



**Statement of Work
For Analytical Measurements**

**GENERAL LABORATORY
REQUIREMENTS**

MODULE GR01-B.3

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GENERAL REQUIREMENTS MODULE

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INTRODUCTION

The Rocky Flats Environmental Technology Site (Site) Statement Of Work For Analytical Measurements (SOW) defines requirements for the determination of organic, metal, water quality, radiochemical, geotechnical, industrial hygiene, bioassay, and other parameters in samples collected at or related to the Site. The complete SOW is composed of several modules, most of which are listed in Table 1. Note that this document, GR01, is one of the modules listed in Table 1.

The Site SOW is composed of several modules, a limited number of which are required for performing work in a specific analytical discipline. The General Laboratory Requirements Module, GR01, provides general technical and administrative requirements common to all analyses performed for the Site. The General Requirements for Electronic Data Deliverables Module, GR02, provides requirements for the electronic delivery of data. Other SOW modules provide parameter-specific analytical, quality assurance/quality control (QA/QC), reporting, and general requirements specific to stated analytical tasks. One or more Parameter Specific Analytical (PSA) Module(s), together with the general requirements modules, are required to comprise an SOW for an individual analysis type.

Where possible, SOW modules incorporate industry standard methods and protocols by reference. In some cases, requirements in these referenced methods are augmented or clarified by SOW modules. Typical references include U. S. Environmental Protection Agency (EPA) Contract Laboratory Program (CLP) Statements of Work, EPA Test Methods for Evaluating Solid Waste (SW-846), EPA methods for wastewater monitoring, and ASTM methods.

General and PSA Modules included in the site SOW are listed in Table 1. The CTR will develop additional modules as required to meet Site analytical requirements. Modules are identified by their two-letter descriptor, module number, and version designation. For example, this module, General Requirements Module 1, Version A, is identified as GR01-A. Version designations will be usually be omitted in module references within the SOW. Instructions contained in PSA Module(s) shall supersede the GR01 module if the requirements do not agree.

TABLE 1 SOW MODULES

Category	Module Title	Module ID
General Requirements	General Laboratory Requirements	GR01
	Electronic Data Deliverables	GR02
Radiochemistry	Isotopic Determinations by Alpha Spectrometry	RC01
	Tritium Analysis by Liquid Scintillation Counting	RC02
	On-Site Determination of Radionuclides by Gamma Spectrometry	RC03
	Gross Alpha and Gross Beta Analysis by Gas Flow Proportional Counting	RC04
	Radiometric Strontium by Gas Proportional Counting	RC05
	Total Uranium by Laser Induced Phosphorescence	RC06
	Radium-226 by Radon Emanation	RC07
	Radium-228	RC08
	General Gamma Spectroscopy	RC09
Standard Services	Volatile Organics	SS01
	Semivolatile Organics	SS02
	PCB/Pesticides	SS03
	Dioxins/Furans	SS04
	Inorganic Metals	SS05
	Water Quality Parameters	SS06
	Biological and Taxonomic Parameters	SS07
	Waste Characteristics	SS08
	Herbicides	SS09
	EPA Method TO-14	SS10
	Whole Effluent Toxicity Testing	SS11
Non-routine Services	Beryllium Filters	NR01
Geotechnical and Geosynthetics	Geotechnical and Geosynthetics Analyses	GG01
Bioassay Services	General Bioassay Services	BA01
	Nuclear Accident Dosimetry (NAD Program Analyses)	BA02
Industrial Hygiene	Industrial Hygiene - General Chemistry	IH01
	Industrial Hygiene - Asbestos	IH02
	Industrial Hygiene - Breathing Air	IH03
Safe Drinking Water	Safe Drinking Water - General Chemistry	DW01
	Safe Drinking Water - Radiochemistry	DW02
	Safe Drinking Water/Surface Water - Microbiology	DW03

EXHIBIT A

SUMMARY OF REQUIREMENTS

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GENERAL LABORATORY REQUIREMENTS

SUMMARY OF REQUIREMENTS

1. GENERAL REQUIREMENTS AND INFORMATION

This Exhibit contains general requirements and information common to all modules under this Statement of Work (Section 1) along with general requirements and information for each analytical category (Sections 2 through 7). PSA Module(s) contain additional method-specific requirements including required analytical parameters, detection limits, and performance criteria.

- 1.1. **SOW Compliance:** Sample analyses shall meet all the requirements specified in this Statement of Work (SOW). That is, compliance to the General Requirements modules and all applicable PSA Module(s) is required. If necessary, the Laboratory shall modify its standard methods to comply in all respects to the SOW requirements and submit the modified methods for approval when requested by the CTR. All work performed under this SOW shall be done by the Laboratory under the guidance of the CTR, or if applicable, by designated agents in accordance with contractual agreements
- 1.2. **Terms and Acronyms:** GR01 Exhibit G is a glossary of terms and acronyms. The Laboratory shall use the glossary meaning when a term is used in the text without definition.
- 1.3. **Key Identifiers:** The terms *Report Identification Number* and *Analytical Batch* are key to this SOW. GR01 Exhibit G gives precise definitions of these terms.
- 1.4. **Potential Hazards Advisement:** The samples to be analyzed by the Laboratory are from the Rocky Flats Environmental Technology Site and may contain potentially hazardous radioactive, inorganic, biological, and/or organic materials. The Laboratory should be aware of the potential hazards associated with the handling and analysis of these samples.
- 1.5. **Nuclear Regulatory Commission (NRC) License:** Laboratories seeking eligibility to receive radioactive or mixed radioactive/hazardous samples shall possess a valid NRC License or a State Radioactive Materials License for radionuclides regulated under the Atomic Energy Act, or must be an exempt facility as designated by a Federal Government Agency. The Laboratory shall provide suitable NRC- or State-licensed facilities to handle analyses of samples that have elevated activity levels. All analyses of radioactive samples, as well as radiochemical analyses, shall be conducted in licensed or exempted facilities. The Laboratory shall notify the CTR of all existing limits on receipt, amounts, and radionuclides that the Laboratory is authorized to handle. Samples without elevated activity levels may be analyzed in nonlicensed facilities. Licenses shall be submitted to the CTR 21 days prior to preaward audit, submitted upon request, and made available for inspection during on-site audits and upon request.
 - 1.5.1. Licensed laboratories shall submit all amendments to their NRC (or State) License to the CTR within five days of amendment receipt.
 - 1.5.2. The Laboratory shall have a radioactive materials inventory system in place that allows a real-time inspection of their nuclear materials inventory (except exempt Federal facilities).
 - 1.5.3. Loss of the NRC license or amendments which restrict the receipt of radioactive or mixed radioactive/hazardous samples may result in a **Subcontract Termination** for these types of samples.
- 1.6. **Timelines:** Timelines given in terms of days are to be interpreted as calendar days throughout this SOW unless otherwise noted.

- 1.7. Sample Size:** The Laboratory shall specify the amount of sample (weight or volume) required to perform analytical determinations. The amount of sample required shall initially be submitted with the Laboratory's bid for services and thereafter in writing to the CTR whenever the Laboratory's analytical needs change.
- 1.8. Sample Shipments:** Sample shipments to the Laboratory's facility will be scheduled and coordinated by the CTR. The Laboratory Shipping/Receiving Officer shall communicate with the CTR by telephone or fax using appropriate documentation as necessary throughout the process of sample scheduling, shipment, analysis, and data reporting, to ensure that samples are properly processed.
- 1.8.1. Samples will routinely be shipped directly to the Laboratory through a delivery service. The Laboratory shall be available to receive sample shipments during regular working hours, and with 24 hours advance notice on weekends and holidays on an as-needed basis. As necessary, the Laboratory shall be responsible for any handling or processing required for the receipt of sample shipments, including pick-up of samples at the nearest servicing airport, bus station, or other carrier service within the Laboratory's geographical area.
- 1.8.2. If there are problems with samples (e.g., broken or leaking containers) or sample documentation/paperwork (e.g., missing, incomplete, or conflicting COC forms), the Laboratory shall immediately contact the CTR for resolution.
- 1.9. Sample Holding Time:** The sample holding time is defined as the elapsed time expressed in days from the date of sampling until the date of analysis for which sample data will be considered valid. Holding times may be exceeded only if the Laboratory has data on file that the specific types of samples under study are stable for a longer time, and the Laboratory has received a written variance from the CTR. Analyses performed outside the holding time without this variance will be considered a nonconformance to subcontract requirements.
- 1.10. Retention of Unused Sample, Extracts, and Digestates:** The Laboratory shall retain unused samples, TCLP extracts (if applicable), and semi-volatiles extracts (if applicable) for 60 days after the CTR receipt of the data. This requires the retention of samples and extracts in a secure, stable environment consistent with preservation requirements. After this time period has elapsed, the Laboratory shall contact the CTR in writing to determine the final disposal of the unused samples. Special requests to dispose of samples and/or extracts prior to the 60 days shall be made in writing to the CTR. The Laboratory shall have written approval from the CTR before any samples are disposed.
- 1.11. Multiple Phased Samples:** A sample may consist of more than one phase (e.g., water miscible, non-water miscible, and solid) contained inside appropriate receptacles. More than one container may be received for a single sample.
- 1.12. QA/QC Requirements:** All QA/QC procedures prescribed in Exhibit E of this module and the PSA Module(s) shall be strictly adhered to by the Laboratory. Good Laboratory Practice (GLP) Standards, 40 CFR 792, shall be followed.
- 1.13. Technical Audits:** The Laboratory shall be subject to routine, on-site technical audits as described in Exhibit E of this module.
- 1.14. Interlaboratory Comparison Studies:** The Laboratory shall participate in an appropriate interlaboratory comparison study as described in Exhibit E of this module.
- 1.15. Information Release:** Communication by laboratory staff of analytical results, procedures, data, or similar matters shall be performed in accordance with procedures established in this module and the

PSA Module(s). In no case shall reports, results, or raw data be released to a third party without prior written approval of the CTR, except stated otherwise in PSA Modules.

- 1.16. Electronic Data Reporting:** Electronic data reporting requirements are specified in the General Requirements for Electronic Data Deliverables Module, GR02.
- 1.17. Completeness of Deliverables:** Sample data packages and electronic data deliverables (EDDs) that are not complete or that have improperly formatted EDDs are considered noncompliant to subcontract requirements.
- 1.18. Response to Site Requests:** The Laboratory shall provide corrected sample data packages, additional information, or explanations in response to Site inspection of sample data packages. Those responses shall be in accordance with the deliverable schedule in Exhibit B.
- 1.19. Equipment and Materials:** The Laboratory shall have sufficient analytical instrumentation, equipment, and materials to meet all requirements of the SOW.
- 1.20. Organizational and Key Position Requirements**

The Laboratory organization shall be clearly structured with well-defined responsibilities for each individual in the management system. This system shall ensure that sufficient resources are maintained to perform the requirements of the SOW. Specifically, all key positions listed below and in PSA modules shall be assigned to individuals. The Laboratory shall maintain a chart or diagram illustrating the Laboratory's organizational structure and all key position assignments. The Laboratory shall provide this chart to the CTR twenty-one days prior to the preaward audit and within fourteen days following changes to key positions.

Unless otherwise noted, the following technically relevant experience may be substituted for educational requirements, such that:

- A Master's degree equals a Bachelor's degree and four years of experience
- A Bachelor's degree equals:
 - ◊ An Associate's degree and four years of experience, which equals
 - ◊ A High School diploma and eight years of experience.

The Laboratory shall provide resumes for personnel holding key positions twenty-one days prior to the preaward audit and within fourteen days of assigning personnel to key positions thereafter. Résumés shall include position description, title, education (pertinent to the duties performed for this SOW), number of years of experience (pertinent to the duties performed for this SOW), month and year hired, previous experience, and publications. An updated chart or diagram illustrating the Laboratory's new organizational structure shall accompany résumé submission.

1.20.1. Key administrative positions are identified below. Additional key technical positions are identified in the PSA Module(s). A qualifying individual may fill more than one key position unless stated otherwise in PSA Modules. Failure to maintain individuals in each Key Positions outlined in GR01 and in PSA Modules may result in a **Subcontract Termination**.

1.20.2. Laboratory Director

Responsibility:	Responsible for all aspects of the analytical laboratory.
Academic Training:	A master's degree (or equivalent) in a science discipline.
Experience:	A minimum of 6 years of laboratory experience, with at least three years of experience in a supervisory capacity.

1.20.3. Technical Supervisor

- Responsibility: Responsible for all technical efforts of an analytical laboratory section.
- Academic Training: A master's degree (or equivalent) in a science discipline.
- Experience: A minimum of four years of laboratory experience, with at least two years of experience in a supervisory position.

1.20.4. Project Manager

- Responsibility: Responsible for overall aspects of this SOW (from sample receipt through data delivery), and serves as the primary contact for the CTR.
- Academic Training: A bachelor's degree (or equivalent) in a science discipline.
- Experience: A minimum of three years of laboratory experience.

1.20.5. Quality Assurance Officer

The Quality Assurance Officer (QAO) shall be a full-time laboratory specific position. The QAO shall have direct access to management at a level where appropriate action can be effected.

- Responsibility: Responsible for assuring the Laboratory's QA Program meets all requirements of this SOW. Reports directly to upper management.
- Academic Training: A bachelor's degree (or equivalent) in a science discipline.
- Experience: A minimum of four years of laboratory experience, including at least two years of applied experience with QA principles and practices in an analytical laboratory.

1.20.6. Health and Safety Officer

- Responsibility: Responsible for overseeing the Health and Safety Program including personnel monitoring activities for hazardous, chemical, and radiological (if applicable) contaminants.
- Academic Training: A bachelor's degree (or equivalent) in a science discipline and certification in industrial hygiene. For laboratories analyzing radioactive samples, the academic training shall also include course work in radiation health and safety.
- Experience: A minimum of four years of experience in chemical safety, including at least two years of applied experience with laboratory health and safety practices. For laboratories analyzing radioactive samples, experience shall include 2 years of applied radiological health and safety practices.

1.20.7. Shipping/Receiving Officer

- Responsibility: Responsible for all shipments to and from the laboratory facility.
- Academic Training: Certification as a "Hazmat" Employee in accordance with 49 CFR 172.
- Experience: A minimum of one year of experience in the transportation of hazardous materials.

1.20.8. Information Systems Specialist

- Responsibility: Responsible for management and quality control of all aspects of the laboratory computer information systems including operation and maintenance, documentation, and training. Responsible for maintaining laboratory data base integrity, including overview of data entry, data updating, and quality control. Responsible for data and system security, backup and archiving.

- Academic Training: A bachelor's degree with four or more intermediate courses in programming, information management, database management systems, or systems requirements.
- Experience: A minimum of three years experience in data or systems management or programming including one year experience with software being utilized for analytical data management.

1.21. Laboratory Health And Safety Program

- 1.21.1. The Laboratory shall ensure that the facility condition, construction, and organization are sufficient for safe and effective analytical operations. Adequate bench space, ventilation, lighting, and temperature control shall be demonstrated.
- 1.21.2. Sample preparation for all analysis involving actual or possible hazardous or radioactive constituents shall be performed within a functional hood (125 ± 25 linear feet per minute average face velocity) or glove box.
- 1.21.3. At a minimum, the Laboratory shall develop and maintain effective programs in all of the following health and safety areas:
 - respiratory protection
 - occupational injury and illness reporting meeting the requirements of 29 CFR 1904
 - chemical hygiene and hazard communication
 - waste management
 - safety training
- 1.21.4. The Laboratory shall document exclusions that are not applicable for the facility.
- 1.21.5. The Laboratory shall provide and document safety training for all personnel.
- 1.21.6. The Health and Safety Officer shall have the responsibility and authority to stop unsafe work that may jeopardize the health of the laboratory staff and/or the environment.

