# ACQUIRITION, TECHNOLOGY AND LOGISTICS

# OFFICE OF THE UNDER SECRETARY OF DEFENSE

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Department of Defense
OFFICE OF PREPUBLICATION AND SECURITY REVIEW

# MEMORANDUM FOR DISTRIBUTION

SUBJECT: Acquisitions Involving Environmental Sampling or Testing Services

The attached policy and guidelines apply to environmental sampling or testing services procured by, or on behalf of, the Department of Defense. This policy supports the Federal Acquisition Regulation (FAR) pertaining to performance-based contracting and higher-level contract quality requirements, and provides proper procurement and administrative procedures for environmental sampling and testing contracts. The implementation of this policy is effective immediately for award of contracts and orders.

The policy will be posted on the Defense Acquisition Regulations System website: <a href="http://www.acq.osd.mil/dpap/dars/pgi/current/pgi">http://www.acq.osd.mil/dpap/dars/pgi/current/pgi</a> <a href="http://www.acq.osd.mil/dpap/dars/pgi/current/pgi</a> <a href="http://www.acq.osd.mil/dpap/dars/pgi/current/pgi/http://www.acq.osd.mil/dpap/dars/pgi/current/pgi</a> <a href="http://www.acq.osd.mil/dpap/dars/pgi/current/pgi/http://www.acq.osd.mil/dpap/dars/pgi/current/pgi/http://www.acq.osd.mil/dpap/dars/pgi/current/pgi/http://www.acq.osd.mil/dpap/dars/pgi/current/pgi/http://www.acq.osd.mil/dpap/dars/pgi/current/pgi/http://www.acq.osd.mil/dpap/dars/pgi/current/pgi/http://www.ac

The policy does not supersede or nullify any requirements of Component Environmental Management Systems (EMS) policies or documentation. Requirements for projects being tracked in EMS must meet the relevant EMS requirements in addition to those specified in this policy.

Our staff points of contact for this subject are Mr. Ed Miller, ODUSD(I&E) Environmental Management, <u>Edmund.miller@osd.mil</u>, (703) 604-1765, and Ms. Sandra Ross, OUSD(AT&L)/DPAP, <u>Sandra.Ross@osd.mil</u>, (703) 695-9774.

Alex A. Beehler

Assistant Deputy Under Secretary of Defense (Environment, Safety and Occupational Health)

Shay D. Assad

Director, Defense Procurement and Acquisition Policy

Attachments:

As stated

**DISTRIBUTION:** 

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# Department of Defense Policy and Guidelines for Acquisitions Involving Environmental Sampling or Testing

**November 2007** 

This document will be maintained and routinely updated on the Defense Procurement and Acquisition Policy (DPAP) and Defense Environmental Network and Information Exchange (DENIX) websites.

# Department of Defense Policy and Guidelines for Acquisitions Involving Environmental Sampling or Testing

# 1. Purpose – This document:

- 1.1. Establishes procedures and responsibilities regarding the implementation of minimum quality systems performance standards through solicitations and contracts involving environmental sampling or testing. Minimum quality systems performance standards are based on the following national and international standards:
  - 1.1.1. ANSI/ASQ E4-2004, Quality systems for environmental data and technology programs requirements with guidance for use;
  - 1.1.2. ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories; and
  - 1.1.3. ISO/IEC 17011:2004, Conformity assessment general requirements for accreditation bodies accrediting conformity assessment bodies.
- 1.2. Implements the following DoD Quality Systems policy: 1
  - 1.2.1. DoD Environmental Laboratory Quality Systems Manual, Version 3, (DoD QSM) January 2006 (or latest version);
  - 1.2.2. Uniform Federal Policy for Implementing Environmental Quality Systems (UFP-QS), March 2005 (or latest version); and
  - 1.2.3. *Uniform Federal Policy for Quality Assurance Project Plans* (UFP-QAPP), March 2005 (or latest version).
- 1.3. Supports compliance with the following Federal laws and regulations:
  - 1.3.1. Federal Acquisition Regulation (FAR) Subpart 46.2 (Contract Quality Requirements) and Subpart 37.6 (Performance-based Contracting)
  - 1.3.2. Public Law 106-554; H.R. 5658, as implemented by the Deputy Secretary of Defense Memorandum *Ensuring the Quality of Information Disseminated to the Public by the Department of Defense* (DoD IQG), 10 February 2003.

