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

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

2.2 Sample Identification

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

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

2.3 Sample Security

2.3.1 The Contractor shall demonstrate that USEPA 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. (Secure areas shall be accessible only to authorized personnel).

2.3.2 The Contractor shall demonstrate security of designated secure areas.

2.3.3 The Contractor shall demonstrate the capability to track sample location and transfers within the laboratory facility.

2.4 Sample Storage

The Contractor shall designate storage areas for USEPA samples and prepared samples.

2.5 Sample Tracking and Document Control

2.5.1 The Contractor shall record all activities performed on USEPA samples.

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

2.5.3 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.

2.5.4 The laboratory name shall be identified on preprinted laboratory documents.

2.5.5 Each laboratory document entry shall be dated with the month/day/year (e.g., 01/01/2007) and signed by the individual(s) responsible for performing the recorded activity at the time the activity is recorded.

2.5.6 Notations on laboratory documents shall be recorded in ink.

2.5.7 Corrections to laboratory data reporting forms and raw data shall be made by drawing single lines through the errors and entering the correct information. Information shall not be obliterated or rendered unreadable. Corrections and additions to information shall be signed (or initialed) and dated.

2.5.8 Unused portions of laboratory documents shall be lined-out.

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

2.5.10 Instrument-specific run logs shall be maintained to enable the reconstruction of run sequences.

2.5.11 Logbook entries shall be in chronological order.

2.5.12 Logbook entries shall include only one SDG per page, except in the events where SDGs "share" Quality Control (QC) samples (e.g., instrument run logs and extraction logs).

2.5.13 Each page in bound and unbound logbooks shall be dated (month/day/year) and signed (no initials) at the bottom by the individual recording the activity (if a single entry is made on a page) or by the last individual recording information on the page (if multiple entries are on the same page).

2.5.14 Information inserted into laboratory documents shall be affixed permanently in place. The individual responsible for inserting information shall sign and date across the insert and logbook page at the time information is inserted.

2.5.15 The Contractor shall document disposal or retention of USEPA samples, remaining portions of samples, and prepared samples.

2.6 Computer-Resident Sample Data Control

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

2.6.2 The Contractor shall make changes to electronic data in a manner which ensures that the original data entry is preserved, the editor is identified, and the revision date is recorded.

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

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

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

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

2.6.5.2 Access to the electronic data collection system functions shall be limited to authorized personnel through utilization of software security techniques (e.g., log-ons or restricted passwords).

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

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

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

2.6.8 The Contractor shall maintain the archives of electronic data and necessary software in a secure location. (Secure areas shall be accessible only to authorized personnel.)

2.7 Complete SDG File (CSF) Organization and Assembly

2.7.1 The Contractor shall designate a document control officer responsible for the organization and assembly of the CSF.

2.7.2 The Contractor shall designate a representative responsible for the organization and assembly of the CSF in the event that the document control officer is not available.

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

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

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

2.7.6 Documents relevant to each SDG including, but not limited to, the following shall be included in the CSF for Stage 2b deliverables:

- logbook pages;
- bench sheets;
- screening records;
- preparation records;
- repreparation records;
- analytical records;
- re-analysis records;
- records of failed or attempted analysis;
- custody records;
- sample tracking records;
- raw data summaries;
- computer printouts;
- correspondence;
- FAX originals;
- library search results; and
- other.

2.7.7 The document control officer or a designated representative shall ensure that sample tags are encased in clear plastic bags before placing them in the CSF.

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

2.7.9 Original documents which include information relating to more than one SDG (e.g., Traffic Reports/Chain of Custody Records, calibration logs) shall be filed in the CSF of the lowest SDG number, and copies of these originals shall be placed in the other CSF(s). The document control officer or a designated representative shall record the following statement on the copies in (indelible) dark ink:

COPY
ORIGINAL DOCUMENTS ARE INCLUDED IN CSF _____

_____
Signature

_____
Date

2.7.10 All CSFs shall be submitted with a completed Form DC-2. All resubmitted CSFs shall be submitted with a new or revised Form DC-2.

