



# Mission Support Alliance

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AIHA ACCREDITED IH MICROBIOLOGICAL ANALYTICAL SERVICES

## Statement of Work

For

## Industrial Hygiene Microbiological Analytical Services

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**Title:** AIHA Accredited IH Microbiological Analytical Services

**Date:** 12/3/2019

**Revision Number:** 0

**Requisition Number:** 335311

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### 1.0 INTRODUCTION / BACKGROUND

The U.S. Department of Energy (DOE) Hanford Site covers approximately 586 square miles along the Columbia River in southeastern Washington State. Past nuclear weapon production activities at the Site involved a plutonium production complex consisting of nine nuclear reactors and associated processing facilities. Mission Support Alliance, LLC (MSA) is a DOE prime contractor on the Hanford Site and involved in environmental remediation activities. MSA's work scope includes the collection of Industrial Hygiene (IH) program samples with funding provided through the DOE's Office of Environmental Management.

Industrial Hygiene samples are submitted to American Industrial Hygiene Association Laboratory Accreditation Program (AIHA-LAP, LLC) accredited offsite laboratories for analysis.

### 2.0 OBJECTIVE

This Statement of Work (SOW) directs the Contractor to provide analytical laboratory support to the Hanford Site by providing media, sampling equipment, and associated analyses, as requested, for evaluating microbiological content of air and other environmental samples from office and industrial settings to evaluate personnel exposure.

### 3.0 DESCRIPTION OF WORK – SPECIFIC

The Contractor shall provide sampling media and equipment, as recommended in the American Conference of Governmental Industrial Hygienists (ACGIH) manual,



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“Guidelines for the Assessment of Bioaerosols in the Indoor Environment,” (ACGIH, 1989) or other industry-recognized standards, for sampling airborne bacteria and fungi in office settings. The Contractor shall also provide sterile containers, sterile swabs, or other collection equipment as requested for microbiological sampling and instructions on how the samples are to be collected.

The Contractor shall analyze samples in accordance with ACGIH Guidelines or other appropriate industry-recognized standards. Sample handling and storage conditions and holding times, defined from the date of sample collection, for the applicable method and/or protocol, shall be met.

The Contractor shall supply all facilities, equipment, materials, documents, and personnel necessary for the performance of work in accordance with the requirements of this SOW, unless otherwise specified. The Contractor shall not subcontract any part of this SOW without written authorization from the Buyer's Technical Representative (BTR). Any authorized subcontracted services shall be performed in accordance with this SOW.

For each request for analysis, the Contractor shall provide a final report detailing the results of the analysis, including identification of predominant biological species observed, or other details as defined in the specified protocols. Interpretation of results shall also be provided when possible and customary. Final sample disposition shall be the responsibility of the Contractor, unless specified otherwise.

The Contractor shall prepay shipping costs, when requested by the Buyer, and then invoice them against this Contract.

\*\*Priority overnight shipment is authorized when required by the sampling protocols.

The Contractor shall interface with various Buyer (and other) organizations through the BTR (or designee).

## 4.0 REQUIREMENTS

### 4.1 General

Will work be performed on site: No

### 4.2 Engineering Requirements

Engineering requirements applicable: No

### 4.3 Types of Analyses

The Contractor shall perform characterizations in accordance with ACGIH guidelines and may include, but are not limited to:

- Fungi
- Bacteria



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## 4.4 Contractor Laboratory Requirements

The Contractor shall have the ability to perform the contracted specified analyses, according to applicable standard methods specified/approved by the Buyer. The contractor shall meet or exceed the analytical requirements specified in:

- AIHA Laboratory Accreditation Modules as appropriate to the method of analysis or equivalent

The Contractor shall contact the designated MSA Contracting Officer at any time to receive clarification, direction, or other concerns pertaining to any requirements in this SOW.