1.22. Chemical Hygiene/Hazard Communication Program

- 1.22.1. The Laboratory shall have a documented Chemical Hygiene/Hazard Communication Program reflecting actual process operations.
- 1.22.2. The Laboratory shall ensure that protective apparel and safety equipment are available and compatible with the degree of protection required for the substances handled. Signs and labels clearly identifying emergency information and equipment shall be prominently posted.
- 1.22.3. The Laboratory shall routinely perform and document safety inspections for housekeeping, safety showers, eyewash stations, fire extinguisher, emergency lighting, and any other areas of concern.
- 1.22.4. The Laboratory shall maintain and document fume hood operation in compliance with ANSI/AIHA Z9.5-1992 (Laboratory Fume Hood Section) and ANSI/ASHRAE 110-1195 procedures.
- 1.22.5. The Laboratory shall meet Federal and State regulations, including radioactive material license requirements, for performing and documenting environmental monitoring of airborne concentrations and laboratory surface contamination for radioactive and highly toxic chemicals. The means for meeting these requirements shall be documented by the Laboratory.

- 1.22.6. The Laboratory shall develop and implement a spill control policy. This policy shall address spill containment, cleanup, reporting, and emergency procedures.
- 1.22.7. The Laboratory shall clearly mark or label all chemicals not in their original container.
- 1.22.8. The Laboratory shall have Material Safety Data Sheets (MSDSs) for all laboratory chemicals. MSDSs shall be readily accessible to employees.

1.23. Waste Management

- 1.23.1. The Laboratory shall develop, and implement, and maintain a Waste Management Program documenting procedures and operating conditions for the handling, storage, shipment, and disposal of hazardous and/or radioactive waste in accordance with Federal, State, and local laws and regulations.
- 1.23.2. The Laboratory shall establish and document an Effluent Monitoring Program to ensure discharges to sanitary sewers meet regulatory limits.
- 1.23.3. Unless directed otherwise by the CTR, the Laboratory shall be responsible for the proper disposal of all waste generated during the analysis of Site samples. This includes waste categorized as hazardous waste, medical waste, low-level (radioactive) waste, and mixed waste (radioactive and hazardous). Waste forms include, but are not limited to, the following:
 - The original sample (if not depleted during analysis)
 - Sample analysis residue
 - Sample extracts, digestates, and leachates
 - Excess chemicals
 - Laboratory materials contaminated by the sample (e.g., lab coats, glassware, pipette tips, planchets, and sample containers)Evidence of improper waste disposition or documentation may result in a **Subcontract Termination**.
- 1.23.4. The Laboratory shall certify the disposition and disposal location of waste generated from the analysis of Site samples and shall maintain the records as required by any applicable federal, state, and/or local laws. These records shall be available for inspection during on-site audits and upon request.
- 1.23.5. The Site will only accept the return of unused samples, partially used samples, or laboratory derived waste with written approval from the CTR.

2. RADIOCHEMISTRY CATEGORY SPECIFIC REQUIREMENTS

- 2.1. Secondary Calibration:** If an individual isotope is not available in calibrated form, the Laboratory may perform a secondary calibration for concentration and purity against a primary standard traceable to the National Institute of Standards and Technology (NIST).
- 2.2. Frequency of QC Samples:** QC samples shall be run at a frequency of one set of QC samples per 10 field samples or a minimum of one set per analytical batch unless otherwise specified in PSA modules.
- 2.3. Holding Times:** For water samples, the holding time for radiochemical analysis shall not exceed 90 days unless otherwise stated in this SOW or the COC forms. For soil and other solid matrix samples, no holding times are specified, but 90 days shall be used as a guideline for the analyses.

- 2.4. **Total Digestion/Dissolution:** Total digestion/dissolution of the aliquoted sample is required for soils, sediments, waste, waste filter socks, and air filters unless otherwise specified in a PSA Module or by the CTR.
- 2.5. **Aliquot Size Determination:** For soils, sediments, and sludges, an aliquot of the sample is taken for homogenization prior to sample preparation/analysis. The method used to determine the aliquot size shall be documented.
- 2.6. **Total vs Dissolved:** Water samples to be analyzed for dissolved radiochemistry parameters will be filtered in the field and noted as such on the COC. Water samples to be analyzed for total radiochemistry parameters shall be subjected to a total digestion/dissolution when they contain sediment/non-dissolved organic matter. If the samples are filtered in the laboratory, the filters shall be subjected to a total dissolution and quantitatively added to the water aliquot prior to analysis.
- 2.7. **Solid Preparation Blanks:** Because there are no suitable soil preparation blank materials for radiochemistry, the Laboratory shall use an aqueous blank to determine if cross-contamination from reagents or procedures affected the preparation of soil samples. **NOTE:** ASTM Type II water shall be used for the aqueous blank.
- 2.8. **Blank Subtraction:** Blank subtraction shall only be performed by the Laboratory if specified in the PSA Module(s) or upon CTR approval.

3. STANDARD SERVICES CATEGORY SPECIFIC REQUIREMENTS

- 3.1. **General Information:** Requirements for standard analytical chemistry services are stated in the SS-series modules. Nationally accepted methods such as EPA CLP SOWs, SW-846, EPA-600, NIOSH, and ASTM have been referenced to specify requirements, when possible. The PSA Modules identify minimum requirements and limitations for analytical systems used for the analysis of Site samples.
- 3.2. **CLP Forms:** For those sample data packages generated using CLP SOW methods, all applicable CLP forms associated with the analyses are to be included in the package deliverable.

EXHIBIT B

REPORTING AND DELIVERABLES REQUIREMENTS

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REPORTING AND DELIVERABLES REQUIREMENTS

1. INTRODUCTION

This Exhibit contains general reporting and deliverable requirements common to all modules under this SOW. Specific reporting and deliverable requirements are contained in PSA Modules, and the subcontract.

2. REPORTING AND DELIVERABLES REQUIREMENTS

SOW reporting and deliverable requirements are summarized in Tables B1 and B2. These tables include the schedules and distributions for each deliverable. All days are listed as calendar days from the Validated Time of Sample Receipt (VTSR) to the date the item is received by the CTR. The VTSR for composite samples is the VTSR of the last sample added to the composite. The *Reference* column in these tables contains designators that refer to modules, exhibits, and sections where more details may be found. This reference column is provided as an aid in locating requirements, but is not expected to be all-inclusive. PSA Modules may specify additional requirements.

Note: Acceptance of samples for priority or rush processing is the option of the Laboratory. Acceptance of such samples by the Laboratory shall constitute acceptance of the expedited delivery schedules listed in Table B1. Samples analyzed on a rush schedule are subject to the same technical, quality control, and completeness requirements established for non-rush samples.

TABLE B1 SCHEDULE FOR SAMPLE DATA PACKAGE DELIVERABLES

Processing	Item	Schedule	Recipient	Reference
Routine	Sample data package	31 days after VTSR	CTR	PSA Module
	EDD	31 days after VTSR	CTR	GR02
Priority	Quick-turn packet (Narrative, COC copies, and results only)	Relayed by fax 14 days after VTSR	CTR	PSA Module
	Sample data package	31 days after VTSR	CTR	PSA Module
	EDD	31 days after VTSR	CTR	GR02
Rush	Quick-turn packet (Narrative, COC copies, and results only)	Relayed by fax 3 days after VTSR	CTR	PSA Module
	Sample data package	14 days after VTSR	CTR	PSA Module
	EDD	14 days after VTSR	CTR	GR02

2.1. **Processing Designators:** Processing requirements are specified by the use of a processing designator. Analyte prescriptions are identified on the COC by selecting Line Item Codes (See GR01 Exhibit C) with a processing designator. The designators used for Routine, Priority, and Rush Processing are provided below:

- “R” designates Routine Processing
- “P” designates Priority Processing
- “U” designates Rush Processing

Parameter Specific Analytical Modules may identify additional Processing Designators.

TABLE B2 SCHEDULE FOR OTHER DELIVERABLES

Item	Schedule	Recipient	Reference GR01, Exhibit/Section
Signed copy of COCs and discrepancy reports	Relayed by fax within 24 hours of sample receipt	CTR	Exhibit F/Section 3
Supporting Documentation Package (Support Package)	Available during audits and within 7 days of request	Maintained at Laboratory	Exhibit B/Section 5 Exhibit F/Section 4
Notification of accidental damage, theft, or malicious mischief of samples or results	Written notification within 48 hours of loss or damage	CTR	Exhibit F/Section 2
Security procedures and documentation of individuals having access to secure areas	Available during audits and upon request	CTR	Exhibit F/Section 6
Notification of problems or laboratory conditions that affect timeliness of analysis, data reporting, missed holding times, etc.	Immediate telephone notification, written confirmation and explanation within 3 days	CTR	Exhibit B/Section 3
Resubmission requests	Routine: 7 days from request Priority: 1 business day from request Rush: 1 business day from request	CTR	Exhibit B/Section 7
EDD resubmittal requests	7 days from request	CTR	Exhibit B/Section 7
Documentation of document shipments	Available during audits and upon request	Maintained at Laboratory	Exhibit F/Section 4
Sample shipping containers (coolers)	2 weeks after VTSR	Sender	Exhibit F/Section 3
List of SOPs	21 days prior to preaward audit and within 14 days of the addition of new or amended SOP(s)	CTR	Exhibit F/Section 6
Written notification of new or amended SOPs	Within 14 days of change	CTR	Exhibit F/Section 6
Requested SOPs	3 days from request	CTR	Exhibit F/Section 6
QA plan	21 days prior to preaward audit during audits and upon request	CTR	Exhibit E/Section 3
QA Training	Available during audits and upon request	CTR	Exhibit E/Section 3
Organizational chart/diagram	21 days prior to preaward audit 14 days following change in key personnel	CTR	Exhibit A/Section 1
Résumé of individuals holding key positions	21 days prior to preaward audit 14 days of assigning new personnel to key positions	CTR	Exhibit A/Section 1
Waste disposal records	Available during audits and upon request	Maintained at Laboratory	Exhibit A/Section 1
Standards and reference materials certificates	Available during audits and within 7 days of request	CTR	Exhibit E/Section 6

TABLE B2. SCHEDULE FOR OTHER DELIVERABLES (continued)

Item	Schedule	Recipient	Reference GR01, Exhibit/Section
Copies of radioactive license	21 days prior to preaward audit, available during audits and upon request	CTR	Exhibit A/Section 1
Amendments to radioactive license	5 days after receipt	CTR	Exhibit A/Section 1
Audit corrective action response	As determined during audit debriefing	Lead Auditor	Exhibit E/Section 10
Intralaboratory certification documentation by analyst	Available during audits and upon request	Maintained at Laboratory	Exhibit E/Section 4
IDLs, IQLs, MDLs, and MDAs	As specified in PSA Modules, available during audits and upon request	CTR	Exhibit B/Section 8
Check weight and Balance certifications	Available during audits and upon request	Maintained at Laboratory	Exhibit E/Section 5
Thermometers and temperature recording device certifications	Available during audits and upon request	Maintained at Laboratory	Exhibit E/Section 5
Automatic pipette and sample dispenser calibration documentation	Available during audits and upon request	Maintained at Laboratory	Exhibit E/Section 5
Refrigerator temperature documentation	Available during audits and upon request	Maintained at Laboratory	Exhibit E/Section 5
Instrument maintenance/repair documentation	Available during audits and upon request	Maintained at Laboratory	Exhibit E/Section 5
Water purity monitoring and corrective action documentation	Available during audits and upon request	Maintained at Laboratory	Exhibit E/Section 6
Sample handling documentation	Available during audits and upon request	Maintained at Laboratory	Exhibit F/Sections 2, 3, and 4
List of PE Program Participation	21 days prior to preaward audit	CTR	Exhibit E/Section 9
Last two PE sample results	21 days prior to preaward audit	CTR	Exhibit B/Section 9
PE sample results	21 days prior to preaward audit 7 days from receipt of results	CTR	Exhibit B/Section 9 Exhibit E/Section 9
Root cause and corrective action reports for failed PE samples	21 days from receipt of results	CTR	Exhibit E/Section 9
Proof of laboratory certifications	21 days prior to preaward audit and upon request	CTR	Exhibit E/Section 10 PSA Modules
Internal Audit Reports	Available during audits and upon request	Maintained at Laboratory	Exhibit E/Section 11

3. REQUIREMENTS FOR ALL DATA DELIVERABLES

- 3.1. **Compliance:** All hard copy, electronic, and other submittals not conforming with requirements shall be considered incomplete. Laboratories will be required to resubmit such documentation with deficiencies corrected.

3.2. Schedules

3.2.1. For items to be received by the CTR, the time interval listed in the *Schedule* column of Table B2 is the elapsed time expressed in days from the time of the information request (for samples, the VTSR) until the date of receipt of a complete item by the CTR. For items requiring resubmittals, this date is the CTR receipt date for the last item of additional data required for a complete and fully compliant deliverable item.

3.2.2. Schedules for resubmittals shall not affect overall delivery schedules.

3.2.3. Schedules identified as “upon request” imply a delivery schedule of 7 calendar days.

3.3. **Notification Requirements for Late Deliverables:** The Laboratory shall notify the CTR immediately of any problems or laboratory conditions that affect the timeliness of analyses and data reporting. In particular, the Laboratory shall notify the CTR in advance regarding sample data that will be delivered late and shall specify the estimated delivery date.

3.4. **Document Control:** Document Control Requirements of GR01 Exhibit F Section 4 must be applied to all deliverables. The Laboratory shall assign a Document Control Officer (DCO) responsible for the organization and assembly of all sample data packages and support packages. The DCO shall ensure that all documents are compiled (in one location where possible) on a report identification number (RIN) basis.

3.5. Labeling Requirements

3.5.1. All reports and documentation prepared for the Site shall be identified with the RIN, where applicable.

3.5.2. All submittals shall be clearly labeled, legible, and completed in accordance with instructions in GR01, Exhibit B, and with the requirements contained in applicable PSA Modules

3.6. **Sample Data Package Format and Content Requirements:** The format and content of sample data packages submitted for review and validation shall conform in all respects to the requirements specified in Exhibit B of this module and the PSA Module(s).

3.6.1. Use of formats other than those designated in this SOW will be considered noncompliant to subcontract requirements. Such data are unacceptable.

3.6.2. Some PSA Modules and cited methods provide forms for data submission. Computer-generated forms may be submitted for these forms if the computer-generated forms are equivalent to those provided. Equivalent forms must contain all data items specified on the provided form. At a minimum, submitted forms must share the following attributes with the provided form:

- Parameter order
- Form number
- Form title
- Form Header information
- Column headers and order
- Form footnotes and comments

3.6.3. Strict compliance with supplied formats is not required for the following:

- Printer font style and size
- Additional information may be included on forms, if this information does not affect the intelligibility of required items. Additional information must either be self-explanatory or be accompanied by notes that explain the content of additional information.

4. SAMPLE DATA PACKAGE REQUIREMENTS

4.1. **Sample Data Package Components:** Required components for Sample Data Packages are listed in Table B3; paragraphs following the table contain minimum requirements for each of these deliverable sections. The *Reference* column in Table B3 contains designators that refer to modules, exhibits, and sections that contain additional information. This reference column is intended as an aid in locating requirements, but is not expected to be all-inclusive. PSA Modules may also specify additional required deliverable sections and will further specify section content and format. Modules may also define an abbreviated sample data package containing fewer units than a sample data package.