2.7.11 Each item in the CSF and resubmitted CSFs shall be inventoried and assembled in the order specified on Form DC-2. Each page of the CSF shall be stamped with a sequential number. Page number ranges shall be recorded in the columns provided on Form DC-2. Intentional gaps in the page numbering sequence shall be recorded in the "Comments" section on Form DC-2. When inserting new or inadvertently omitted documents, the Contractor shall identify them with unique accountable numbers. The unique accountable numbers and the locations of the documents shall be recorded in the "Other Records" section on Form DC-2.

2.7.12 Before shipping each CSF, the document control officer or a designated representative shall verify the agreement of information recorded on all documentation and ensure that the information is consistent and the CSF is complete.

2.7.13 The document control officer or a designated representative shall document the shipment of deliverable packages including what was sent, to whom, the date, and the carrier used.

2.7.14 Shipments of deliverable packages, including resubmittals, shall be sealed with custody seals by the document control officer or a designated representative in a manner such that opening the packages would break the seals.

2.7.15 Custody seals shall be signed and dated by the document control officer or a designated representative when sealing deliverable packages.

3.0 WRITTEN STANDARD OPERATING PROCEDURES

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

3.1 Sample Receiving

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

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

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

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

3.1.2.3 The presence or absence of the following documents/items accompanying the sample shipment is verified and recorded on Form DC-1 by the sample custodian or a designated representative:

- Custody seals;
- Traffic Reports/Chain of Custody Records or Packing Lists;
- Airbills or airbill stickers;
- Sample tags; and
- Cooler temperature indicator bottle.

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

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

- Custody seal numbers, when present;
- Airbill or airbill sticker numbers;
- Sample tag numbers listed/not listed on Traffic Reports/Chain of Custody Records;
- Condition of sample bottles;
- Cooler temperature;
- Date of receipt;
- Time of receipt;
- EPA sample numbers;
- pH of all aqueous/water samples;
- Sample tag numbers;
- Assigned laboratory numbers;
- Remarks regarding condition of sample shipment, etc.;
- Samples delivered by hand; and
- Problems and discrepancies.

3.1.2.6 All accompanying forms are signed, dated, and the time is recorded, when applicable, at the time of sample receipt (e.g., Traffic Reports/Chain of Custody Records or packing lists, and airbills) by the sample custodian or a designated representative.

3.1.2.7 The Sample Management Office (SMO) is contacted to resolve problems and discrepancies including, but not limited to: absent documents; conflicting information; absent or broken custody seals; insufficient sample volume; unsatisfactory sample condition (e.g., leaking sample container); and samples not preserved to the proper pH.

3.1.2.8 The resolution of all problems and discrepancies communicated through SMO is recorded.

3.2 Sample Identification

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

3.2.2 The written SOPs for sample identification shall ensure that the procedures listed below are in use at the laboratory.

3.2.2.1 The identity of USEPA samples and prepared samples is maintained throughout the laboratory when:

- The Contractor assigns unique laboratory sample identification numbers, the written SOPs shall include a description of the procedure used to assign these numbers;

- The Contractor uses prefixes or suffixes in addition to laboratory sample identification numbers, the written SOPs shall include their definitions; and
- The Contractor uses methods to uniquely identify fractions/parameter groups and matrix type, the written SOPs shall include a description of these methods.

3.2.2.2 Each sample and sample preparation container is labeled with the SMO number or a unique laboratory sample identification number.

3.3 Sample Security

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

3.3.2 The written SOPs for sample security shall include the items listed below.

3.3.2.1 Procedures which ensure the following:

- Sample custody is maintained; and
- The security of designated secure areas is maintained.