# 2. Applicability – This document applies to:

- 2.1. The Office of the Secretary of Defense (OSD), the Military Departments (including their reserve components), the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities in the Department of Defense (hereafter referred to collectively as "the DoD Components").
- 2.2. The preparation of solicitations and contracts, purchases, task orders, and delivery orders that involve environmental sampling or testing at DoD operations, activities, and installations worldwide, including Government-owned, contractor-operated facilities and formerly-used defense sites (FUDS).
- 2.3. The preparation of orders placed by non-DoD agencies (e.g. General Services Administration) on behalf of the Department of Defense.

<sup>1</sup> The latest versions of DoD Quality Systems documents can be downloaded free of charge from the Defense Environmental Network Information Exchange (DENIX). See: https://www.denix.osd.mil/denix/Public/Library/Compliance/EDQW/admin.html

# 3. Scope – This document:

- 3.1. Provides flexible guidelines, so that Components can apply them in a commonsense and workable manner. It incorporates the principle of a graded approach, i.e., quality systems will vary according to the objectives and requirements of specific organizations and programs, and the level of detail in quality systems documents will vary according to the type of work being performed and the intended uses of the data. It is important that these guidelines not impose unnecessary administrative burdens that would inhibit the timely collection and use of environmental data. In this regard, Components may incorporate the guidelines, including minimum performance standards, into their existing procurement processes, rather than create duplicative processes. Components must ensure their guidelines are consistent with the guidelines described herein.
- 3.2. Describes the acquisition process for the following general types of contracts, whether issued by the Department of Defense or other non-DoD agencies (e.g. GSA) on behalf of the Department of Defense:
  - 3.2.1. Contracts for which specific statements of work (SOW) or performance work statements (PWS) are defined in the solicitation. In these types of contracts, the Prime contractor can either perform all services, or use the services of subcontractors, including laboratories, that are generally selected in advance of contract award.
  - 3.2.2. Contracts for which a general SOW or PWS covers a variety of potential tasks. Task-specific PWS and detailed specifications can be developed and issued on a task-by-task basis following award, or a specific SOW can cover a variety of potential tasks. In these types of contracts, it is not always possible for the Prime Contractor to select all subcontractors before contract award, and some of the steps that normally would be completed before award (e.g. laboratory selection) must be performed following award.

## 4. Definitions:

Terms used in this Policy are defined in Attachment 1.

# 5. Performance Standards:

5.1. Performance Standards for Contractor Quality Systems. Performance standards for contractor quality systems documentation will be set forth in the solicitation and resulting contract using contract language provided in Attachment 2. The contractor will be required to flow down these requirements to the appropriate subcontractors, including laboratories. Existing quality systems documentation, such as that conforming to the International Organization for Standardisation (ISO) 9000 series of quality standards, may be used in certain instances to fulfill the requirements listed below. The contractor quality systems documents collectively shall specify the quality assurance responsibilities of the contractor and contain measurable inspection and acceptance criteria corresponding to project-specific performance standards. Work involving environmental sampling or testing shall not commence until the Government has accepted the Contractor's quality systems documentation. Quality systems documentation to be provided by the contractor will include one or more of the following:

- 5.1.1. Documentation of the organization's Quality System (usually called a Quality Management Plan), in accordance with the *Uniform Federal Policy for Implementing Environmental Quality Systems* (UFP-QS). The UFP-QS was developed to facilitate consistent implementation across Federal agencies of the quality system requirements of ANSI/ASQC E4-1994 (superseded by ANSI/ASQ E4-2004).
- 5.1.2. Documentation of project-specific quality assurance (QA) and quality control (QC) activities (usually called a Quality Assurance Project Plan or QAPP) in accordance with the *Uniform Federal Policy for Quality Assurance Project Plans* (UFP-QAPP). The UFP-QAPP provides policy and guidance to Federal agencies for developing QAPPs for the collection and use of environmental data.
- 5.1.3. Documentation of the laboratory quality system in accordance with the DoD Quality Systems Manual for Environmental Laboratories (DoD QSM). The DoD QSM provides guidance for implementing environmental quality systems based on the National Environmental Laboratory Accreditation Conference (NELAC) Quality Systems standard, which is based on ISO/IEC 17025.
- 5.1.4. Some procurement activities may cover environmental sampling or testing programs involving multiple tasks, multiple locations, and/or an extended period of performance. (For example, a large-scale environmental monitoring program operating at many different locations). In this case, a program-wide QAPP may be required to describe the general performance standards that are to be applied throughout the program. Project-specific performance standards must either be added to the approved program-wide QAPP, or issued in a separate, project-specific QAPP, on a task-by-task basis.
- 5.1.5. For certain environmental sampling or testing procurements (e.g. those for which sampling or testing are the only activities being performed), quality systems documentation and project-specific performance standards may be combined into a single document (e.g. Quality Management Plan) covering work performed under the contract. The decision to use a combined document can only be made by the DoD Project Manager (PM) after consultation with the Contracting Officer and Government Quality Assurance Manager (QAM). This requirement shall be established in the solicitation, and the decision shall be documented in the file.
- 5.2. Performance Standards for Laboratory Quality Systems. Laboratories providing services to the Department of Defense must possess any required state or host nation certification and/or be accredited for each applicable test method by a nationally recognized laboratory accreditation body (e.g. NELAP) compliant with ISO/IEC 17011:2004. All laboratories must demonstrate the ability to generate acceptable results from the analysis of proficiency-testing (PT) sample(s), subject to availability, using each applicable method in the specified matrix. Upon request, laboratories must make available, to the Department of Defense, the results of all PT samples analyzed by the laboratory during the

- period of performance. Laboratories must have an established and documented laboratory quality system that conforms to ISO/IEC 17025 as implemented by the *DoD Quality Systems Manual for Environmental Laboratories*, (latest version). The laboratory must declare conformance to the DoD QSM, using Attachment 3 to this Policy. All laboratories are subject to on-site assessments by authorized representatives of the Department of Defense.
- 5.3. Government Quality Assurance Surveillance. In all cases where environmental sampling or testing services are performed, government quality assurance surveillance must be performed. Project-planning documents must describe all government quality assurance surveillance activities as well as specific procedures government personnel will use to review and substantiate the quality of environmental data before they are disseminated by the Department of Defense. Quality systems documentation must support, and be consistent with, established Component administrative mechanisms allowing affected persons to seek and obtain correction of information that does not comply with the DoD IOG.
- 6. Government Roles and Responsibilities: The acquisition process and the composition of the acquisition team will vary based on Component-specific contracting requirements and the size and complexity of the procurement. Key government staff for procurements involving environmental sampling or testing should include the Project Manager (PM), Contracting Officer, Contracting Officer's Representative (COR), Government Quality Assurance Manager (QAM), and Government Chemist. For large programs, government quality assurance surveillance usually will be coordinated by a Government QAM, with assistance from a Government Chemist. With proper qualifications and experience, the same person may fill multiple roles (e.g., Government QAM, Government Chemist, and/or COR). [Note: Installations are not required to have Government QAMs or Chemists on site, but rather, to have access to their services.] Examples of specific government roles and responsibilities are described below. It should be noted that not all activities will be necessary for all procurements.
  - 6.1. Government Quality Assurance Manager (QAM) The Government QAM provides quality assurance surveillance during the procurement process and following award of the contract. The Government QAM must be independent from units or activities generating the data and must have direct access to senior project management. During the procurement process, the QAM verifies that the proper acquisition team has been assembled and provides input on contract quality systems documentation and performance standards as necessary to ensure the acquisition of qualified contractors, including laboratories. The QAM reviews the solicitation before it is issued, and participates in the technical evaluation of contractor submittals to determine compliance with solicitation requirements pertaining to environmental sampling or testing. Following contract award, the Government QAM:
    - Reviews and makes recommendations concerning the approval or rejection of project-specific quality systems documentation;
    - Monitors compliance with contract and project performance standards;

- Oversees project-specific laboratory assessments, if needed;
- Notifies the PM and the Contracting Officer concerning any nonconformance issues;
- Notifies the Contracting Officer concerning any potential breaches of contract (e.g. prohibited practices); and
- Monitors corrective action.
- 6.2. *Government Chemist* The Government Chemist provides the environmental sampling and testing expertise to ensure that the solicitation and contract are technically adequate. During the procurement process, the Government Chemist determines technical performance standards, develops technical performance evaluation criteria, and evaluates the technical acceptability of proposals. Specifically, the Government Chemist reviews the contractor's quality systems documentation to assess compliance with the specific contract quality systems requirements (e.g. DoD QSM and UFP-QS). Following award, the Government Chemist:
  - Develops or reviews project-specific performance standards and measurement quality objectives (MQOs);
  - Verifies the appropriateness of sampling and analytical methods;
  - Provides oversight for development and correct implementation of the QAPP;
  - Notifies the government QAM and Contracting Officer of nonconformance issues, including prohibited practices (Attachment 4 may be used for this purpose);
  - Monitors corrective action, where necessary; and
  - Performs data review as specified in the QAPP.