## 4.5 Accreditation

The Contractor shall maintain applicable accreditation for all analyses performed from AIHA-LAP, LLC for microbiological analysis of bacteria and fungi. A copy of the accreditation certificate shall be provided to MSA or obtained from AIHA website for approval, prior to implementation of work under this Contract, and at other times upon request.

## 4.6 Proficiency Evaluation Programs

The Contractor shall participate and maintain proficiency in the AIHA –Proficiency Analytical Testing Program (AIHA-PAT, LLC) for microbiological workplace monitoring. Equivalent proficiency evaluation programs may be used with prior approval of the BTR.

Results of each round of testing shall be provided to the BTR upon request. The Contractor shall notify the BTR immediately if it fails to maintain proficiency or accreditation in the Environmental Microbiology Proficiency Analytical Testing (EMPAT) program. If this happens, the Buyer, at their discretion, may choose to discontinue use of this Contract without penalty.

## 4.7 Environment, Safety, & Health

The Contractor shall perform work safely, in a manner that ensures adequate protection for employees, the public, and the environment, and shall be accountable for the safe performance of work. The Contractor shall comply with, and assist the Contract Specialist in complying with Environmental, Safety, Health, and Quality (ESH&Q) requirements of all applicable laws, regulations and directives.

The Contractor shall exercise a degree of care commensurate with the work and the associated hazards. The Contractor shall ensure that management of ESH&Q functions



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and activities is an integral and visible part of the Contractor's work planning and execution processes. As a minimum, the Contractor shall:

- Thoroughly review the defined scope of work;
- Identify hazards and ESH&Q requirements;
- Analyze hazards and implement controls;
- Perform work within controls; and
- Provide feedback on adequacy of controls and continue to improve safety management

Analytical Standard Operating Procedures (SOPs) and Quality Assurance (QA) documents utilized by the Contractor for performance of work under this SOW shall reflect the actual operating conditions in effect during analysis of MSA samples.

The Contractor shall maintain and demonstrate the security, integrity and traceability of samples, data, and documentation while in its possession.

A health and safety plan that addresses hazardous and radioactive materials is required during performance of this Contract as applicable. The Contractor shall have an industrial hygiene/chemical hygiene plan and a radiation safety plan which meets and implements all laboratory safety requirements outlined by OSHA in the most current revision of 29 CFR 1910.1450, "Occupational Exposures to Hazardous Chemicals in Laboratories."

## 4.8 Quality Assurance

Are quality assurance requirement applicable to this scope of work: Yes

The work activities for this Statement of work has been designated as a Quality Level F - Q Level 3 - GS

The Contractor shall ensure the integrity and validity of all analytical results through implementation of an internal QA Program in accordance with an accredited laboratory. Prior to start of any work activities on this SOW, the Contractor shall submit a copy of their accreditation certificate, QA Program, and SOPs for review as part of the submitted technical proposal. Failure to provide required documentation will be justification for technical non-acceptance. Additional requests for QA documentation may be requested at any time after the implementation of this work. The Contractor shall ensure Buyer has current copies of accreditation documentation throughout the period of performance.

### 4.8.1 Quality Assurance Plan

The Contractor shall have a written QA Plan and supporting SOPs defining the laboratory's QA program and its implementation. This plan shall be based on the most recent AIHA -LAP, LLC Policy Modules or equivalent. The written plan shall, at a minimum, address the following elements:



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- Organization and Responsibility
- QA Objectives and Policies
- QA Manual Maintenance and Update Procedures
- Personnel Qualifications and Training
- Procurement
- Sampling Materials and Procedures
- Chain-of-Custody (COC)/Sample Receiving and Handling Procedures
- Reagents and Standards
- Equipment Calibration and Maintenance Procedures
- Analytical Methods, including Uncertainty
- Data Reduction, Validation, and Reporting
- Internal Quality Control Procedures
- Performance and System Audits
- Corrective and Preventive Action
- Client Communications
- QA Reports
- Documentation Control and Record Keeping and Control
- Sample Retention and Disposal
- Subcontracting of analyses

A copy of the QA Plan shall be provided to in accordance with the submittal register. Copies of Analytical Methods and SOPs used for Hanford analyses shall be submitted and will be reviewed as part of the submitted technical proposal. Failure to provide required documentation will be justification for technical non-acceptance. Additional requests for QA documentation may be requested at any time after the implementation of this work. Contractor shall ensure Buyer has current copies of accreditation documentation throughout the period of performance.