3.3.2.2 A list of authorized personnel who have access to locked storage areas.

3.4 Sample Storage

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

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

3.5 Sample Tracking and Document Control

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

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

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

3.5.2.2 Procedures which ensure the following:

- All activities performed on USEPA samples are recorded;
- Titles which identify the activities recorded are printed on each page of all laboratory documents;
- Information recorded in columns is identified with column headings;
- Reviewers' signatures are identified on laboratory documents;
- The laboratory name is included on preprinted laboratory documents;

- Laboratory document entries are signed and dated with the month/day/year (e.g., 01/01/2007);
- Entries on all laboratory documents are recorded in ink;
- Corrections and additions to laboratory documents are made by drawing single lines through the errors, entering the correct information, and initialing and dating the new information;
- Unused portions of laboratory documents are lined-out;
- Pages in bound and unbound logbooks are sequentially numbered;
- Instrument-specific run logs are maintained to enable the reconstruction of run sequences;
- Logbook entries are recorded in chronological order;
- Entries are recorded for only one SDG on a page, except in the event where SDGs "share" Quality Control (QC) samples (e.g., instrument run logs and extraction logs);
- Each page in bound and unbound logbooks shall be dated (month/day/year) and signed (no initials) at the bottom by the individual recording the activity (if a single entry is made on a page) or by the last individual recording information on the page (if multiple entries are on the same page);
- Information inserted in laboratory documents is affixed permanently, signed, and dated across the insert; and
- The retention or disposal of USEPA samples, remaining portions of samples, and prepared samples is documented.

3.6 Computer-Resident Sample Data Control

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

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

3.6.2.1 Procedures which ensure the following:

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

- Off-site backup and storage of electronic data is maintained.

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

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

3.7 CSF Organization and Assembly

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

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

- Documents relating to the CSF are maintained in a secure location.
- All original laboratory forms and copies of SDG-related logbook pages are included in the CSF.
- Laboratory documents are photocopied in a manner to provide complete and legible replicates.
- All documents relevant to each SDG are included in the CSF.
- Sample tags are encased in clear plastic bags by the document control officer or a designated representative before placing them in the CSF.
- The CSF is organized and assembled on an SDG-specific basis.
- Original documents which contain information relating to more than one SDG are filed in the CSF of the lowest SDG and copies are referenced to originals in the event that an original document contains information relating to more than one SDG.
- Each CSF is submitted with a completed Form DC-2, and resubmitted CSFs are submitted with a new or revised Form DC-2.
- Each page of the CSF is stamped with a sequential number and the page number ranges are recorded in the columns provided on Form DC-2. Intentional gaps in the page numbering sequence are recorded in the "Comments" section of Form DC-2. Inserted documents are recorded in the "Other Records" section of Form DC-2.
- Consistency and completeness of the CSF are verified by the document control officer or a designated representative.
- Shipments of deliverable packages are documented by the document control officer or a designated representative.
- Deliverable packages are shipped by the document control officer or a designated representative using custody seals in a manner such that opening the packages would break the seals.
- Custody seals are signed and dated by the document control officer or a designated representative before placing them on deliverable packages.

EXHIBIT G

GLOSSARY OF TERMS

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ABSORBANCE - A measure of the decrease in incident light passing through a sample into a detector. It is defined mathematically as:

Absorbance

$$A = -\log \frac{I}{I_O}$$

WHERE, I = Radiation intensity of a sample.
I_o = Radiation intensity of a blank.

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 introduction of the sample, standard, or blank into the analysis system.

ANALYTE - The element or ion an analysis seeks to determine; the element of interest.

ANALYTICAL REFERENCE STANDARD - Standards purchased from private chemical supply houses 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, Initial Calibration Verification (ICV), Initial Calibration Blank (ICB), Continuing Calibration Verification (CCV), Continuing Calibration Blank (CCB), and tunes. Note the following are all defined as analytical samples: undiluted and diluted samples (USEPA and non-USEPA), matrix spike samples, duplicate samples, serial dilution samples, analytical spike samples, post-digestion spike samples, Interference Check Samples (ICSs), Laboratory Control Samples (LCSs), Performance Evaluation (PE) samples, Preparation Blanks, and cyanide MIDRANGE samples.

ANALYTICAL SEQUENCE - The actual instrumental analysis of the samples from the time of instrument calibration through the analysis of the final Continuing Calibration Verification (CCV) and Continuing Calibration Blank (CCB). All sample analyses during the analytical sequence are subject to the QC protocols set forth in Exhibits D and E of this contract unless otherwise specified in the individual methods.