For procurements in which the government contracts laboratory services directly, the Government Chemist will serve a dual role as Project Chemist, following contract award.

- 7. Contractor Roles and Responsibilities: For contracts in which the prime contractor subcontracts laboratory services, a Contractor QAM and Project Chemist must be designated by the prime contractor. The Government QAM (described above) will monitor the prime to ensure that appropriate oversight of environmental sampling and testing activities is being provided.
  - 7.1. *Contractor Quality Assurance Manager (QAM)* The Contractor QAM provides internal quality assurance surveillance during the implementation of the project. The contractor QAM:
    - Approves project-specific MQOs that will meet the project-specific performance standards;
    - Verifies appropriateness of sampling procedures, analytical methods, and laboratory quality systems;
    - Approves the final QAPP (if prepared by the Contractor);
    - Verifies the selection of appropriately qualified laboratories;
    - Coordinates field and laboratory quality assurance surveillance, per contract specifications;

- Notifies the Government QAM of any problems or nonconformance issues (Attachment 4 may be used for this purpose);
- Directs the performance of data review, per contract specifications; and
- Monitors corrective action.
- 7.2. *Contractor Project Chemist* The Contractor Project Chemist provides coordination and quality assurance surveillance of laboratory services, including:
  - Defines project-specific MQO's that will meet the project-specific performance standards;
  - Determines appropriateness of sampling and analytical methods and laboratory quality systems;
  - Oversees QAPP preparation;
  - Verifies laboratory qualifications;
  - Makes recommendations for laboratory selection;
  - Coordinates with the laboratory during contract execution;
  - Notifies the Contractor QAM of any problems or nonconformance issues;
  - Performs data review, per contract specifications; and
  - Implements and monitors corrective action, as needed.
- 8. Personnel Qualifications: Project teams should establish the level(s) of qualifications and experience necessary for the procurement of specific sampling or testing services. The following are recommended minimum qualifications for Government and Contractor personnel performing quality assurance surveillance:
  - 8.1. *Government/Contractor QAM* Minimum qualifications are a Bachelor's degree with at least 4 years of combined experience in the laboratory and/or as part of a consultant project management team. If not a degreed chemist, the QAM must have knowledge and experience in the sampling and analysis of environmental media, and associated quality assurance. The solicitation and contract may specify additional qualifications for the Contractor QAM as necessary.
  - 8.2. *Government Chemist* Minimum qualifications include 30 semester hours in chemistry, supplemented by course work in mathematics through differential and integral calculus, and at least 6 semester hours of physics. As applicable to the specific project, the Government Chemist should have knowledge of environmental analytical chemistry methodologies; general knowledge of the chemistry of remedial treatment technology and chemical fate and transport; and experience in the sampling and analysis of toxic/hazardous chemicals in environmental matrices.
  - 8.3. *Contractor Project Chemist* Minimum qualifications are a Bachelor's degree in chemical, environmental, biological sciences, physical sciences or engineering, with at least 30 semester hours in chemistry, supplemented by course work in mathematics through differential and integral calculus, at least 6 semester hours of physics, and at least 2 years of experience in areas of environmental sampling and analytical testing relevant to the project. An advanced degree in one of the above disciplines may be substituted for equivalent experience. As applicable to the specific project, the Project Chemist

must also have knowledge of environmental analytical chemistry methodologies, chemistry of remedial treatment technology, chemical fate and transport, and experience in the sampling and analysis of toxic/hazardous chemicals in environmental matrices. The solicitation and contract may specify additional qualifications for the Contractor Project Chemist as necessary.