## **4.8.2 Audits and Surveillances**

The Contractor shall be subject to Buyer QA audits and surveillances at any time during the implementation period of this Contract. The Buyer, or designated representative(s) shall be granted access to all facilities, equipment, files, documents, and records associated with this SOW. The Buyer, at their discretion, shall also have the right to accompany the Contractor on QA audits or surveillances of any subcontractors used for Hanford Site



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analyses. The Buyer has the authority to stop work on Hanford Site samples under conditions of noncompliant quality-affecting activities.

The Contractor shall provide corrective action responses for audit findings and observations, or for surveillance-identified deficiencies. Responses shall include a schedule for implementation agreed to by the Contractor and the Buyer. The BTR shall verify satisfactory completion of the corrective actions. The Buyer shall notify the Contractor a minimum of seven (7) calendar days in advance to arrange any audit or surveillance activities. The Buyer shall provide the Contractor an agenda and/or checklist, detailing the scope of the audit/surveillance activities, a minimum of three (3) Contractor working days in advance of the scheduled activity.

## **4.8.3 Corrective Action Program**

The Contractor shall have a corrective action program for documenting resolution of quality-affecting problems that may arise during analysis of Buyer samples and implementation of this SOW. When equipment calibration issues or other system failures are involved, resolution shall include evaluation of the validity of Buyer analytical results reported since the last documented proof the system or equipment in question was in control.

## **4.9 Quality Control/Calibrations**

The Contractor shall ensure that all equipment and instruments are calibrated and in working order prior to the analysis of Buyer samples. Culture media, water, and analytical reagents shall be routinely checked for appropriate sterility, microbial growth, and analytical reactions.

The Contractor shall have an internal quality control program that includes, as a minimum, 5% replicate and 5% duplicate analyses. This program shall be documented in appropriate QC databases or control charts. Acceptance criteria shall be established.

The laboratory shall have a procedure for determining analytical uncertainty as it applies to microbiological analyses. Analytical uncertainty for any analysis performed under this contract shall be available to the BTR upon request.

## **4.10 Contamination Control**

The Contractor shall have documented procedures in place to prevent contamination or cross-contamination of samples from the time of media preparation through the final analysis. These procedures shall specify the type of air monitoring, surface wipes, analytical blanks, or other types of activities used to demonstrate that contamination control is in place.



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## 4.11 Sample Management

The Contractor shall provide sampling media, in accordance with this SOW, only when and as requested by the Buyer. This material shall be shipped prepaid by the Contractor. Sample Management Office (SMO) personnel will serve as the primary point of contact for all communications and deliverables associated with sample scheduling, shipment, receipt, analysis, and sample disposal specific to the Buyer. Prior to shipping samples, an agreement will be reached with the Contractor regarding the requested analyses, priority (e.g., turnaround time), required constituents, and the required reporting limits to be achieved. If the Contractor receives samples that do not meet required minimum volumes or weights, the Contractor shall contact the SMO for specific guidance before proceeding with the analysis.

The Buyer shall be responsible for preserving sample custody and integrity, as required by the method requested, while the samples are under its control. Samples shall be shipped under COC protocol, by the Buyer to the Contractor, in accordance with Hanford Site and U.S. Department of Transportation (DOT) requirements. Cost of shipment of samples to the Contractor shall be at the expense of the Buyer.