TABLE B3 SAMPLE DATA PACKAGE DELIVERABLES

Deliverable Section Title	Reference (GR01, Exhibit/Section or Title)
Sample Data Package Cover Page	Exhibit B/Section 4
Table of Contents	Exhibit B/Section 4
Data Review Checklist	Exhibit B/Section 4 Checklists are included in PSA Modules
Chain of Custody (COC)	Exhibit B/Section 4
Narrative	Exhibit B/Section 4
Sample and QC Sample Result Summaries	Exhibit B/Section 4
Preparation Raw Data	Exhibit B/Section 4 Exhibit F/Section 4
Standards Summary	Exhibit B/Sections 4 and 5 Exhibit E/Section 6
Instrument Raw Data	Exhibit B/Section 4 Exhibit F/Section 4
Electronic Data Deliverable (EDD) - Hard Copy	Exhibit B/Section 4

4.2. **Original Documents:** All components of sample data package deliverables shall contain all original documents where possible. Photocopies of original documents shall be included in the sample data package when the original is bound in a logbook maintained by the Laboratory. Photocopies of original documents may also be submitted if the original data were previously submitted under another RIN.

4.3. **RINs and Sample Data Packages:** Each sample data package shall contain all required information associated with the preparation and analysis of all samples in the RIN (i.e., the sample data package shall be a stand-alone document). One and only one sample data package shall be submitted for each PSA Module request for each RIN. Information may not be separated into multiple sample data packages for a given PSA Module deliverable. Inclusion of required items by reference to other sample data packages is not acceptable. The Laboratory may combine Site samples with non-Site samples in a single analytical batch with the following provisions:

4.3.1. All original documentation associated with the analytical batch is included in the Site data package as described in GR01 Exhibit B, Section 4.

- 4.3.2. Site samples are exclusively used for matrix QC.
- 4.3.3. Site and non site samples are not reported together in any way.
- 4.4. **Pagination:** The complete sample data package shall be single sided and consecutively paginated.
- 4.4.1. If original data included in the sample data package are two-sided, the original sheets shall be included immediately followed by a photocopy of the second side of the original.
- 4.5. **Colored Paper:** Under no circumstances shall colored paper be used in a sample data package.
- 4.6. **Sample Data Package Cover Page Requirements**
- 4.6.1. The cover page of the sample data package shall be clearly labeled "Cover Page." The cover page shall contain all of the following:
- **Laboratory Name**
 - **Laboratory Code** (The laboratory code is assigned by the CTR and shall not be modified without prior written approval from the CTR.)
 - **Subcontract Number**
 - **RIN**
 - **Laboratory Report Identification** (The laboratory's report identification for the RIN.)
 - **Line Item Code(s)** (A list of all Line Item Codes associated with the RIN.)
 - **Site Sample Numbers** (Site Sample Numbers are to be ordered as they appear on the COC and cross-referenced with laboratory ID numbers.)
 - **Sample Matrix**
 - **Comments** (Comments shall describe, in detail, any problems encountered in receiving the samples, e.g., broken containers, incorrect COC documentation, etc., or a statement indicating that no problems were encountered with sample receiving.)
- 4.6.2. Sample Numbers shall be included on the cover page even if analyses were not conducted due to broken containers, incorrect sample preservation, etc.
- 4.6.3. The cover page shall contain the following statement, verbatim:
- "I certify that this sample data package is in compliance with SOW requirements, both technically and for completeness, other than the conditions detailed above. Release of the data contained in this hard-copy sample data package and the computer-readable EDD, as applicable, submitted on diskette or by modem, has been authorized by the laboratory Manager or the Manager's designee, as verified by the following signature."*
- 4.6.4. This statement shall be directly followed by the signature of the Laboratory Manager or his/her designee with a typed line below it containing the signer's name and title, and the date of signature.
- 4.6.5. In the event that the Laboratory Manager or his/her designee cannot validate all data reported for each sample, he/she shall provide a detailed description of the problems associated with the sample(s) in the sample data package narrative.
- 4.7. **Table of Contents:** A table of contents shall be included in each sample data package. This table shall include, at minimum, all sample data package deliverable section titles specified in the PSA Module. These section titles shall be listed with the beginning page number of each section. (The page number of the sample data package section cover sheet is entered for those sections requiring a cover sheet.)

4.8. **Data Review Checklist**

- 4.8.1. The Laboratory shall complete the Data Review Checklist provided in the relevant PSA Module. Inaccuracies in the completion of the Data Review Checklist will be considered a nonconformance to requirements.
- 4.8.2. All Data Review Checklist blocks that are NOT shaded shall be completed as “Y” for *yes*, “N” for *no*, or “NA” for *not applicable* by the laboratory reviewer. Any blocks marked “N” or requiring further explanation shall be explained in the Narrative section of the Sample Data Packages. The laboratory manager or designee shall sign and date the checklists.

4.9. **Chain of Custody (COC)**

The signed and completed original COC shall be included as part of the sample data package. See Exhibit F, Section 3 for more details regarding COCs. A photocopy of the COC may be submitted if the original COC was previously submitted to the CTR with a Sample Data Package for another RIN or another PSA Module. The COC section of sample data package shall include records that document the sample receiving process per the requirements of Exhibit F, Section 3. This documentation may include copies of sample receipt logs, preprinted sample log-in sheets, etc.

4.10. **Sample Data Package Narrative**

A narrative describing all problems or unusual circumstances encountered in the analytical processing of samples shall be prepared. At a minimum, the narrative shall address each of the following items, even if no deficiencies or unusual occurrences were experienced:

- Header that includes: RIN, Laboratory Report Identification, PSA Module (i.e., SS01), and a Report Date
- Method reference numbers and revisions
- Descriptions of matrix interferences
- Description of required dilutions
- The Site Sample Numbers used for each QC sample for each Analytical Batch
- Explanations of any QC deficiencies, missed holding times, or inability to achieve the RDLs or a statement indicating that no QC deficiencies were noted
- Reasons for reanalysis, reanalysis Analytical Batch Identification Numbers, and a synopsis of the reanalysis Analytical Batch QC assessment
- Explanations and descriptions of all deviations from routine protocols, including deviations from approved SOPs, detection limit modifications, etc. If it was necessary to contact the CTR for instructions due to the nature of the deviation, the Laboratory shall document those instructions in the narrative.
- Explanations for each item marked “N,” on the Data Review Checklist
- All information as required in PSA Modules
- All other information that might affect data assessment
- Signature and date of sample case narrative author

4.11. **Sample and QC Sample Results Summary**

- 4.11.1. Sample results shall be submitted as specified in the PSA Modules for all samples in the RIN. Sample results shall be presented in the order of sample appearance on the COC.
- 4.11.2. The Site Sample number shall be included on all sample report forms. When report forms cannot accommodate the full Site Sample Number, the Site Sample Number shall be provided in the form’s comment section and a statement shall be added to the sample case narrative that

describes how Site Samples numbers are reported. For example, the following paragraph in the sample case narrative would meet this requirement:

“The last 6 digits of the Site Sample Number are used in the field for the SDG # on all CLP forms and in the EPA Sample No. column. The full Site Sample Number is provided in the Form 1 Comment Section.”

- 4.11.3. QC summaries shall be reported as specified in the PSA Modules. These reports will typically summarize calibration parameters, system performance check results, calibration verification results, control sample results, and other QC elements specified in PSA Modules.
- 4.11.4. When reanalysis is required, these data shall be included in QC summary reports. QC summary reports must be presented so that reanalysis data are clearly linked to reanalysis analytical batch identifiers.
- 4.11.5. Required instrument performance demonstrations shall be performed and reported for each instrument used to generate data for the RIN under this SOW.

4.12. **Preparation Logs**

Preparation and/or pretreatment logs shall be submitted as specified in the PSA Modules. Submitted preparation logs must include all of the following:

- Preparation date
- SOP Identifier
- Analytical batch identification(s)
- Sample Numbers
- Sample weights and/or volumes
- QA Sample identifications
- Comments describing significant sample changes or reactions occurring during preparation
- Initials of analyst and reviewer

4.13. **Standards Summary**

Standards summaries shall be submitted as specified in the PSA Modules. These summaries shall be maintained so that all standards used for sample result reporting can be traced through all preparation steps back to primary standards. The standards shall have unique identifications and be traceable back to primary standard certificates. Specific requirements for logbook entries are covered in Exhibit E Section 6, Exhibit F Section 4, and in PSA Modules.

4.14. **Instrument Raw Data**

Reporting requirements for raw data are provided in PSA Modules. The Laboratory shall include all raw data for each reported value. Raw data also include analyses performed but not used for reporting; data for all preparation, chemistry, and counting, and instrument data generated during sample analysis. Instrument raw data must include all of the following:

- Analysis date and time
- Instrument identifications
- SOP Identifier
- Sample Numbers
- QA Sample identifications
- Analyst initials

4.15. **Electronic Data Deliverable (EDD) - Hard Copy**

- 4.15.1. Format requirements for the Electronic Data Deliverable (EDD) are specified in Module, GR02.
- 4.15.2. When an EDD is required, a hard copy of the EDD shall be included with the data package. In addition to the required data in the EDD, the hard copy shall include the following information:
- data filename
 - specific means of file transmittal and destination
- 4.15.3. Signature of person transmitting the file and date of transmittal

5. **SUPPORTING DOCUMENTATION PACKAGE REQUIREMENTS**

The Supporting Documentation Package (Support Package) is an ordered compilation of laboratory information relevant to all aspects of data integrity for a single RIN. Much of this information is included by reference to Laboratory document storage locations. One Support Package is compiled for each RIN and is maintained by the Laboratory.

- 5.1. **Supporting Documentation Package (Support Package) Components:** Required components for support packages are listed in Table B4; paragraphs following the table contain minimum requirements for these deliverable sections. The "Reference" column in Table B4 refers to the document, exhibit, and section where more details may be found. The information in this column is intended as an aid in locating requirements; additional requirements will be found in GR01 Exhibits B, E, and F and in PSA Modules.

TABLE B4 SUPPORT PACKAGE

Deliverable Section Title	Reference (GR01, Exhibit/Section Number)
Document Inventory	Exhibit B/Section 5
Sample Receipt, Storage, Tracking, and Internal COC records	Exhibit F/Sections 2 and 3
Copy of Sample Data Package	Exhibit B/Sections 4 and 5
Original SRM Certificates	Exhibit E/Section 6
Original Log Sheets and/or Logbooks	Exhibit F/Section 4
Standard Operating Procedures	Exhibit F/Section 6
Software Quality Assurance	Exhibit F/Section 5

5.2. **Support Package Schedules and Maintenance**

- 5.2.1. All items listed in Table B4 shall be maintained at the Laboratory and be available for review during an on-site inspection and within seven calendar days of CTR request.
- 5.2.2. One support package shall be compiled and maintained at the Laboratory for each RIN.

- 5.2.3. The location of original documents that are not part of the sample data package and cannot be included in the support package (e.g., logbook entries) shall be referenced in the support package.
- 5.2.4. The support package shall be maintained well organized for convenient retrieval and reproduction of all items.
- 5.3. **Document Inventory:** The document inventory for the support package includes a list of all documents in the file and the locations of all required documents that are not physically in the file. The document inventory shall be the first item in the support package and shall include the RIN. All items listed in the document inventory shall be titled exactly as given under the "Deliverable Section Title" column of Table B4 or as required by PSA Modules. Documents shall appear in the order listed on the document inventory.
- 5.4. **Copy of Sample Data Package:** The support package includes a photocopy of the Sample Data Package.
- 5.5. **Original Log Sheets and Logbooks:** Logs sheets and/or logbooks include (but are not limited to) preparation logs, instrument run logs, standard dilution logs, balance calibration logs, pipette calibration logs, instrument maintenance logs, and ASTM II water logs.

6. DATA IN COMPUTER READABLE FORM (EDD)

Requirements for the EDD are specified in Module GR02 and/or in the parameter-specific analytical module(s).

- 6.1. **Systematic Errors:** Systematic errors in the EDD deliverable may result in a **Subcontract Termination**. See GR01 Exhibit E, Section 13 for additional information regarding EED completeness and accuracy expectations.

7. DATA ACCEPTANCE AND RESUBMISSIONS

- 7.1. **Sample Data Packages:** Only complete sample data packages (based on the requirements in the parameter-specific analytical modules) will be accepted. Incomplete, illegible, or unusable sample data packages will not be accepted.
- 7.2. **Resubmission Requirements**
 - 7.2.1. The Laboratory shall respond to resubmission requests within seven calendar days after the resubmission request is received.
 - 7.2.2. For priority and rush deliverables, the Laboratory shall respond to resubmission requests within one business day of the request.
 - 7.2.3. For EDD resubmissions, the Laboratory shall respond to resubmission requests within seven calendar days from the request.
 - 7.2.4. **Types of Resubmissions:** The Laboratory may be required to submit or resubmit data as a result of a resubmission request, an on-site laboratory evaluation, a incomplete deliverable, an amendment to a previously submitted deliverable or through a CTR action.. A cover letter shall be included that describes which data are being delivered, to which Site RINs the data pertain, who requested the data and the date of the resubmission request, and the reason for

the resubmission. The resubmission shall be clearly marked as described below and shall be sent to the attention of the CTR.

7.2.4.1. *Previously Submitted Deliverables*: A resubmission of a deliverable without change from what was originally submitted shall be clearly marked as “Previously Submitted”.

7.2.4.2. *Additional Data*: Submission of data that was not included in the original submission shall be clearly marked as “Additional Data”.

7.2.4.3. *Amended Data*: Submission of data that differs from the original submission shall be clearly marked as “Amended Data”.

7.3. **Preliminary Use of Data**

7.3.1. Analytical data may be used prior to actual acceptance due to stringent reporting requirements imposed on the Site by oversight and regulatory agencies.

7.3.2. Preliminary use of data does not constitute acceptance.

7.4. **Criteria for Unacceptable Data**: Data may be classified as unacceptable for one or more of the following reasons (additional criteria may be identified in PSA Modules):

7.4.1. Data cannot be validated as a result of the Laboratory's actions (e.g., not correcting an instrumentation nonconformance).

7.4.2. Reported data detection limits exceed the required detection limits (unless approval from the CTR was received prior to data submission).

7.4.3. QC samples fail to meet acceptance criteria provided in the PSA Modules.

7.4.4. The EDD did not meet requirements.

8. **REPORTING LIMITS AND REQUIREMENTS**

8.1. **Media Types and Reporting Units**: Media types and reporting units are specified in Exhibit C of PSA Modules.

8.2. **Required Detection Limits**: A required lower level for demonstrated method performance is specified in PSA Modules by listing Required Detection Limits (RDLs). RDLs represent the highest acceptable value for demonstrated analyte detection performance measures. Designators for these detection performance measures vary by analytical discipline. For example, the performance measure compared to RDL is the Instrument Detection Limit (IDL) for inorganics, Method Detection Limit (MDL) for organics and applicable Water Quality Parameters, Minimum Detectable Activity for radiochemical analyses, and Minimum Detectable Amount for bioassay.

8.3. **IDL, IQL, or MDA Reporting Requirements**: The Laboratory shall submit applicable Instrument Detection Limits (IDLs) for inorganics, Method Detection Limits (MDLs) for organics, and applicable Water Quality Parameters, Minimum Detectable Activity for radiochemical analyses, and Minimum Detectable Amount for bioassay. These deliverables shall be submitted in accordance with PSA Modules. These performance measures shall be submitted as specified in PSA Modules and shall be available during audits and upon request.

8.4. **Significant Figures**: The number of significant figures required for reporting sample results are specified in PSA Modules.