# Attachment 1

# **Definitions**

# **Environmental data**

Measurements or information that describe environmental processes, locations, or conditions; ecological or health effects and consequences; or the performance of environmental technology. (ANSI/ASQ E4-2004)

# **Environmental programs**

Work or activities involving the environment, including characterization of environmental processes and conditions; environmental monitoring; environmental research and development; design, construction, and operation of environmental technologies, and laboratory operations on environmental samples. (ANSI/ASQ E4-2004)

# **Performance-based contracting (PBC)**

Performance-based contracting means structuring the acquisition around the purpose of the work to be performed versus manner by which works is to be performed. Contracting methods intended to ensure that required performance quality levels are achieved and that total payment is related to the degree that services performed meet contract standards. Performance-based contracts:

- 1. Describe the requirements in terms of results required rather than the methods of performance of the work;
- 2. Use measurable performance standards and quality assurance surveillance plans;
- 3. Specify procedures for reductions of fee or for reductions to the price of a fixed-price contract when services are not performed or do not meet contract requirements; and
- 4. Include performance financial incentives and institute cost-effective methods of performing work where appropriate. (FAR Subpart 37.6)

# **Performance work statement (PWS)**

A statement in the solicitation that identifies the technical, functional, and performance characteristics of the agency's requirements. The PWS is performance-based and describes the agency's needs (the "what"), and not specific method for meeting those needs (the "how"). The PWS identifies essential outcomes to be achieved, specifies the agency's required performance standards, and specifies the location, units, quality and timeliness of the work. (OMB Circular A-76)

# Performance standards

Verifiable, measurable levels of service in terms of quantity, quality, timeliness, location, and work units. Performance standards are used to 1) assess (i.e. inspect and accept) the work during a period of performance; 2) provide a common output-related basis for preparing private sector offers and public tenders; and 3) compare the offers and tenders to the performance work statement (PWS). (OMB Circular A-76)

# **Proficiency-testing sample**

A sample, the composition of which is unknown to the analyst, provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria. (NELAC)

# Quality assurance surveillance

The government's monitoring of a service provider's performance in accordance with the quality assurance surveillance plan and the performance requirements identified in the solicitation. (OMB Circular A-76)

# **Quality system**

A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. (ANSI/ASQ E4-2004)

# Statement of work (SOW)

Clear, concise language identifying specific work to be accomplished. Statements of work are individually tailored to consider the period of performance, deliverable items, if any, and desired degree of performance flexibility. The preferred method of identifying work to be performed is through a PWS versus a SOW.

# Attachment 2 **Language to Incorporate into a Solicitation**

[In addition to existing FAR/DFARS requirements, the Contracting Officer, in consultation with Government QAM, will incorporate the following language into solicitations and contracts involving environmental sampling or testing, where appropriate. For example, the language may be included in the Performance Work Statement to address the minimum qualifications, or into Sections L and M of a solicitation to address the content of the Technical proposal and the evaluation factors for contract award. The contractor will be required to flow down these requirements to the appropriate subcontractors. The solicitation language may be tailored to reflect contract-specific quality systems requirements and performance standards identified by the Acquisition Team.]

# A: Higher-Level Contract Quality Requirements

The Contractor shall comply with the higher-level quality standard(s) indicated below: [Contracting Officer, in consultation with Government QAM, to select all that apply.]

Selection (x)	Title	Specification
	Quality Systems for Environmental Data and Environmental Technology Programs	ANSI/ASQ E4-2004
	General requirements for the competence of testing and calibration laboratories	ISO/IEC 17025:1999
	Conformity assessment – general requirements for accreditation bodies accrediting conformity assessment bodies	ISO/IEC 17011:2004
	Other [insert relevant standard]	

The solicitation and contract require Offeror/Contractor to demonstrate conformance to the relevant standards by submitting the quality systems documentation specified in [(B), (C), and/or (D)] below. (Contracting Officer to select which paragraph applies.)

Following award of the contract, Contractor shall revise, when applicable, quality systems documentation submitted before award to address any deficiencies identified by the Government Chemist and/or Government Quality Assurance Manager (QAM). Contractor shall submit the revised documentation to the Contracting Officer, vice the Contracting Officer's Representative (COR).

Following award of the contract, Contractor shall implement and comply with all quality systems documentation and project-specific performance standards accepted by the Government. Work involving environmental sampling or testing shall not commence until the Government has determined that Contractor's quality systems documentation meets all specifications contained in the contract

# B: Required Quality Systems Documentation (For use when documentation is to be submitted with the technical proposal)

The Offeror shall submit the following quality systems documentation (however named) as a separate and identifiable part of its technical proposal. The quality systems documentation must

recognize the responsibility of the Contractor to carry out its quality control obligations. [Contracting Officer to select all that applies as identified by the program office.]