Upon receipt of samples, the Contractor's sample custodian shall inspect the shipping container and sample containers/security seals to verify sample integrity. The Buyer will provide a COC with each sample shipment. The sample check-in shall be documented with notes regarding any anomalies including missing samples, non-matching sample identification numbers (IDs), lack of signatures, etc. The sample custodian shall print, sign, date, and record the time of receipt on all appropriate receiving documents including the MSA COC.

The Contractor shall notify the Buyer within 24 hours of discovery of lost, damaged, or inadvertently destroyed samples, failure to meet hold times, errors in handling samples or reporting, loss of capability, or other conditions which may adversely affect analytical results or delivery of analytical reports within times specified. The Contractor shall work with the SMO personnel to determine a mutually acceptable resolution to the problem. If the Buyer deems it appropriate, the Buyer may require the Contractor to develop and provide an Action Plan in writing to the SMO within five (5) Contractor business days of notification.

The Contractor shall email (as a PDF file) copies of all COCs, sample check-in lists, sample acknowledgement forms, and any anomalies, if applicable, associated with each sample shipment to the SMO within one Contractor business day of sample receipt.

The Contractor shall have procedures to ensure that sample custody and sample identity are maintained and documented from the time the samples reach its facility through analysis and final disposition. The Contractor shall be able, at all times, to cross-reference its sample identifiers to the Buyer's identifiers.

Samples shall be maintained in accordance with temperature and storage conditions specified in sampling and analytical protocols to ensure sample integrity. Sample



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preservation and holding time requirements, as they are defined from the date of sample collection for the applicable method and/or protocol, shall be met. Temperatures other than ambient shall be monitored by calibrated temperature sensing devices.

The Contractor shall store unused sample(s) or sample preparation(s) in accordance with applicable analytical procedures until the analytical hold times are exceeded or for a minimum of three (3) months where there are no hold times. At the end of that time, the Contractor may dispose of the samples and/or preps. If a sample is to be held beyond this time, the Buyer shall notify the Contractor before the end of the normal hold time. Samples held shall be maintained per the method requirements.

## 4.13 Client Communications

The Contractor shall have policies and procedures, as necessary, to ensure client communications and issues are appropriately addressed. Management of contracts, handling client complaints, maintenance of confidentiality and routine communications should all be addressed.

## 4.14 Records Management

The Contractor shall maintain controlled access storage for all records of data and other technical information generated in the performance of services described in this SOW. Storage shall prevent tampering, water or fire damage, and rodent or insect damage.

Controlled documents and records shall be traceable to the originator and date of origin, both by being signed/initialed and dated or by being traceable to a signed/initialed and dated record. Controlled documents shall include, but are not limited to:

- Logbooks, bench sheets, or sample work sheets,
- COC records, sample tracking records, and shipping documentation,
- Quality Control (QC) records,
- Analyst qualification records,
- Raw data,
- Analytical reports,
- Calibration records,
- Corrective action documents,
- QA Program and SOP documentation.

Per DOE requirements, controlled documents and records, pertaining to Hanford analyses, shall be maintained until disposal is authorized by a Buyer or DOE representative. If the Contractor cannot adequately maintain or protect these documents and records, the Contractor shall return them to the BTR.



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## 4.15 Government Property

Government property is not required to be used by the Contractor for this effort.

## 5.0 PERSONNEL REQUIREMENTS

### 5.1 Training and Qualifications

The following types of training qualifications are required:

All personnel working on Mission Support Alliance Samples must be trained in accordance with the most recent AIHA-LAP, LLC Policy Modules or equivalent.

The Contractor shall ensure that its personnel meet and maintain the appropriate training, qualification and certification requirements.

### 5.2 Security and Badging Requirements

The scope of work will not require access authorization (security clearance).

### 5.3 Work Location / Potential Access Requirements

Work is not performed on the Hanford Site.

### 5.4 Site Access and Work Hours

Hanford personnel at the Hanford Site work a standard 4/10 schedule. The standard work week consist of ten (10) hours of work between 6:00 am and 4:30 pm, with one-half hour designated as an unpaid period for lunch, Monday through Thursday.