8.5. **Sample Dilutions**

- 8.5.1. Sample dilutions are allowed when necessary to quantify a requested analyte; all required analytes must meet the required detection limits unless otherwise stated in PSA Modules..
- 8.5.2. When dilutions are required due to off-scale responses, the Laboratory shall dilute the sample as necessary to return the response to approximately the midpoint of the valid analytical range. The Laboratory shall not dilute the results to below required detection limits.
- 8.5.3. When dilutions are required due to analytical interferences, the Laboratory shall use the least dilution necessary to eliminate the interference or reduce the interference to acceptable levels. The Laboratory shall notify the CTR when dilutions cause results to fall outside of reporting limits. Upon CTR request, proof demonstrating intermediate dilutions could not eliminate the interference shall be provided. This information shall be included as part of the narrative.
- 8.5.4. When a dilution is warranted (GR01 Exhibit B, Section 8.5) both original and diluted results shall be reported as separate analyses.

8.6. **Reanalysis**

- 8.6.1. When reanalysis is performed due to QA failure, the Laboratory shall report a single final result.
- 8.6.2. Reanalysis shall be explained in the sample data package narrative.
- 8.6.3. All reanalyses shall be traceable to the reanalysis analytical batch identification and to the reanalysis analytical batch QC samples.
- 8.6.4. QA/QC requirements for analytical batches containing samples requiring reanalysis shall be identical to those for the initial analyses.
- 8.6.5. Certain reanalyses are considered separate sample analyses for which the Laboratory will be paid. The parameter-specific analytical module(s) identify these circumstances.

9. **RESULTS OF INTERCOMPARISON/PERFORMANCE EVALUATION (PE) SAMPLE ANALYSES**

- 9.1. Intercomparison study/PE sample analyses results shall be reported in accordance with requirements specified in the PE program.
- 9.2. PE samples shall be carried through the entire analytical procedure specified with the PE samples.
- 9.3. PE samples shall be run using routine analysis procedures, where possible. The Laboratory shall analyze the PE samples within the required holding times and delivery schedules.
- 9.4. The Laboratory shall provide to the CTR their Site Identification Code (SIC) for PE programs in which they participate, and allow the Site to directly access PE results through the use of the laboratory's SIC. The Laboratory shall send the CTR copies of the last two PE results 21 days prior to preaward audit, and within seven days of receiving PE results thereafter.

EXHIBIT C

COMPOUND AND ANALYTE LISTS

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COMPOUND AND ANALYTE LISTS

1. INTRODUCTION

The PSA Modules specify requirements for target analytes/compounds, including required detection limits, reporting limits, quality control components, and approved methods. These requirements are identified through the use of Line Item Codes provided in Exhibit C of PSA Modules.

EXHIBIT D

ANALYTICAL METHODS

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ANALYTICAL METHODS

1. SAMPLE ANALYSIS REQUIREMENTS

- 1.1. **Analytical Method Selection:** Specific requirements for sample analysis are included in the PSA Modules identified in the introduction to GR01. The laboratory shall follow all analytical, reporting, and QA/QC criteria provided in applicable PSA Modules.
- 1.2. **Method Sources:** In general, method requirements for organic and inorganic determinations are consistent with those specified in *Test Methods for Evaluating Solid Waste (SW-846)*, EPA Contract Laboratory Program Statements of Work (CLP SOW), *Methods for the Chemical Analysis of Water and Wastes (EPA-600 Methods)*, and other nationally-accepted analytical methods and protocols.
- 1.3. **Adherence to Cited Methods:** Methods cited in PSA Modules shall be followed without modification except where such changes are approved in writing by the CTR.
- 1.4. **Implementation of Method Updates:** Updates to cited methods shall be used by the Laboratory once the methods are promulgated and approved for use by the Site. The Contractor Technical Representative (CTR) shall provide the Laboratory with implementation dates for any new methods.
- 1.5. **Alternate Method Approval:** Any alternative method or modification/revision to standard methodology shall be approved in writing by the CTR prior to implementation, and documented by the Laboratory in the sample data package narrative.
- 1.6. **Holding Times and Preservation:** Maximum holding time and preservation requirements are summarized in PSA Modules. For analyses where no holding time is defined, the maximum holding time shall be 90 days.

EXHIBIT E

QUALITY ASSURANCE REQUIREMENTS

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QUALITY ASSURANCE REQUIREMENTS

1. INTRODUCTION

This Exhibit outlines minimum requirements for laboratory QA/QC Programs. These programs are designed to ensure that each laboratory generating data for this SOW has systems for assuring that the precision, accuracy, completeness, and representativeness of data generated are known and documented. These requirements do not release the Laboratory from maintaining additional QC checks on method and instrument performance. Evidence that the implementation of QA/QC program requirements fail to control activities that could have an impact on the validity of data or that established program requirements are not being followed may result in a **Subcontract Termination**.

2. THE QUALITY ASSURANCE PROGRAM

The Laboratory shall establish a QA Program with the objective of providing sound analytical measurements. This program shall incorporate a QA Plan, QC procedures, corrective action systems, and documentation required during data collection as well as the quality assessment measures performed by management to ensure acceptable data. Some QA Program requirements are summarized in Table E1. The "Reference" column refers to the document, exhibit and section number, and/or title where more details may be found. This reference column is intended as an aid in locating requirements, but is not expected to be all-inclusive.

TABLE E1 QA PROGRAM REQUIREMENTS SUMMARY

Requirement	Reference (GR01, Exhibit/Section)
Development and implementation of a QA Program and documentation of the key elements of that QA Program through a written QA Plan	Exhibit E/Sections 2 and 3
Preparation of and adherence to written SOPs	Exhibit F/Section 6
Adherence to the analytical methods and associated QC and documentation requirements provided in the PSA Modules	PSA Modules
Verification of analytical standards and documentation of the purity of reference standard materials and the purity and accuracy of solutions obtained from commercial suppliers	Exhibit E/Section 6
Participation in performance evaluation programs, including adherence to corrective action procedures	Exhibit E/Section 9
Participation in on-site laboratory evaluations, including adherence to corrective action procedures	Exhibit E/Section 10
Submission of all raw data and pertinent documentation	Exhibit B/Section 4 PSA Modules
Submission of original documentation	Exhibit B/Section 4 PSA Modules

3. QUALITY ASSURANCE PLANS

- 3.1. **Schedules:** The Laboratory shall implement and maintain a written QA Plan that presents the policies, organization, objectives, and specific QA and QC activities designed to achieve the data quality requirements of this SOW. The Laboratory shall provide the CTR with a copy of the QA Plan 21 days prior to the preaward audit. The QA Plan shall also be delivered upon written request by the CTR and made available during on-site laboratory evaluations.
- 3.2. **QA Plan Review:** The Laboratory's management shall regularly review the status and adequacy of the QA Plan and develop and maintain a system to promote continuous quality improvement, including a system to monitor laboratory performance.
- 3.3. **QA Training:** The laboratory staff shall receive QA training appropriate to their participation. Training shall be performed as necessary to assure that each staff member understands the QA and technical requirements applicable to their work. Documentation of training, whether specific or general, shall be maintained by the Laboratory and be available during on-site inspections and upon CTR request.
- 3.4. **References:** The QA Plan shall be based on one or more of the following references: 10 CFR 830.10, DOE Order 5700.6C, ANSI/ASQC E4-1994, ASME-NQA-1-1989, ISO 9000, and/or Good Laboratory Practice Standards (40 CFR 792). Complete references are included in GR01 Exhibit H. Additional information relevant to the preparation of a QA Plan can be found in DOE, EPA, and ASTM publications.
- 3.5. **QA Plan Key Elements:** The QA Plan shall address all key elements listed below. Requirements associated with these elements are found in this Exhibit, other Exhibits in GR01, PSA Modules, and the references cited in the previous paragraph. Where procedures are indicated below, the QA Plan shall include these procedures in text or by reference.
- 3.5.1. Laboratory QA Policy and Objectives
- 3.5.2. Organization and Personnel
- Staff resumes
 - Education and experience requirements
 - Indoctrination and training procedures and requirements
 - QA management organization
 - Assignment of QC and QA responsibilities
 - QA management reporting relationships
- 3.5.3. Facilities and Equipment
- Guidance for measuring and test equipment calibrations
 - Procedures for maintaining measurement system stability and reproducibility
 - Maintenance activities and schedules
 - Instrumentation and backup alternatives
- 3.5.4. Control of Purchased Items and Services
- Criteria for approving vendors
 - Requirements for assuring procurements identify or reference quality criteria
 - Procedures for acceptance of purchased items

3.5.5. Document Control

- Procedures for measurement process documentation
- Sample and data tracking/custody procedures and documentation requirements
- Logbook content, format, maintenance, and archiving
- Laboratory notebook policy
- RIN file organization, preparation, and review procedures
- Procedures for preparation, approval, review, revision, and distribution of SOPs

3.5.6. Analytical Methodology

- Sample/extract handling and storage procedures
- Sample preparation/extraction procedures
- Standard preparation procedures
- Calibration procedures and frequency
- Sample analysis procedures

3.5.7. Data Generation

- Data collection procedures
- Data reduction procedures
- Data review procedures
- Data reporting and authorization procedures
- Data management procedures
- Software QA procedure

3.5.8. Quality Control Program

- Confirmation of laboratory materials (e.g., solvent, reagents, etc.)
- Control of age-sensitive materials
- Reference material analysis
- Internal QC checks
- Corrective action and determination of QC limit procedures

3.5.9. Quality Assurance Program Assessment

- Data audits
- Systems audits
- Performance audits
- Corrective action procedures
- QA reporting procedures
- Control of nonconformances

4. PERSONNEL

4.1. QA Personnel

- 4.1.1. QA personnel shall operate independently from cost and schedule considerations and shall have the responsibility and authority to stop unsatisfactory work.

4.2. **Analyst Certification**

- 4.2.1. Procedures shall be in place for the establishment and implementation of an intralaboratory certification program for the indoctrination and training of personnel performing activities under this SOW (analysts). This program must define how sufficient analyst proficiency is defined, achieved, maintained, and documented.
- 4.2.2. Analysts that have not passed intralaboratory certification for a method shall not conduct analyses under this SOW. The certification documentation shall be maintained by the laboratory and be available during on-site inspections and upon CTR request.
- 4.2.3. Analysts shall be recertified at least every two years.

5. **MEASURING AND TESTING EQUIPMENT (M&TE)**

5.1. **General Requirements for M&TE:** The Laboratory shall establish and document calibration methods and intervals for M&TE. M&TE shall include analytical instruments, balances, thermometers, pipettes and other devices used to generate analytical results and to demonstrate compliance to procedural requirements. Also included is equipment used to demonstrate other aspects of conformance to this contract, such as sample preservation.

- 5.1.1. The Laboratory shall assign unique identifiers to all M&TE.
- 5.1.2. All data generated by M&TE must be labeled with the unique M&TE identifier.
- 5.1.3. The Laboratory shall identify the instrument manufacturer, model, instrument configuration, and instrument settings (e.g., temperature programs, gas flows, etc.) on laboratory bench sheets or appropriate instrument logbook unless these parameters are precisely specified in SOPs.
- 5.1.4. The Laboratory shall maintain records (and if applicable, mark equipment) indicating calibration status. Records shall include the unique equipment identifier, calibration interval, traceable standard identifiers, chronological equipment condition history, and the personnel performing the calibration.
- 5.1.5. Standards used for M&TE calibrations shall meet analytical standards requirements of GR01 Exhibit E and PSA Modules.
- 5.1.6. The Laboratory shall establish a system to identify and prevent the use of M&TE that do not meet performance standards. Failure to meet standards may be due to M&TE that are out-of-calibration, are under expired certification status, or exhibit conditions indicating compromised performance.

5.2. **Instrument Maintenance, Repair, Configuration**

- 5.2.1. The Laboratory shall document all maintenance and repairs on laboratory instrumentation, including date of maintenance/repair and personnel performing the task.
- 5.2.2. The Laboratory shall develop preventive maintenance schedules in accordance with instrument manufacturer recommendations.
- 5.2.3. Any repair, reconfiguration, or replacement of an instrument component shall be followed by verification of the calibration of the system. If the calibration verification parameters are not met, an appropriate calibration shall be performed. If instrument components are changed, the Laboratory shall also verify and report instrument parameters as specified in Exhibit B of this module and the PSA Module(s).
- 5.2.4. Instrument maintenance/repair documentation shall be maintained by the Laboratory and be available upon request and during on-site audits.

5.3. **Balances**

- 5.3.1. Balances shall be located in an area where the environment has little or no effect on the measurement accuracy.
- 5.3.2. All balances shall be calibrated and labeled annually by a certified technician.
- 5.3.3. Working weights used for daily balance verifications shall be certified annually.
- 5.3.4. The type, grade, and class of weights used for balance verifications shall meet all requirements of “Working standards for calibration and precision analytical work,” as stated in ASTM E 617, *Laboratory Weights and Precision Mass Standards*.
- 5.3.5. Daily Balance Verification Requirements
 - 5.3.5.1. The Laboratory shall check weigh the balance, at a minimum, every working day prior to use.
 - 5.3.5.2. Check weighing shall be performed at two points within the balance range using certified working weights.
 - 5.3.5.3. Results of check weight measurements shall be documented by the Laboratory. Documentation of check weight measurements shall be maintained at the Laboratory and be available for review during an on-site inspection and within seven calendar days of CTR request.
- 5.3.6. Check weight and balance certifications shall be maintained by the Laboratory and be available upon request and during on-site audits.

5.4. **Thermometers and Temperature Recording Devices**

- 5.4.1. Liquid-in-glass thermometers shall be calibrated against an NIST traceable standard at a five year interval.
- 5.4.2. Liquid-in-glass thermometers shall be inspected annually for conditions that may degrade performance. At a minimum, this inspection must include examination for evidence of liquid column separation and evidence of other conditions that might affect the column.
- 5.4.3. Thermometer and temperature device certifications and documentation of annual inspections shall be maintained by the Laboratory and available upon request and during on-site audits.

5.5. **Refrigerators**

- 5.5.1. The temperature of refrigerators used to store Site samples shall be verified and documented every working day. Documentation shall be maintained by the Laboratory and available upon request and during on-site audits.
- 5.5.2. The Laboratory shall develop and implement procedures for sample and extract storage and preservation in the event of refrigerator failure.
- 5.5.3. The Laboratory shall clearly identify refrigerators exceeding temperature requirements to prevent use until corrective actions have been completed.

5.6. **Automatic Pipettes and Dispensers**

- 5.6.1. The Laboratory shall verify the accuracy of all non-Class A pipettes and automatic sample dispensers used for quantitative measurement. This verification shall be performed monthly or whenever degradation of measuring equipment performance is suspected, whichever is more frequent. Conditions that may initiate immediate recalibration include but are not limited to:

Evidence of corrosion, leakage, movement of continuously-adjustable volume settings, improper treatment such as dropping and exposure to nonroutine temperatures, or degradation of laboratory performance as indicated by control charts.

- 5.6.2. Pipette and automatic sample dispenser calibration documentation shall be maintained by the Laboratory and be available upon request and during on-site audits.

6. ANALYTICAL STANDARDS AND REAGENTS

This Section contains requirements for acquisition, maintenance, and documentation of standards and reagents. It is the responsibility of the Laboratory to obtain those analytical reference standards required for direct analytical measurements and for the purpose of traceability.