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

ANALYTICAL SPIKE - A spike that is fortified just prior to analysis by adding a known quantity of the analyte to an aliquot of the prepared sample. (Also called post digestion spike)

ASTM - ASTM International. A developer and provider of voluntary consensus standards.

AUTOZERO - Zeroing the instrument at the proper wavelength. It is equivalent to running a standard blank with the absorbance set at zero.

BACKGROUND CORRECTION - A technique to compensate for variable background contribution to the instrument signal in the determination of trace elements.

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

BLANK - An analytical sample designed to assess specific sources of contamination. See the individual definitions for types of blanks.

CALIBRATION - The establishment of an analytical curve based on the absorbance, emission intensity, or other measured characteristic of known standards. The calibration standards must be prepared using the same type of reagents or concentration of acids as used in the sample preparation.

CALIBRATION BLANK - A blank solution containing all of the reagents and in the same concentration as those used in the analytical sample preparation. This blank is not subjected to the preparation method for ICP-AES and ICP-MS, but is digested for mercury and cyanide.

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).

CONCENTRATION LEVEL (low or medium) - For inorganics analysis, low or medium level is defined by the appropriate designation by the sampler on the Traffic Report/Chain of Custody Record.

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. However, all parameters being measured by the particular system must be represented in this standard and the standard must have the same matrix (i.e., the same amount of reagents and/or preservatives) as the samples. The CCV should have a concentration in the middle of the calibration range and shall be run at the beginning of the day prior to the analysis of samples, and every 2 hours (1 hour for Hg and CN).

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

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

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.

CRITICAL LEVEL (L_c) - An estimate of the smallest amount or concentration of analyte that can be distinguished from a blank at 99% confidence. Values above this level should not represent false positives.

CYANIDE (Total) - Cyanide ion and complex cyanides converted to hydrocyanic acid (HCN) by reaction in a reflux system of a mineral acid in the presence of magnesium ion.

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 = 2007, 2008, 2009 etc.

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

DIGESTION LOG - An official record of the sample preparation (digestion).

DIRECT ANALYSIS - Analysis of a sample, standard, or blank that has not been taken through a preparation procedure (digestion or distillation).

DISSOLVED METALS - Analyte elements in an aqueous/water sample which will pass through a 0.45 micrometer (μm) filter.

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

DUPLICATE - A second aliquot of a sample that is treated the same as the original sample in order to determine the precision of the method.

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

FIELD QC - Any Quality Control (QC) sample 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.

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 analysis.

Holding time = (sample analysis date - sample receipt date)

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.

INDUCTIVELY COUPLED PLASMA-ATOMIC EMISSION SPECTROSCOPY (ICP-AES) – A technique for the simultaneous or sequential multi-element determination of elements in solution. The basis of the method is the measurement of atomic emission by an optical spectroscopic technique. Characteristic atomic line emission spectra are produced by excitation of the sample in a radio frequency inductively coupled plasma.

INDUCTIVELY COUPLED PLASMA-MASS SPECTROMETRY (ICP-MS) - A technique for the multi-element determination of elements in solution. The basis of the technique is the detection of atomic ions produced by an ICP and sorted by mass-to-charge (m/z) ratio.

IN-HOUSE - At the Contractor's facility.

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

INITIAL CALIBRATION VERIFICATION (ICV) - Solution(s) prepared from stock standard solutions, metals, or salts obtained from a source separate from that utilized to prepare the calibration standards. The ICV is used to verify the concentration of the calibration standards and the adequacy of the instrument calibration. The ICV should be traceable to NIST or other certified standard sources when USEPA ICV solutions are not available.

INJECTION - Introduction of the analytical sample into the instrument excitation system to measure absorbance, emission, or concentration of an analyte. May also be referred to as exposure.

INSUFFICIENT QUANTITY - When there is not enough volume (aqueous/water sample) or weight (soil/sediment) to perform any of the required operations: sample analysis, percent solids, etc. Exhibit D provides guidance for addressing this problem.

INTERFERENCE CHECK SAMPLE (ICS) - A solution containing both interfering and analyte elements of known concentration that can be used to verify background and interelement correction factors.