## 6.0 MEETINGS

The Contractor shall participate in all meetings as required by the BTR. Due to extensive travel time and associated expenses, telephone conferencing will be the normal mode for meetings when requested by either the Buyer or Contractor.

## 7.0 DELIVERABLES AND PERFORMANCE SCHEDULE REQUIREMENTS

### 7.1 Analytical Data Deliverables

Deliverables are required to be furnished by the Contractor.

The Contractor shall submit the results of the analytical testing in a lab standard analytical report format, following completion of analysis of each Sample Delivery Group. The Contractor shall email a PDF file to [MIHD@rl.gov](mailto:MIHD@rl.gov) and [MSA\\_SMO@rl.gov](mailto:MSA_SMO@rl.gov)



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(and others if specifically noted on the COC) or submit a hardcopy data package to the BTR. Results should normally be provided within 21 calendar days of sample receipt, unless analytical protocols require longer analysis times.

The analytical reports shall be reviewed by the Contractor for completeness prior to submittal to the Buyer. The following Certification Statement, including signature by the Laboratory Director or a designate, shall be part of each analytical report:

"I certify that this analytical report is in compliance with the Hanford Site SOW, both technically and for completeness. Release of the data contained in this hard copy report has been authorized by the Laboratory Director or a designee as verified by the following signature."

The final analytical report shall include, at a minimum, the following:

- Reference to the Method of Analysis,
- Documentation of any QC, sample, shipment and/or analytical problems encountered, or any modifications to the test method required during processing of the samples,
- Analytical results and associated identifications/interpretations, identified by both the Buyer's and the Contractor's sample identifiers when applicable,
- Analytical reporting limits,
- Each page number and total page number, along with the report identifier on each page,
- Date samples were received by the Contractor, date of analysis and date the report was issued,
- Printed name and title of the person certifying the report by signature, as described above.

Copies of all sample receipt and shipping documentation (Buyer COC, packing list, air bill, sample receipt and analysis request forms, activity screen results, etc.) shall be sent, with the hard copy report, to the BTR.

Corrected or revised analytical reports shall be clearly marked or identified by the Contractor as such.

Under no circumstances shall the Contractor release reports or analytical data to a third party (outside of the Buyer) without the prior written permission of the Buyer.

The Contractor shall maintain a legible copy of all analytical deliverables, for re-submittal to the Buyer, at no additional cost, for one (1) year following submittal of the hard copy report.

## 7.2 Data Package Billing Invoice Summary



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The Contractor shall submit completed data package invoices to the BTR on a monthly basis. The Contractor may be requested to submit invoices more frequently at the request of the MSA Contracting Officer or BTR. The invoice shall be sufficiently complete for the Buyer to explain the basis for costs billed. The invoice shall include the following information at a minimum: Buyer Survey Identification (ID), Contractor sample group ID, sample identification number(s), analytical tests performed, quantity of each analytical test performed, unit rate and total cost for each analytical test performed.

## **7.3 Notification of Reporting Errors or Other Laboratory Issues**

The Contractor shall notify the SMO within one (1) Contractor business day of discovering errors in reporting or laboratory issues that may adversely affect analytical results or the delivery of analytical data packages. In such cases, an Action Plan shall be developed by the Contractor and provided in writing to the SMO within five (5) Contractor business days of notification. When corrections to previously reported results are required, the corrections and an explanation shall be reported in writing to the SMO within the allotted five Contractor business days.

The Contractor shall notify the SMO within one (1) Contractor business day of any changes in certification, notice of violation, changes to technical staff that may impact analytical capabilities, or other significant issues.

## **8.0 SPECIAL REQUIREMENTS**

The Contractor will provide a comprehensive and expanded list of analytes, reference method, laboratory reporting limits (RLs), and Government Services Administration (GSA) fee schedule. The Buyer may request special analyses based on the GSA fee schedule. The Buyer reserves the right to request specific methods/modifications and/or laboratory RL requirements.