6.1. Laboratory Water

- 6.1.1. The Laboratory shall have a water system capable of providing laboratory water meeting the American Society for Testing and Materials (ASTM) specifications for Type II water (ASTM D1193).
- 6.1.2. The Laboratory's water system shall be monitored with each use. Results of this monitoring shall be recorded at least once each day the system is in use. The conductivity shall not exceed 1.0 $\mu\text{S}/\text{cm}$ at 25° C (i.e., the resistivity shall be greater than 1.0 $\text{M}\Omega \text{ cm}$ at 25° C). If this level is exceeded, the Laboratory shall take immediate corrective action before the water can be used for sample determinations under this SOW. Monitoring and corrective action documentation shall be maintained by the Laboratory and available upon request and during on-site audits.

6.2. Purchase of Analytical Reagents and Standards

- 6.2.1. The Laboratory shall have a documented program for controlling the quality of purchased reagents and standards.
- 6.2.2. The Laboratory shall have an established system for approving vendors to procure supplies and services. All analytical reagents shall be obtained from these approved vendors.
- 6.2.3. Material Safety Data Sheets (MSDSs) received from reagent suppliers shall be maintained by the Laboratory and submitted upon CTR request.

- 6.3. **Purchase of Standards:** Whenever possible, the Laboratory shall purchase NIST Standard Reference Materials (SRMs), NIST-traceable SRMs, or NIST-approved certified reference materials. If appropriate NIST reference materials are unavailable, the Laboratory can purchase standards necessary to perform the analyses required in this SOW from other approved suppliers. Analytical reference standards purchased from these other suppliers must meet the following criteria:

- 6.3.1. The supplier must provide standard values with error estimates and a description of the statistical method for obtaining these estimates. (Additional information concerning statistical certification of analytical standards can be found in QA/QC requirements of applicable CLP-SOWs or other applicable method references.)
- 6.3.2. The Laboratory shall perform an independent verification of the supplier-determined standard value. This verification shall be performed by absolute or comparison methods; however, if a comparison method is used, the comparison shall be to two standard sources independent of the supplier. Laboratory and supplier standard values shall be identical at the 5% significance level.

6.4. **Standard Certificates:** Standard certificates shall be kept on file in the Laboratory and available to laboratory personnel. Copies of the standard certificates shall be made available during on-site inspections or within 7 calendar days of request. Standard certificates shall include, at a minimum, all of the following items:

- An identifier for the standard unique to the actual material (or lot) certified
- Identification of the certifying entity
- Signature of a representative of the certifying entity, a certificate printed on official letterhead, or a certificate affixed with certification seals
- A description of the material certified [including matrix and values for parameter(s) certified]
- Error estimates for certified parameter values
- Definition of a finite certification period
- Certificates for NIST-traceable standards must contain SRM identifiers of all NIST materials used for traceability and a description of the process used for relating parameter values to NIST values shall be included.

6.5. **Maintaining Traceability to Primary Standards:** The certified material received by the Laboratory from NIST or other certifying entity is defined as the primary standard. The Laboratory shall be able to trace all standards used in analysis back to the certificates maintained on file. Traceability shall include control and NIST traceability for all measurement equipment used to prepare dilutions and/or reconfigurations of the primary; this measurement equipment includes, but is not limited to, pipettes, balances, and volumetric glassware.

To maintain traceability, all standards used must be prepared, handled, and stored according to the applicable instructions in GR01, PSA Modules, and referenced documents. Proper storage and handling of chemical standards must be addressed in analyst training programs, SOPs, and facility requirements in order to safeguard against decomposition and contamination and to minimize risk of human exposure. Inability to document traceability of standards to NIST or other recognized standards agencies may result in a **Subcontract Termination**.

6.6. **Documentation of the Verification and Preparation of Chemical Standards and Reagents**

6.6.1. The Laboratory must maintain the necessary documentation to show that the standards used in the performance of Site analysis conform to requirements. Supporting documentation such as standard logs, weighing logs, calculations, and detection system spectra (whether produced by the Laboratory or purchased from chemical supply houses) shall be maintained by the Laboratory and may be subject to review during on-site inspection visits. Standard preparation documentation must be provided by the Laboratory if requested by the CTR for verification of SOW compliance.

6.6.2. Standard logs shall be kept for all weighing and dilutions performed for standard preparation and/or verification. All subsequent dilutions of the primary standard shall be recorded and all calculations for determining their concentrations are to be documented. Standard logs shall contain the following information:

- Primary standard identification
- Secondary standard tracking identification number
- All compounds or components of the standard
- Weight or volume of primary standard used
- Final volume or dilution data
- Final concentration or activity with units
- Preparer's initials

- Preparation date
- Secondary standard expiration date

6.7. **Labeling Standards and Reagents**

6.7.1. The Laboratory shall label all purchased stock mixtures and reagents with the following information:

- Date received
- Date opened (Required when used to establish expiration date)
- Expiration date

6.7.2. All secondary standard solutions shall be clearly labeled with a unique identification that is traceable to a standards preparation log. If the container size precludes this requirement, this information shall be documented in a logbook maintained at the Laboratory. Labels shall contain, as a minimum, the following information:

- Secondary standard tracking identifier
- Preparer's initials
- Preparation date
- Secondary standard expiration date

6.8. **Expiration Dates for Reagents and Standards**

6.8.1. Expiration dates established by the manufacturer shall be used when available. The Laboratory shall not use original stock standard solutions or reagents beyond the expiration date provided by the manufacturer.

6.8.2. If an expiration date is not defined, the Laboratory shall document how the shelf life of the reagent/standards is determined.

6.8.3. The expiration date (manufacturer or laboratory established), date received, and date opened shall be clearly identified on all reagent/standard solution containers. If an expiration date is not required, it shall be indicated on the container.

6.9. **Preparation of Standards for Radiochemical Parameters from Certified Stock Materials**

The Laboratory may prepare radioactive chemical standards from certified stock materials. The solvent used to dissolve the solute must be compatible with the method in which the standard is to be used. The solute must be soluble, stable, and nonreactive with the solvent. In the case of a multicomponent solution, the components must not react with each other.

All calculations for determining the required weight of stock material from the analyte activity of the certified material and the desired activity shall be recorded. These calculations shall be verified by a second analyst or laboratory technical staff member, and the secondary verification shall be recorded and retained with the calculations. The calculation sheet shall also record accuracy requirements for balances used in standard preparation. (Documentation of calculations in laboratory SOPs may fulfill some of these verification requirements.)

7. METHOD SPECIFIC QC REQUIREMENTS

- 7.1. **Laboratory Blank Preparation:** Where possible, the Laboratory shall use equivalent media for preparing laboratory preparation blanks. Synthetic matrices may be used for bioassay if equivalency is proven. The blank medium shall not contain any of the target parameters.
- 7.2. **Additional Requirements:** Method specific QC requirements are provided in the PSA Module(s).

8. DATA MANAGEMENT

Data management activities include specifying the acquisition, entry, update, correction, deletion, storage, and security of computer readable data and files. GR01 Exhibit F, Section 5 contains procedural requirements for data management and software QA.

9. LABORATORY EVALUATION SAMPLES

Although intralaboratory QC may demonstrate laboratory and method performance that can be tracked over time, an external performance evaluation (PE) program is an essential feature of a QA program. As a means of measuring laboratory and method performance, the Laboratory shall participate in interlaboratory comparison studies. Results from the analysis of these laboratory evaluation samples will be used to verify the Laboratory's continuing ability to produce acceptable analytical data. The results are also used to assess the precision and bias of the analytical methods for specific analytes.

- 9.1. **Program Requirements:** The Laboratory shall participate in an interlaboratory comparison study for each method used for this SOW. The Laboratory shall provide the CTR a list of PE program participation that meets the requirements of this SOW 21 days prior to preaward audit. The Laboratory is responsible for identifying and participating in an appropriate program. Examples of acceptable PE programs include, but are not limited to, the EPA's Characterization Research Division, Las Vegas (CRD-LV), EPA's Water Supply (WS) and Water Pollution (WP) programs, NIST, DOE's Environmental Monitoring Laboratory (EML), DOE's Mixed Analyte Performance Evaluation Program (MAPEP), and those provided by commercial suppliers such as Environmental Resource Associates or Analytical Products Group. The PSA Module(s) may further specify acceptable programs and the required frequency of participation.
- 9.2. **Blind Standards:** Standards for interlaboratory comparison studies shall be submitted to the Laboratory as single-blind or double-blind samples. That is, true values shall not be available to the Laboratory or to any person affiliated with the Laboratory before final results have been submitted to the agency which issued the standard. The agency issuing these standards shall not be affiliated with the Laboratory.
- 9.3. **Unacceptable Performance:** Production of a value falling outside the warning limits, as calculated by the program, will result in a probationary period until the next reporting period for that compound, element, or isotope. If the Laboratory fails a second evaluation, the Laboratory will not receive samples for analysis by the failed method until an acceptable PE score has been achieved. Root cause and corrective action reports for PE samples outside of acceptable limits are to be submitted to the CTR within 21 days from receipt of the scores.

- 9.4. **Acknowledgment of PE Score Disclosure:** The Laboratory understands that the PE scores and the names of laboratories under this SOW will be available to the DOE and any other appropriate organization and/or individual procuring analytical services for DOE.
- 9.5. **Site-Provided PE Samples**
- 9.5.1. PE samples may be sent either by the CTR or the end-user, and may be used for subcontract action. Sample sets may be provided to participating laboratories as frequently as on a RIN-by-RIN basis as a recognizable QC sample of known composition, as a recognizable QC sample of unknown composition, or not recognizable as a QC material.
- 9.5.2. Laboratories are required to analyze Site PE samples and return the data package and all raw data within the SOW required turnaround time.
- 9.5.3. At a minimum, the results are evaluated for parameter identification, quantification, and sample contamination.
- 9.5.4. The Laboratory shall provide a response regarding its performance on laboratory evaluation samples as requested by the CTR.

10. ON-SITE LABORATORY EVALUATIONS

- 10.1. **Audit Types:** The Laboratory may be subject to three types of audits: pre-award, routine, and follow-up.
- 10.1.1. Pre-award: A pre-award audit is a comprehensive audit performed prior to subcontract award, or if the Laboratory will perform previously unaudited analyses.
- 10.1.2. Routine: A routine audit is a comprehensive audit performed to verify adherence to and effectiveness of QA/QC requirements. The Laboratory shall be subject to routine, on-site audits not more than two times per calendar year during performance of this SOW. The preliminary pre-award audit performed prior to subcontract award does not count as one of these routine audits.
- 10.1.3. Follow-up: A follow-up audit verifies that adequate corrective action has been implemented by the Laboratory in response to a previous audit.
- 10.2. **Schedules and Notifications:** On-site inspections, surveillance, or audits for the purpose of identifying and resolving deficiencies or verifying corrective actions may be performed at any time during performance of the subcontract. Unannounced and announced inspections may be performed at any time during the subcontract period; written notification shall be provided to the Laboratory for announced inspections. Laboratories shall make all requested data and documentation related to this SOW available during audits.
- 10.3. **Corrective Action Reports in Response to Audit Reports:** Following an on-site evaluation, the auditors will conduct an audit closing conference with laboratory staff to discuss identified deficiencies and establish a schedule for corrective action. The Laboratory shall address corrective actions taken to resolve the deficiencies identified during the on-site visit according to the schedule set during the audit closing conference. Failure to meet the established timeline for responding to the identified deficiencies and/or failure to meet the established corrective action schedule may result in a **Subcontract Termination**.

11. INTERNAL AUDIT PROGRAM

- 11.1. The Laboratory shall implement and maintain an internal audit program, which includes corrective action procedures.
- 11.2. Internal audits shall be conducted by personnel knowledgeable of, but independent from, the operations performed.
- 11.3. Internal audits shall be conducted in accordance with written procedures and/or checklists. Audit reports shall identify the auditors, personnel interviewed during the audit, a synopsis of the audit scope, and a summary of the final results in sufficient detail to enable corrective action. The report shall be signed by the appropriate management and submitted for retention as specified in GR01, Exhibit B, Section 2. Internal audit reports shall be maintained at the Laboratory and made available for review during on-site audits, and upon request from the CTR.

12. NONCONFORMANCES:

Nonconformances must be identified, documented, evaluated, and resolved. Conditions adverse to quality shall be promptly identified and corrected.

- 12.1. Nonconforming items shall be identified and/or segregated until disposition.
- 12.2. The identification of adverse conditions and corrective actions shall be documented and reported to laboratory management.
- 12.3. The Laboratory shall implement a corrective action tracking system to ensure follow-up actions are taken to confirm and document corrective action implementation.

13. PERFORMANCE CRITERIA

Laboratory performance will be continually assessed by the CTR. The general areas of performance that are monitored include: sample data package delivery schedules, sample data package completeness, data validation, and PE program participation. Additional performance criteria may be included within the PSA Modules.

- 13.1. **Sample Data Package (SDP) Delivery Expectations:** The Laboratory shall meet the delivery schedules outlined in Exhibit B of this module and the PSA Modules. The Site shall use turn around times as defined in the glossary (GR01 Exhibit G) to assess conformance to delivery schedules. A 95-percent compliance with delivery schedules is expected.
- 13.2. **Sample Data Package Completeness and Accuracy Expectations:** The Laboratory shall meet the requirements for SDPs outlined in Exhibit B of this module and the PSA Module(s). EDD requirements outlined in GR02 and in PSA Modules shall also be met. Completeness screens are performed on initial receipt of SDPs and a comprehensive check is performed on SDPs and EDDs during formal data assessment. SDPs and EDDs are scored for completeness on a point system that assesses points for omissions and errors. The Data Completeness and Accuracy score is expected to be zero for all SDPs and EDDs.

- 13.3. **Data Assessment Expectations:** Each SDP is subject to assessment for data quality and subcontract compliance. SDPs will be scored based on a point system that assesses points for the qualification of parameter results, the cause and severity of the qualification and the type and severity of contractual non-compliances. The Data Assessment score is expected to be zero for all SDPs and EDDs.

14. CERTIFICATIONS AND APPROVALS

- 14.1. Requirements for participation in laboratory certification and approval programs are specified in PSA Modules. The PSA Modules will specify minimum certification requirements. However, laboratories are encouraged to provide proof of all certifications or approvals for any programs in which the Laboratory is participating.
- 14.2. Some samples covered by this SOW require additional certifications not included in PSA Module minimum requirements. In order to receive these samples, laboratories must supply proof of laboratory certification (or approvals) to the CTR according to the schedule in GR01 Exhibit B Table B2. These additional certifications are optional for participation in the SOW, but will increase the potential sample load for Laboratories providing proof of these certifications.

EXHIBIT F

EVIDENTIARY REQUIREMENTS

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EVIDENTIARY REQUIREMENTS

1. INTRODUCTION

This Exhibit describes the evidentiary requirements that must be followed for the preparation and analysis of Site samples under this SOW, including requirements for chain-of-custody, document control, and SOPs.

2. SAMPLE CHAIN-OF-CUSTODY

A sample is physical evidence collected from a facility or from the environment; gathered evidence must be controlled. To accomplish this, the following sample identification, chain-of-custody, sample receiving, and sample tracking procedural requirements have been established. Evidence that samples are not identifiable and traceable at all stages may result in a **Subcontract Termination**.

2.1. Sample Identification

- 2.1.1. The Laboratory shall have a specified method for maintaining identification of samples throughout their facility to assure traceability of samples in possession of the Laboratory.
- 2.1.2. Each sample and sample preparation container shall be labeled with the Site sample number or a unique laboratory identifier. If a unique laboratory identifier is used, it shall be traceable through the preparation documentation and cross-referenced to the Site sample number.

2.2. **Chain-of-Custody and Sample Tracking Requirements:** The Laboratory shall maintain a traceable custody chain for samples from receiving through retention and return or disposal. The Laboratory shall have procedures ensuring that Site sample custody is maintained and documented.