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

INTERNAL STANDARD - A non-target element added to a sample at a known concentration after preparation but prior to analysis. Instrument responses to internal standards are monitored as a means of assessing overall instrument performance.

LABORATORY - Synonymous with Contractor as used herein.

LABORATORY CONTROL SAMPLE (LCS) - A sample spiked at a known concentration. LCSs are analyzed using the same sample preparation, reagents, and analytical methods employed for the USEPA samples received.

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 VTSR (Validated Time of Sample Receipt).

LIMIT OF DETECTION (L_d) - An estimate of the smallest value that protects against false negatives; the smallest value that must be present to be detected. The lowest possible value for the confident reporting of a non-detect.

LIMIT OF QUANTITATION (L_q) - An estimate of the lowest concentration that produces quantitatively reliable results. For the purposes of this contract, this is defined as two times the Limit of Detection.

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, wipe, or small (e.g., 37 mm) air filter. Matrix is <u>not</u> synonymous with phase (liquid or solid).

MATRIX EFFECT - In general, the effect of particular matrix constituents.

MATRIX SPIKE - Aliquot of a sample (aqueous/water or soil/sediment) fortified (spiked) with known quantities of specific compounds and subjected to the entire analytical procedure to indicate the appropriateness of the method for the matrix by measuring recovery.

PERCENT DIFFERENCE (%D) - As used in this Statement of Work (SOW) and elsewhere to compare two values. The difference between the two values divided by one of the values.

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

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

PREPARATION BLANK - An analytical control that contains reagent water and reagents, which is carried through the entire preparation and analytical procedure.

PREPARATION LOG - An official record of the sample preparation (digestion or distillation).

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

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".

REFERENCE MATERIAL - Standards, typically provided by USEPA, used to verify method and instrument performance. Examples include Initial Calibration Verification (ICV) standards, and Interference Check Solution (ICS) standards.

RELATIVE PERCENT DIFFERENCE (RPD) - As used in this Statement of Work (SOW) and elsewhere to compare two values, 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).

REPRESENTATIVE - Alternate or designee who has the knowledge and authority to perform a specific task.

ROUNDING RULES - If the figure is greater than or equal to 5, round up, otherwise round down. As an example, 11.443 is rounded down to 11.44 and 11.455 is rounded up to 11.46. 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 forms instructions (Exhibit B) for exceptions.

RUN - A continuous analytical sequence consisting of prepared samples and all associated Quality Assurance (QA) measurements as required by the contract Statement of Work (SOW). A run begins with the instrument calibration or tune.

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 (3 calendar day period for 7 day turnaround) 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 and/or sample fractions assigned to an SDG must have been scheduled under the same contractual turnaround time. Preliminary Results have **no impact** on defining the SDG.

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 USEPA.

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

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

SENSITIVITY - The slope of the analytical curve (i.e., functional relationship between instrument response and concentration).

SERIAL DILUTION - The dilution of a sample by a factor of five. When corrected by the dilution factor, the diluted sample must agree with the original undiluted sample within specified limits. Serial dilution may reflect the influence of interferents.

SOIL - Synonymous with soil/sediment as used herein.

SOP - Standard Operating Procedure.

SOW - Statement of Work.

STANDARD ANALYSIS - An analytical determination made with known quantities of target analytes.

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

TARGET ANALYTE LIST (TAL) - A list of Inorganic Analytes (metals and cyanide) as designated in Exhibit C.

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 USEPA sample identification form filled out by the sampler, which accompanies the sample during shipment to the laboratory and is used for documenting sample identity, sample chain-of-custody, and sample receipt by the laboratory.

TUNE - Analysis of a solution containing a range of isotope masses to establish ICP-MS accuracy, resolution, and precision prior to calibration.

USEPA OSRTI ASB INORGANIC PROGRAM MANAGER (ASB PM) - The USEPA, OSRTI ASB Official who manages the CLP Inorganic Program.

USEPA REGIONAL CLP PROJECT OFFICER (CLP PO) - The Regional USEPA official responsible for monitoring laboratory performance and/or requesting analytical data or services from a CLP laboratory.

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 Traffic Report/Chain of Custody Record.

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