- 2.2.1. A sample is under custody if any of the following applies:
 - It is in your possession;
 - It is in your view after being in your possession; or
 - It was in your possession and you locked it up
- 2.2.2. The Laboratory shall maintain records documenting all phases of sample handling from receipt to final analysis. This documentation shall be available upon request and during on-site audits. The records shall include documentation of the movement of samples and prepared samples into and out of designated laboratory storage areas.
- 2.2.3. COC documents shall demonstrate the location of the sample or extract/digestate at all times. The COC documents shall show transfer of the sample or extract/digestate between individuals, and into and out of the secure areas. Internal COC records shall include the initials of the person in possession, the date, and the time of transfer.
- 2.2.4. The Laboratory shall maintain internal COC records documenting the handling of samples and extracts/digestates throughout the laboratory from the receipt to final disposal or return. In the event that the entire laboratory is maintained as a secure area, tracking of extract/digestates within the secure area is not required.

2.3. **Sample Protection and Integrity:** The Laboratory shall ensure that security is maintained in all assigned areas and shall ensure that samples and results are protected from accidental damage, theft, or malicious mischief. The Laboratory shall advise the CTR in writing of any losses or damage within 48 hours. In addition, the Laboratory shall identify and document which individuals have access to secure areas. Procedures and documentation for access shall be available for review during on-site audits and upon written request from the CTR.

3. SAMPLE RECEIVING REQUIREMENTS

- 3.1. **Radiological Screening:** The Laboratory shall establish, implement, and document procedures to ensure that the sample's radioactivity levels are consistent with the accompanying documentation and that Laboratory regulatory levels are not exceeded.
- 3.2. **Sample Custodian:** The Laboratory shall designate a sample custodian responsible for receiving all samples and an alternate custodian to receive samples in the event that the sample custodian is not available.
- 3.3. **Shipping Container Inspection:** The condition of shipping containers, sample containers, and custody seals (intact or not intact) shall be inspected upon receipt by the sample custodian or alternate.
- 3.4. **Opening Containers:** Shipping containers shall be opened in a contamination-free area within the airflow of a functioning hood (125 ± 25 linear feet per minute) which is vented outside the laboratory facility.
- 3.5. **Receiving Documentation Checks and Reporting Requirements:**
 - 3.5.1. The sample custodian or their representative shall check for the presence or absence of the following documentation accompanying the sample shipment.
 - Airbills or airbill stickers
 - Custody seals
 - Site custody records
 - Site packing lists
 - 3.5.2. The sample custodian or alternate shall sign and date all documents accompanying the samples (including those documents listed above) at the time of sample receipt.
 - 3.5.3. The sample custodian or alternate shall contact the CTR to resolve discrepancies and problems such as absent documents, conflicting information, broken custody seals, and unsatisfactory sample condition (e.g., punctured sample container). The Laboratory shall resolve all discrepancies and problems through written correspondence with the CTR or its representative.
 - 3.5.4. The sample custodian or alternate shall fax copies of COC records to the CTR within 24 hours of sample receipt. In addition, if discrepancies were encountered between samples received and COC records, any internal laboratory "discrepancy reports" and their resolutions shall be transmitted along with the COCs.
 - 3.5.5. Results of the preceding checks shall be recorded by the sample custodian (or alternate) on COC forms, in the sample log, or on preprinted sample log-in sheets as samples are received and inspected. The following information shall also be checked and recorded:
 - Condition of the shipping container;
 - Presence or absence and condition of custody seals on shipping and/or sample containers;
 - Custody seal numbers, when present;
 - Condition of the sample containers;
 - Presence or absence of airbills or airbill stickers;
 - Airbill or airbill sticker numbers;
 - Presence or absence of Site custody records;
 - Presence or absence of Site packing lists;
 - Presence or absence; and consistency of Site ID numbers;

- Verification of agreement or non-agreement of information recorded on shipping documents and sample containers;
- Temperature of shipping container, if appropriate;
- pH of the samples when appropriate (following procedures to maintain the integrity of the samples); and
- Problems or discrepancies.

3.6. **Return of Shipping Containers:** The Laboratory shall return shipping containers to the sender within 2 weeks of VTSR.

3.7. **Receipt of Improperly Preserved Samples**

3.7.1. The Laboratory shall contact the CTR immediately if improperly preserved samples are received.

3.7.2. The Laboratory shall not perform any pH adjustment of Site samples unless prior approval is obtained from the CTR.

3.7.3. The Laboratory shall document all issues associated with improperly preserved samples (and their resolution) in the case narrative.

4. DOCUMENT CONTROL REQUIREMENTS

The goal of the laboratory document control program is to assure that all documents will be accounted for when the project is completed and that meaningful information can be extracted from these documents when retrieved. Accountable documents used by laboratories shall include (but not be limited to) logbooks, COC records, sample work sheets, bench sheets, SOPs, and other documents relating to the sample or sample analyses, procurement of services, and generation of electronic deliverables. Document control procedures shall be established to assure that all laboratory records related to Site samples are properly maintained.

4.1. **General Requirements**

4.1.1. All laboratory documents and required retention copies shall be complete and legible.

4.1.2. All observations and results recorded by the Laboratory shall be on preprinted laboratory forms or shall be entered into permanent laboratory logbooks.

4.1.3. The laboratory name and a descriptive form name shall be included on all laboratory documents used to record information related to the preparation and analysis of Site samples.

4.1.4. Unused portions of documents (raw data forms, bench sheets, COC documentation, etc.) shall be Z'd out, initialed, and dated in black or blue ink.

4.1.5. All records shall be maintained in black or blue ink.

4.1.6. When columns are used to organize information recorded on laboratory records such as preprinted forms or logbook pages, the information recorded in that column shall be identified in a column heading.

4.1.7. To preserve confidentiality, references to the Site shall not appear in any documents accessible to non-laboratory personnel. Any sample handling documentation that are not a part of other deliverable items shall be available during audits and upon request.

- 4.1.8. QC sample identification on all documentation shall unequivocally denote the QC type (e.g., laboratory control samples, blanks and duplicates) either through the identifier or by cross-referencing the identifier with the QC type. QC identifiers shall be unique.
- 4.1.9. Sample data must be labeled with Site Sample Numbers or with lab identifiers cross-referenced to Site Sample Identifiers on the Sample Data Package Cover Page.
- 4.1.10. Data labels must clearly identify samples designated as duplicates, spiked samples, sample serial dilutions, controls, and blanks.
- 4.1.11. The identification scheme used must provide an unequivocal and unique link between all samples and QC samples (lab duplicate, spiked sample, laboratory control sample, preparation blank) prepared as an analytical batch.
- 4.1.12. All standards referenced in raw data must be identified by the unique identifier assigned as required in GR01 Exhibit E Section 6.
- 4.1.13. All numerical data shall be accompanied by applicable units.
- 4.2. **Error Correction:** Corrections and updates to supporting documentation and raw data shall be performed in a manner that preserves record integrity. The following procedures must be followed when correcting errors:
 - 4.2.1. A single line shall be drawn through the error and the correct information recorded in black or blue ink.
 - 4.2.2. No information shall be obliterated or made unreadable.
 - 4.2.3. All corrections, additions, and crossed out information shall be initialed and dated in black or blue ink.
 - 4.2.4. Use of correction fluid is prohibited.
- 4.3. **Requirements for Logbooks**
 - 4.3.1. The Laboratory's name, address and a unique logbook identifier shall appear on the cover of all logbooks. The type of activity recorded within a logbook shall be on the cover of the logbook.
 - 4.3.2. Pages in both bound and unbound logbooks shall be sequentially numbered.
 - 4.3.3. Logbook entries shall be dated (month/day/year) and signed by the person responsible for performing the activity at the time an activity is performed.
 - 4.3.4. Logbook entries shall be in chronological order.
- 4.4. **Requirements for Preprinted Forms:** Preprinted laboratory forms shall contain the name of the Laboratory, revision identifier or revision date (month/day/year), and signature/initials of the person responsible for performing the activity at the time an activity is performed.
- 4.5. **Document Control Officer:**
 - 4.5.1. The Laboratory shall assign a Document Control Officer (DCO) responsible for the organization and assembly of the Sample Data Package and Supporting Documentation Package (Support Package).
 - 4.5.2. Before releasing analytical results, the DCO shall assemble and cross-check the information on custody records, laboratory bench sheets, personal and instrument logs, and other relevant records. This check shall ensure that data pertaining to each particular sample or Sample Data Package are consistent throughout the Sample Data Package and Support Package.

4.6. **Document Numbering and Inventory Procedures**

- 4.6.1. In order to provide document accountability of the completed analysis records, each item in a Sample Data Package and Support Package shall be assembled as described in Exhibit B of this module.
- 4.6.2. All documents relevant to each RIN or analytical batch, including logbook pages, bench sheets, instrument logs, re-preparation records, re-analysis records, records of failed or attempted analysis, and custody records, shall be inventoried.
- 4.6.3. The DCO shall be responsible for ensuring that all documents generated are placed for inventory and are maintained at the laboratory for review during on-site inspection or for reproduction.

4.7. **Shipping Sample Data Packages and Support Packages:** The Laboratory shall document shipment of deliverable packages to the recipients. These shipments require custody seals on the containers placed such that they cannot be opened without damaging or breaking the seal. The Laboratory shall document what was sent, to whom, the date, and the method (carrier) used.

4.8. **Corrections and Updates to Submitted Deliverables:** The record of changes as 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:

- 4.8.1. Justification or rationale for the change.
- 4.8.2. Initials of the person making the change or changes. Data changes shall be implemented and reviewed by a person or group independent of the source generating the deliverable.
- 4.8.3. Change documentation shall be retained according to the schedule of the original deliverable.
- 4.8.4. Resubmitted deliverables shall be reevaluated as a part of the laboratory's internal inspection process prior to resubmission. The entire deliverable, not just the changes, shall be inspected.
- 4.8.5. The Laboratory Manager shall approve changes to originally submitted deliverables.
- 4.8.6. Documentation of data changes may be requested by laboratory auditors.

4.9. **Storage of Site Files**

- 4.9.1. The Laboratory shall maintain Site documents in a secure location that is protected from damage and deterioration.
- 4.9.2. The Laboratory shall maintain written records and documents to be used as evidence for each analytical activity. Documents and records maintained by the Laboratory shall be legible, identifiable, and retrievable.

4.10. **Document Retention:** Documentation and records generated by the Laboratory shall be retained at the laboratory facility for a period of five calendar years. After this period, records may be disposed of with the following provisions:

- 4.10.1. Six months prior to the date the Laboratory intends to dispose of documentation and records related to Site sample analyses, the Laboratory shall notify the CTR or designated representative in writing. Documentation and records shall not be disposed without written approval from the CTR.
- 4.10.2. The Site retains the right to request physical reproduction of the documentation and records by the Laboratory at any time during the retention period.

4.11. Handling of Confidential Information

- 4.11.1. A laboratory conducting work under this SOW may receive Site-designated confidential information. Confidential information shall be handled separately from other documentation developed under this SOW. To accomplish this, the following procedures for the handling of confidential information have been established.
- 4.11.2. The CTR shall notify the Laboratory prior to sample receipt concerning confidentiality requests.
- 4.11.3. All confidential documents shall be under the supervision of a designated DCO.
- 4.11.4. Any samples or information received with a request of confidentiality shall be handled as "confidential." A separate locked file shall be maintained to store this information and shall be segregated from other nonconfidential information. Data generated from confidential samples shall be treated as confidential. Upon receipt of confidential information, the DCO logs these documents into a Confidential Inventory Log. The information is then made available to authorized personnel but only after it has been signed out to that person by the DCO. The documents shall be returned to the locked file at the conclusion of each working day. Confidential information may not be reproduced except upon approval by the CTR. The DCO will enter all copies into the document control system. In addition, this information may not be disposed of except upon approval by the CTR. The DCO shall remove and retain the cover page of any confidential information disposed of for one year and shall keep a record of the disposition in the Confidential Inventory Log.

5. SOFTWARE QA DOCUMENTATION REQUIREMENTS

The Laboratory shall maintain a program that addresses measures taken to ensure computer programs used to generate data are validated, verified, and documented for both vendor-supplied and in-house software packages. This program shall incorporate the "Computer Hardware and Software" requirements from ANSI/ANQC E4-1994. This program shall include the following minimum requirements:

- 5.1. Software validation shall occur before initial use and following subsequent revisions.
- 5.2. A correlation between the validation documentation and the software shall be established.
- 5.3. A historical file of software revisions and associated validation documentation shall be maintained. The historical file shall be maintained in chronological order.
- 5.4. Computer programs and analytical data on electronic media shall be handled, stored, safeguarded, and controlled to prevent damage and deterioration.

6. STANDARD OPERATING PROCEDURES

A Standard Operating Procedure (SOP) is a written document that provides step-by-step directions or requirements for performance of certain tasks. These procedures are necessary to ensure that analytical data produced under this SOW are acceptable.

- 6.1. **The Laboratory SOP Program:** The Laboratory shall establish a system and implement procedures that define when SOPs are required and that define processes by which SOPs are created, reviewed, approved, controlled, updated, and retained. At a minimum, this system shall define, establish, and implement the following:
- 6.1.1. **Document Control:** A document control process shall be established to identify the title, unique SOP identifier, current revision, custodian, and copy number of all SOPs. The process shall insure that procedures are approved for release only by authorized personnel. Document control procedures shall be designed to preclude the use of outdated or inappropriate SOPs and insure that outdated or uncontrolled SOPs shall not be in the possession of laboratory personnel.
 - 6.1.2. **Periodic SOP Review:** SOPs shall be reviewed periodically and updated as necessary when subcontract, facility, or laboratory procedural modifications are made.
 - 6.1.3. **Document Retention:** Current SOPs and superseded revisions of SOPs shall be retained as accountable documents by the Laboratory as described in Exhibit F, Section 4.
 - 6.1.4. **Document Availability:** Current SOPs shall be available at specific work stations as appropriate. SOPs shall be available during an on-site laboratory evaluation. A complete set of SOPs shall be available for inspection at such evaluations. During on-site evaluations, laboratory personnel may be asked to demonstrate the application of the SOPs.
 - 6.1.5. **Format and Content Requirements:** The format for SOPs may vary depending upon the kind of activity for which they are prepared. However, at a minimum, SOPs shall accurately describe the activity as performed at the laboratory and include QC acceptance criteria and corrective action procedures. Additional content requirements follow.
- 6.2. **SOP Delivery Requirements**
- 6.2.1. Twenty-one days prior to the pre-award audit, a complete list of SOPs relevant to this SOW shall be sent to the CTR. The list shall include procedure identifier, title, and effective date.
 - 6.2.2. Within the twenty-one days period prior to the pre-award audit, the CTR will request copies of specific SOPs selected from this list. The Laboratory shall deliver to the CTR copies of the requested SOPs within three calendar days from when the request is received.
 - 6.2.3. During the term of performance of the subcontract, the Laboratory shall notify the CTR, in writing, of new or amended SOPs applicable to this SOW within 14 days of the change. This notification shall identify the new or amended SOP(s) and include a revised SOP list. In the case of updated SOPs, a brief description of the change shall be included.
 - 6.2.4. The CTR may request a copy of an SOP at any time. The Laboratory shall deliver SOP copies to the CTR within three calendar days after the request is received.
- 6.3. **Requirements Common to all Laboratory SOPs:** All SOPs shall:
- 6.3.1. Be functional (i.e., clear, comprehensive, up-to-date, and sufficiently detailed) to permit duplication of results by qualified analysts.
 - 6.3.2. Describe actual processes as performed in the laboratory.
 - 6.3.3. Include QC acceptance criteria and corrective action procedures
 - 6.3.4. Be consistent with current DOE regulations, EPA regulations, State regulations, and SOW requirements.

- 6.3.5. Be consistent with instrument manufacturer's specific instruction manuals.
 - 6.3.6. Provide for the development of documentation that is sufficiently complete to record the performance of all tasks required by the protocol.
 - 6.3.7. Describe the mechanism for demonstrating the validity of data reported by the laboratory and explain the action taken for missing or inconsistent results.
 - 6.3.8. Describe the corrective measures and feedback mechanism used when analytical results do not meet protocol requirements.
- 6.4. **Requirements for Evidentiary SOPs:** The Laboratory shall develop and use adequately written SOPs to ensure sample and data accountability. Evidentiary SOPs shall include specific procedures for the following processes as they are performed by the laboratory.
- 6.4.1. Sample Receipt and Logging
 - 6.4.1.1. The Laboratory shall have written SOPs for receiving and logging samples. At a minimum, these procedures shall describe the systems and performed tasks that ensure fulfillment of Sample Receiving Requirements of GR01 Exhibit F Section 3.
 - 6.4.1.2. The Laboratory shall have detailed SOPs describing the procedures and equipment used for radiological screening of Site samples specified in GR01 Exhibit F Section 3.
 - 6.4.2. Sample Identification
 - 6.4.2.1. The Laboratory shall have written SOPs describing steps taken to ensure fulfillment of Sample Identification Requirements of GR01 Exhibit F Section 2.
 - 6.4.2.2. If the Laboratory assigns unique laboratory identifiers, written SOPs shall include a description of the method used to assign these identifiers. SOPs shall provide instructions for building cross-references to Site sample numbers.
 - 6.4.2.3. If the Laboratory uses prefixes or suffixes in addition to sample identification numbers, the written SOPs shall include their definitions.
 - 6.4.3. Sample Security and Protection
 - 6.4.3.1. The Laboratory shall have written SOPs for sample security and protection. At a minimum, these procedures shall describe the systems and performed tasks that ensure fulfillment of Sample Protection and Integrity requirements of GR01 Exhibit F, Section 2.
 - 6.4.4. Internal Chain-of-Custody
 - 6.4.4.1. The Laboratory shall have written SOPs for the Internal Chain-of-Custody requirements of GR01 Exhibit F Section 2. These SOPs shall include procedures for sample identification, chain-of-custody, sample receiving, and sample tracking.
 - 6.4.5. Laboratory Document and Information Control
 - 6.4.5.1. The Laboratory shall have written SOPs for laboratory document and information control.
 - 6.4.6. Laboratory Waste Management
 - 6.4.6.1. The Laboratory shall have written SOPs for laboratory waste management including the handling and tracking of unused samples.

- 6.5. **Requirements for Analytical SOPs:** The Laboratory shall have written SOPs for performing sample analysis. At a minimum these procedures shall address all issues listed in this section.
- 6.5.1. Analytical SOPs shall include acceptance limits for each method used to report results under this SOW.
 - 6.5.2. Analytical SOPs shall include steps required to perform the analysis. A reference to a standard, published method is not an acceptable substitute for an analytical SOP. However, laboratory SOPs may reference a published item (such as standard methods or instrument manuals) for procedural steps if steps in the published item are used verbatim. References shall include version or published date.
 - 6.5.3. Analytical SOPs shall include examples of laboratory documents, forms, and logbook formats used to document activities. Formulas for all calculations used to derive analytical results shall be included in the SOP. Calculations performed by computer codes written, supplied, and controlled by instrument manufacturers are exempt from this requirement.
 - 6.5.4. Analytical SOPs shall address procedures to prevent sample contamination during sample preparation, sample analysis, glassware cleaning, and sample storage.
 - 6.5.5. The Laboratory shall address QC items required under this SOW that are not included (or are incomplete) in the analytical method.
 - 6.5.6. Analytical SOPs shall include all steps necessary to ensure traceability of standards and tracers used in sample analysis QA/QC.
 - 6.5.7. Analytical SOPs shall address equipment maintenance and calibration.
 - 6.5.8. Analytical SOPs shall describe calculations of IDLs and MDAs, whichever is required by the PSA Module(s).
 - 6.5.9. Analytical SOPs shall describe the purchase, receipt, storage, preparation, control of expiration date, and disposal of outdated standards and stock solutions.
- 6.6. **Requirements for Quality Management SOPs:** The Laboratory shall have written SOPs for technical and managerial review of laboratory operations, Sample Data Package preparation, Support Package preparation, laboratory data review, and laboratory self-inspection systems. At a minimum procedures shall document the following information:
- Data flow and chain-of-command for data review;
 - Procedures for measuring precision and bias;
 - Evaluation of parameters for identifying systematic errors;
 - Procedures to assure that hardcopy deliverables are complete and compliant with the requirements in Exhibit B;
 - Procedures to assure that electronic data deliverables are complete and compliant with the requirements in GR02;
 - Demonstration of internal QA inspection procedure (demonstrated by supervisory sign-off on personal notebooks, internal PE samples, etc.);
 - Frequency and type of internal audits (e.g., random, quarterly, spot checks, perceived trouble areas);
 - Demonstration of problem identification-corrective actions and resumption of analytical processing and the sequence resulting from internal audits (i.e., QA feedback);
 - Documentation of audit reports (internal and external), laboratory responses to audit reports, and corrective actions taken to correct identified deficiencies.
 - The routine use of control charts as specified in PSA Modules.
 - Tracking and identifying trends for nonconforming items, and for implementing corrective action procedures.

- 6.7. **Requirements for Document Organization SOPs:** The Laboratory shall have written SOPs for the organization and assembly of all documents relating to each Site RIN. The procedures shall ensure that all document assembly and organization requirements of GR01 Exhibits B, E, and F and GR02 are specified. The system shall include a document numbering and inventory procedure, a description of the method used by the Laboratory to verify consistency and completeness of the Support Package, and procedures for the shipment of the deliverables.
- 6.8. **Requirements for Data Management SOPs:** The Laboratory shall have written SOPs for the management, handling, and reporting of data. At a minimum, these procedures shall include the following:
- 6.8.1. Procedures for controlling data entry errors;
 - 6.8.2. Procedures for reviewing changes to data and deliverables and ensuring traceability of updates;
 - 6.8.3. Software QA procedures for testing, modifying and implementing changes to existing computing systems including hardware, software, and documentation or installing new systems;
 - 6.8.4. Database security, backup and archival procedures including recovery from system failures;
 - 6.8.5. System maintenance procedures and response time;
 - 6.8.6. Individual(s) responsible for system operation, maintenance, data integrity and security; and
 - 6.8.7. Specifications for staff training procedures.
- 6.9. **Requirements for Software QA SOPs:** The Laboratory shall have written SOPs addressing measures taken to ensure computer programs used to generate data are validated, verified, and documented for both vendor-supplied and in-house software packages. These SOPs shall incorporate the "Computer Hardware and Software" requirements from ANSI/ANQC E4-1994. SOPs shall also address all requirements listed in GR01, Exhibit F, Section 5.
- 6.10. **Requirements for Laboratory Health and Safety SOPs:** The Laboratory shall have written SOPs for laboratory health and safety.

EXHIBIT G

GLOSSARY OF TERMS AND ACRONYMS

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GLOSSARY OF TERMS AND ACRONYMS

1. INTRODUCTION

The glossary of terms and acronyms in this Exhibit and in Exhibit G of the PSA Module(s) ensures the proper understanding of language used in this SOW. The definitions in the PSA Module(s) shall supersede the definitions in this Exhibit in cases of conflicting definitions.

2. GLOSSARY OF TERMS

ACTINIDE SERIES: The series of elements beginning with actinium, element number 89, and continuing through lawrencium, element number 103.

ALIQOT: A measured portion of a field sample or working standard taken for analysis.

ALPHA DECAY: The spontaneous emission of an alpha particle during radioactive decay of a nucleus. An alpha particle is a strongly ionizing particle from the nucleus having a mass and charge equal to that of a helium nucleus (2 protons and 2 neutrons).

ANALYSIS DATA SHEET: A form used to tabulate and report sample analysis results for target analytes. In CLP-SOW reporting protocols, this form is usually designated as *Form 1*. For non-CLP methods, the Analysis Data Sheet should contain, at a minimum, the following information: Site sample numbers and Laboratory sample identifiers, measured concentrations with units for all requested analytes, and necessary comments. Quality control and concentration qualifiers shall also be included when appropriate.

ANALYSIS DATE/TIME: The date and military time (24-hour clock) of the initiation of counting of a sample, standard, or blank in a radioactive counting system.

ANALYSIS RUN: The actual instrumental analysis of the sample preparations, from the time of instrumental calibration through the running of the final check.

ANALYTE: The specific component measured in a chemical analysis; the parameter/isotope of interest.

ANALYTICAL BATCH: A set of samples analyzed together as a unit for the purpose of method QA/QC. An analytical batch may contain several RINs. It is also possible that several analytical batches could comprise a single RIN. Each analytical batch shall have a unique identifier that associates client and QC samples within the batch.

ANALYTICAL PREPARATION METHOD: - A method (digestion, dilution, extraction, fusion, etc.) used to dissolve or otherwise release the analyte(s) of interest from its matrix and provide a final substrate or solution containing the analyte in a form which is suitable for instrumental or other analysis methods.

ANALYTICAL SAMPLE: A substance or sample submitted from an outside entity to the laboratory for analysis.

ASTM TYPE I WATER: Reagent water with a conductivity of less than 0.1 $\mu\text{mho/cm}$ at 25° C and has been polished with a 0.45 μm membrane filter. For additional specifications, refer to ASTM D1193-77, "Standard Specification for Reagent Water."

ASTM TYPE II WATER: Deionized water with a conductivity of less than 1.0 $\mu\text{mho/cm}$ at 25° C. For additional specifications, refer to ASTM D1193-77, "Standard Specification for Reagent Water."

BACKGROUND CORRECTION: A technique for measuring background (non-analyte) contribution to the instrument signal and performing mathematical compensation for the resulting error. In radiochemical analysis, correction for the background contribution in the determination of radionuclides for a specific detector.

BETA DECAY: The emission of a beta particle during radioactive decay of a nucleus. A beta particle is a charged particle emitted from the nucleus, having a mass and charge equal in magnitude to that of an electron.

BLIND SAMPLE: A surrogate sample containing known amounts of analyte(s) of interest, submitted as an audit sample.

BOTTLE IDENTIFICATION NUMBER: A unique identifying number assigned to each sample container associated within a RIN and Sample Event. This number begins at '001' and increases sequentially until the event changes.

CALIBRATION: The establishment of an analytical curve relating the response of an instrument to a quantifiable characteristic of the analyte in known standards.

CALIBRATION STANDARDS: A series of known standard solutions used by the analyst for calibration of the instrument (i.e., preparation of the analytical curve).

CHEMICAL YIELD: The yield determined by a physical or radiochemical measurement of the recovered carrier or tracer.

COEFFICIENT OF VARIATION (CV): The standard deviation as a percent of the arithmetic mean.

CONTRACTOR TECHNICAL REPRESENTATIVE (CTR): Person responsible for providing technical oversight of the subcontract.

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

CORRELATION COEFFICIENT: A number (r) which indicates the degree of dependence between two variables (i.e., concentration - activity).

COUNTING EFFICIENCY: The ratio of the net count rate of a radionuclide standard source to its corresponding known activity.

COUNTING EFFICIENCY FACTOR: The fraction of actual disintegrations in the sample which are counted by the detector as a function of residue weight.

CURIES: The traditional unit used to express the activity (amount) of radioactive material. The SI unit for activity is the becquerel.

1 curie (Ci)	=	2.22×10^{12} disintegration/minute
1 millicurie (mCi)	=	2.22×10^9 disintegration/minute
1 microcurie (μCi)	=	2.22×10^6 disintegration/minute
1 picocurie (pCi)	=	2.22 disintegration/minute
1 becquerel (Bq)	=	1 disintegration/second

CUSTODY SEAL: Adhesive seal applied to sample bottles to maintain Chain of Custody until sample is delivered to the laboratory.

DAUGHTER: A nuclide formed by radioactive decay of a parent radionuclide.

DAY: Unless otherwise specified, day shall mean calendar day. There are 365.25 days per year.

DETECTION LIMIT: A stated limiting value which designates the lowest concentration that can be estimated or determined with confidence and that is specific to the analytical procedure used.

DISSOLVED: The concentration of an analyte determined on a sample which has been filtered in the field prior to preservation. Protocols for sample pretreatment for dissolved analytes are specific to analyte and procedure source.

DISSOLVED SOLIDS: Radionuclide isotopes and other solid materials which have not been digested prior to analysis and which will pass through a 0.45 μm filter.

DRY WEIGHT: The weight of a sample based on percent solids. The weight after drying in an oven at 103-105 C until a constant weight is obtained.

DUPLICATE SAMPLE: A second aliquot of a sample that serves as a Batch QC Sample, demonstrating analytical method precision and sample homogeneity.

EFFICIENCY: A measure of the fraction of actual disintegrations in the sample which are counted by a detector.

ENERGY CALIBRATION: The correlation of the multichannel analyzer (MCA) channel number to decay energy, obtained from the location of peaks from known radioactive standards..

ERROR: An estimation of the analytical measurement uncertainty, expressed as an error term with a specific analytical result, or as a typical value for a specific analytical technique.

ESTIMATED QUANTITATION LIMIT (EQL): Also known as the Practical Quantitation Limit (PQL). The lowest level that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions. The EQL is a multiple of Method Detection Limit (MDL) and is highly dependent on sample matrices and analysis method.

FIELD BLANK: A sample prepared in the field by transferring ASTM Type II Water to a clean sample container. The field blank is used to indicate the presence of contamination due to sample collection and handling.

FIELD SAMPLE: A portion of material received to be analyzed that is contained in single or multiple containers and identified by a unique Site sample number.

GAMMA RADIATION: Electromagnetic radiation of nuclear origin usually accompanying another form of radioactive decay.

HALF-LIFE ($T_{1/2}$): The time required for 50 percent of a radioactive isotope to decay.

HIGH LEVEL: A decision level for purposes of segregation for gross alpha activities known or suspected to be greater than approximately 20 dpm per aliquot

HOLDING TIME: The elapsed time expressed in days from the date of sampling until the date of analysis for which sample data will be considered valid.

Holding time = (sample analysis date - sampling date)

INDEPENDENT STANDARD: A standard solution that is composed of analytes from a different source than those making up the standard used for the initial calibration.

INSPECTION PERIOD: This is the period from the day after the receipt of data until the day the laboratory receives notification of the nonconformities or acceptance of the data.

IN-HOUSE: At the laboratory facility which is identified in the subcontract.

INSTRUMENT DETECTION LIMIT (IDL): Exact definitions are method-specific; however, these definitions usually involve estimating the analyte concentration or activity which creates the smallest signal above the background noise that an instrument can detect reliably.

INTERFERENTS: Undesired substances that affect quantification of the parameter of interest.

INTERNAL DOSIMETRY: The Internal Dosimetry Department of the Rocky Flats Radiological Health Section of the Radiological Control Program.

INTERNAL STANDARD: A material present in or added to samples that serves as an intensity reference for spectral measurements.

IONIZING RADIATION: Any electromagnetic or particulate radiation capable of producing ions directly or indirectly in its passage through matter.

ISOTOPES: Elements which contain the same number of protons, but a different number of neutrons in the nucleus.

LABORATORY: Synonymous with subcontractor as used herein.

LABORATORY CONTROL SAMPLE (LCS): A QC sample (control) of known analyte value. Laboratory control samples are analyzed using the same sample preparation, reagents, and analytical methods employed for the Client samples processed as part of the Analytical Batch.

LABORATORY RECEIPT DATE: The date on which a sample is received at the laboratory facility, as recorded on the shipper's delivery receipt. Also referred to as VTSR (validated time of sample receipt).

LABORATORY REPORT IDENTIFICATION: The laboratory's identification for samples contained in a RIN for a Parameter Specific Analytical Module.

LINE ITEM CODE: This code, included on the COC or other documentation received with samples, designates the analyte prescription.

MATRIX: The predominant material of which the sample to be analyzed is composed. For the purpose of this SOW, a sample matrix is either water, soil/sediment, or waste. Matrix is not synonymous with phase (liquid or solid).

MATRIX BLANK: Synthetic sample containing no measurable amount of analyte being assessed.

MATRIX SPIKE: An aliquot of a sample fortified with known quantities of specific parameters and subjected to the entire analytical procedure in order to judge the appropriateness of the method for the matrix by measuring recovery.

METHOD DETECTION LIMIT (MDL): For organic and inorganic analyses, the MDL is defined as the minimum concentration of an analyte that can be determined with 99% confidence that the true value is greater than zero. Instructions for the determination of MDL are usually provided by, and specific to, the method of analysis.

In radiochemical analyses, the MDL is defined as the minimum activity (concentration) of an analyte (radioisotope) that can be determined with 95% confidence that true value is greater than zero, provided by and specified to the sample type and method of analysis. In radiochemistry, the MDL considers not only the

instrument characteristics, but all other factors and conditions (i.e., sample size and sample type) that influence the measurements.

MINIMUM DETECTABLE ACTIVITY (MDA): An estimate of the level of the smallest activity that can be detected in a sample with a 95% confidence level. The MDA considers not only the instrument characteristics, but all other factors and conditions, such as sample size and matrix, which affect the analysis.

MINIMUM DETECTABLE AMOUNT (MDA): The smallest amount of a radionuclide which will be detected with an b probability of non-detection of 0.05 while accepting an a probability of 0.05 for falsely detecting the activity in a matrix sample.

MIXED WASTE: Waste containing both radioactive and hazardous components as defined by the Atomic Energy Act and the Resource Conservation Recovery Act respectively.

MODULES: Documents which, together, make up the complete Statement of Work for the analysis of samples collected at the Site. Modules are identified by their two-letter descriptor, module number, and version letter designation.

NEAT STANDARD: A pure original analyte obtained from a chemical supply house.

NIST-TRACEABLE STANDARD: A Standard Reference Material (SRM) purchased either directly from the National Institute of Standards and Technology (NIST) or the other approved vendors who provide the traceability certificate to the NIST.

NUCLIDE: An atomic species characterized by the constitution of its nucleus, specifically by the number of protons and neutrons.

PARAMETER SPECIFIC ANALYTICAL MODULE (PSA Module): Provides parameter-specific technical requirements, quality control procedures, and analysis structure for obtaining data of known and documented quality. Examples of PSA Modules include; Volatile Organics, SS01; Tritium Determinations by Scintillation Counting, RC02; General Bioassay Services, BA01, etc.

PRACTICAL QUANTITATION LIMIT (PQL): Synonymous with Estimated Quantitation Limit.

PERCENT SOLIDS: The proportion of solid in a sample determined by drying an aliquot of the sample.

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

PREPARATION BLANK (reagent blank, method blank): An analyte-free matrix to which all reagents are added in the same volumes or proportions as used in sample processing. The preparation blank should be carried through the complete sample preparation and analytical procedure and is used to assess contamination resulting from the entire analytical process.

PROCESSING DESIGNATOR: Designations used to identify, on a COC, sample data package turnaround requirements, i.e., Routine, Priority, Rush, etc.

PROTOCOL: A compilation of the procedure to be followed with respect to sample receipt and handling, analytical methods, data reporting and deliverables, and document control. Used synonymously with the Statement of Work (SOW).

QC SAMPLE: For a batch of samples for radiochemical analysis, these are the Preparation Blank, the Duplicate Sample and the Laboratory Control Sample. For other analysis methods, QC samples typically

include the following when required by the PSA Modules: preparation blanks, laboratory duplicate samples, spiked samples, spiked duplicates, and laboratory control samples.

RADIOACTIVE DECAY: The process by which a spontaneous change in nuclear state takes place. This process is accompanied by the emission of energy and subatomic particles.

RADIOACTIVE WASTE: Solid, liquid, or gaseous materials containing radionuclides regulated under the Atomic Energy Act of 1954 as amended, and of negligible economic value considering recovery costs.

RADIATION YIELD: The amount of radiation of the type being measured that is produced per each disintegration which occurs. For gamma spectrometry, this is commonly called gamma abundance.

REGION OF INTEREST (ROI): In radiochemical analysis, the Multichannel Analyzer region defining the isotope of interest displayed in terms of energy or channels.

REPORT IDENTIFICATION NUMBER (RIN): A grouping of samples identified by the CTR to be included in a single sample data package for a given PSA Module. An RIN may be comprised of more than one analytical batch, in which case, each analytical batch shall have a unique identifier that associates client and QC samples within the batch. Conversely, if two or more RINs are combined into one analytical batch, each RIN data package must contain all required QC results. RINs are formatted as YY*NNNN, where YY is the 2-digit designator for the Federal fiscal year in which the sample was assigned, * is the letter P, J, or L, and NNNN designates a four-digit number.

RESOLUTION PERIOD: The time allowed for the correction of non-compliant sample data package or response to a Client's question.

REQUIRED DETECTION LIMITS (RDL): The minimum detection level acceptable for analyses performed under this contract.

ROUNDING RULES: If the number following those to be retained is less than five, the number is dropped, and the retained numbers are kept unchanged. As an example, 11.443 is rounded off to 11.44. If the number following those to be retained is five and if there are no numbers other than zeros beyond the five, the number is dropped, and the last place number retained is increased by one if it is an odd number or it is kept unchanged if an even number. As an example, 11.435 is rounded off to 11.44 while 11.425 is rounded off to 11.42. If the number following those to be retained is greater than five, the number is dropped, and the last place number retained is increased by one. If a series of multiple operations is to be performed (add, subtract, divide, multiply), all numbers are carried through the calculations. Then the final answer is rounded to the proper number of significant figures.

SAMPLE DATA PACKAGE: A deliverable that includes data from analysis of all samples in one RIN for a given PSA Module, including analytical and field samples, PE sample, sample reanalyses, blanks, spikes, duplicates, and LCSs.

SAMPLE DATA PACKAGE NARRATIVE: The section of the sample data package describing all problems or unusual circumstances encountered in the analytical processing of the sample. The narrative should include descriptions of matrix interferences, dilutions required, explanations of any Quality Control deficiencies, method modifications and all other information that might affect the validation of the data.

SAMPLE EVENT NUMBER: A unique identifier number beginning at '001' that identifies a sampling event(s) within an individual RIN. This identifier increases sequentially until the RIN changes.

SAMPLE NUMBER (SITE SAMPLE NUMBER): A unique identification number generated by concatenation of the Report Identification Number, Sample Event Number, and the Bottle Identification Number. The format for the site sample number is YY*NNNN-EEE.BBB, where YY*NNNN' is the RIN (* may be any character), 'EEE' is the sample event number that starts at '001' and increases sequentially until the RIN changes and resets the sample event number back to '001', 'BBB' is the Bottle Identification Number that starts at '001'

and increases sequentially for all sample bottles taken within an event. The following is an example of a site sample number: 97J1234-001.001. All components of the sample number may be found on the COC.

SCINTILLATOR: A transparent substance that emits visible or near-ultraviolet light when traversed by an ionizing particle.

SECONDARY STANDARD: A standard solution prepared at a medium concentration by dilution of the stock standard. Secondary standards also may be purchased from a chemical supply house.

SITE: The Rocky Flats Environmental Technology Site.

SITE SAMPLE IDENTIFIER: See SAMPLE NUMBER.

SOIL: Synonymous with soil/sediment or sediment as used herein.

SPIKE: In radiochemical analysis, an accurately measured amount of tracer quantitatively introduced or transferred into a sample aliquot.

STATEMENT OF WORK (SOW): As used herein, the general requirements modules (GR01 and GR02) and the PSA Module(s).

STOCK STANDARD: A standard solution at a relatively high concentration which can be diluted to derive other standards. Stock standards may be purchased from a chemical supply house or prepared from neat compounds at the laboratory. Synonymous with parent or primary standard.

SUPERNATANT: Liquid material above a precipitate or solid.

SUPPORT PACKAGE: Short form of *Supporting Documentation Package*.

SUPPORTING DOCUMENTATION PACKAGE (Support Package): The Supporting Documentation Package (Support Package) is an ordered compilation of laboratory information relevant to all aspects of data integrity for a single RIN. Much of this information is included by reference to Laboratory document storage locations. One Support Package is compiled for each RIN and is maintained by the Laboratory.

TOTAL RECOVERABLE: The concentration of an analyte determined in a non-filtered sample following an sample digestion procedure specific to the analyte and procedure.

TRACER: A radionuclide that chemically mimics and does not interfere with the target radioanalyte through the chemical preparation and instrument analysis.

TRACER CHEMICAL RECOVERY: The percent yield of the recovered tracer radio-isotope after the sample/tracer aliquot has undergone preparation and instrument analysis.

TURN AROUND TIME: A performance measure used to assess Laboratory compliance to delivery schedules. The elapsed time from the date a laboratory receives a sample(s) (VTSR) to the date the Site receives the complete sample data package deliverable as stated in GR01 and in PSA Modules.

VALIDATED TIME OF SAMPLE RECEIPT (VTSR): Synonymous with Laboratory Receipt Date as used herein.

WATER: Synonymous with aqueous or wastewater as used herein.

WET WEIGHT: The weight of a sample aliquot including moisture (non-dried).

WORKING STANDARD: A daily calibration standard solution prepared by diluting the secondary standard. Working standards are prepared at multiple concentrations from the same secondary standards.

10% FREQUENCY: A frequency specification during an analytical sequence allowing for no more than 10 analytical samples between required calibration verification measurements, as specified by the Statement of Work.

3. ACRONYMS

AA	Atomic Absorption
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
APHA	American Public Health Association
APO	Analytical Projects Office
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
BNA	Base Neutral Acid (Semivolatile organic)
BOD	Biological Oxygen Demand
CBOD	Carbonaceous Biological Oxygen Demand
CCB	Continuing Calibration Blank
CCV	Continuing Calibration Verification
CDPHE	Colorado Department of Public Health and Environment (formerly CDH, Colorado Department of Health)
CFR	Code of Federal Regulations
CL	Confidence Limit
CLP	Contract Laboratory Program
COC	Chain-of-Custody
COD	Chemical Oxygen Demand
cpm	Counts Per Minute
CRDL	Contract Required Detection Limit
CRQL	Contract Required Quantitation Limit
CTR	Contractor Technical Representative
CVAA	Cold Vapor Atomic Absorption Spectrometry
DCO	Document Control Officer
DEAR	Department of Energy Acquisition Regulations
DI	Deionized (water)
DIC	Dissolved Inorganic Carbon
DOC	Dissolved Organic Carbon
DOE	Department of Energy
DOT	U. S. Department of Transportation
dpm	Disintegration Per Minute
dps	Disintegration Per Second
EDCN	Environmental Data Collection Network
EDD	Electronic Data Deliverable
EM	Environmental Management
EML	U. S. DOE Environmental Monitoring Laboratory
EMSL	U. S. EPA Environmental Monitoring Systems Laboratory
EPA	U. S. Environmental Protection Agency
EPA-600	EPA-600/4-79-020 <i>Methods for Chemical Analysis of Water and Wastes</i>
EQL	Estimated Quantitation Limit
ERM	Environmental Restoration Management
ERWM	Environmental Restoration & Waste Management
FEP	Full Energy Peak or Photopeak
FLAAS	Flame Atomic Absorption Spectrometry
FWHM	Full Width at Half Maximum
GAC	Granular Activated Carbon
GC	Gas Chromatography
GC/MS	Gas Chromatography/Mass Spectrometry

GFAAS	Graphite Furnace Atomic Absorption Spectrometry
GLP	Good Laboratory Practice
GPC	Gas Proportional Counter
GRRASP	General Radiochemistry and Routine Services Protocol
IC	Ion Chromatography
ICB	Initial Calibration Blank
ICP	Inductively Coupled Plasma
ICPES	Inductively Coupled Plasma Emission Spectrometry
ICP-MS	Inductively Coupled Plasma Mass Spectrometry
ICRP	International Commission on Radiological Protection
IDL	Instrument Detection Limit
IPA	Instrument Performance Assessment
IR	Infra-red
KLP	Kinetic Laser Phosphorescence
KPA	Kinetic Phosphorescence Analysis
LSC	Liquid Scintillation Counter
MAPEP	Mixed Analyte Performance Evaluation Program
M&TE	Measuring and Testing Equipment
MB	Matrix Blank
MDA	Minimum Detectable Activity (Radiochemistry Modules), Minimum Detectable Amount (Bioassay Modules)
MDL	Method Detection Limit
MS	Matrix Spike
MSD	Matrix Spike Duplicate
MSDS	Material Safety Data Sheet
N/A	Not Applicable
NB	No Bid
ND	Not Determined
NEG	No Established Guidelines
NARA	National Archive Record Act
NIOSH	National Institute of Occupational Safety and Health
NIST	National Institute of Standards and Technology
NPDES	National Pollutant Discharge Elimination System
NRC	Nuclear Regulatory Commission
NVSS	Non-Volatile Suspended Solids
OMB	Office of Management and Budget
OSWER	U. S. EPA Office of Solid Waste and Emergency Response
PB	Preparation Blank
PCB	Polychlorinated Biphenyls
PE	Performance Evaluation
PN	Price Negotiable
PQL	Practical Quantitation Limit
PSA	Parameter-Specific Analytical (Module)
QA	Quality Assurance
QAO	Quality Assurance Officer
QC	Quality Control
RASP	Radioanalytical Services Protocol
RCRA	Resource Conservation and Recovery Act
RDL	Required Detection Limit
RFEDS	Rocky Flats Environmental Data System

RFETS	Rocky Flats Environmental Technology Site
RFP	Rocky Flats Plant
RIN	Report Identification Number
ROI	Region of Interest
RPD	Relative Percent Difference
RSD	Relative Standard Deviation
SDP	Sample Data Package
SIC	Site Identification Code
SM	Standard Methods
SOP	Standard Operating Procedure
SOW	Statement of Work
SRM	Standard Reference Material
SW-846	U. S. EPA-OSWER Document <i>Test Methods for Evaluating Solid Waste</i>
TAT	Turn Around Time
TAL	Target Analyte List
TCLP	Toxicity Characteristic Leaching Procedure
TDS	Total Dissolved Solids
TIC	Tentatively Identified Compound
TIC	Total Inorganic Carbon
TKN	Total Kjeldahl Nitrogen
TOC	Total Organic Carbon
TOX	Total Organic Halides
TPH	Total Petroleum Hydrocarbons
TS	Total Solids
TSD	Treatment Storage Disposal
TSS	Total Suspended Solids
TVSS	Total Volatile Suspended Solids
USEPA	United States Environmental Protection Agency
VTSR	Validated Time of Sample Receipt
VOA	Volatile Organic Analysis
VOC	Volatile Organic Compound
WQP	Water Quality Parameter

EXHIBIT H

REFERENCES

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