Selection	Documentation	Specification
(x)		
	Contractor Quality Management Plan	UFP-QS
	Combined Quality Control Plan	UFP-QS and UFP-QAPP
	Program-wide Quality Assurance	UFP-QAPP
	Project Plan	
	Laboratory Quality Management Plan	DoD QSM
	Laboratory Declaration of	Attachment 3
	Conformance to DoD QSM	
	Data Management Plan	DoD IQG
	Other	[If required, insert relevant specification]

# C: Required Quality Systems Documentation (For use when documentation is to be submitted following award of the contract)

Following award of the contract, Contractor shall submit the following quality systems documentation to the Contracting Officer, vice the Contracting Officer's Representative. Submitted documents shall recognize the responsibility of Contractor to carry out its quality control obligations and contain measurable inspection and acceptance criteria corresponding to the performance standards contained in the Statement of Work: [Contracting Officer, in consultation with Government QAM, to select all that apply]

Selection	Documentation	Specification	<b>Due Date</b>
(x)			
	Contractor Quality	UFP-QS	
	Management Plan		
	Combined Quality Control Plan	UFP-QS and UFP-QAPP	
	Program-wide Quality Assurance Project Plan	UFP-QAPP	
	Project-specific Quality Assurance Project Plan	UFP-QAPP	
	Laboratory Quality Management Plan	DoD QSM	
	Laboratory Declaration of Conformance to DoD QSM	Attachment 3	
	Data Management Plan	DoD IQG	
	Other	[If required, insert relevant specification]	

The Government will review and return the quality systems documentation, with comments, indicating acceptance or rejection. If necessary, Contractor shall revise the documentation to address all comments and shall submit the revised documentation to the Government for acceptance.

Work involving environmental sampling or testing shall not commence until the Government has accepted Contractor's quality systems documentation.

# D: Required Contractor Certifications and Quality Control Reports (For use when the submittal of these reports is required during project implementation.))

Following award of the contract, and during project implementation, Contractor shall submit the following quality control reports to the Contracting Officer, vice the Contracting Officer's Representative: [Contracting Officer to select all that apply as identified by the program manager]

Selection	Documentation	Specification	Schedule
(x)			
	Contractor Daily Quality	[insert relevant specification]	Daily
	Control Report	_	·
	Contractor Daily	[insert relevant specification]	Daily
	Production Report	_	
	[Other]	[insert relevant specification]	[List]

#### E: Remedies

The following procedures will be used to assess reductions to fee, or fixed price, as appropriate, when services provided fail to meet established performance standards. Contractor engagement in any prohibited practice identified in Attachment 3a will be considered material non-compliance, which may result in contract termination or other remedies as appropriate. This does not limit the Government's exercise of other available rights and remedies.

[Contracting Officer to complete this clause]

# F: Additional Language:

## Minimum Performance Standards for Environmental Laboratories

Laboratories performing analyses in support of this procurement must have an established and documented laboratory quality system that conforms to ISO/IEC 17025:2005 as implemented by the *DoD Quality Systems Manual for Environmental* Laboratories (latest version). The laboratory's authorized contract representative and the laboratory Quality Assurance Officer (however named) must declare laboratory conformance to the DoD QSM (latest version) using Attachment 3.

Laboratories must possess any required state or host nation certification and/or be accredited for each applicable test method, by a nationally recognized laboratory accreditation body (e.g. NELAP), compliant with ISO/IEC 17011:2004. All laboratories must demonstrate the ability to generate acceptable results from the analysis of proficiency-testing (PT) sample(s), subject to availability, using each applicable method in the specified matrix. Upon request, laboratories must make available to the Department of Defense, the results of all PT samples analyzed by the laboratory during the period of performance. The Contractor shall ensure the laboratory makes appropriate documentation available to the Government Chemist/QAM. All laboratories are subject to on-site assessments by authorized representatives of the Department of Defense.

The Contractor shall ensure the Government is notified in writing of any change in laboratory certification or accreditation status within 30 calendar days of the change. This written notification requirement applies, but is not limited, to suspension or revocation of certification or accreditation.

# Minimum Qualifications for Contractor QAM

The Contractor QAM must have a Bachelor's degree with at least 4 years of combined experience in the laboratory and/or as part of a consultant project management team. If not a degreed chemist, the QAM must have knowledge and experience in the sampling and analysis of environmental media, and associated quality assurance. Specific qualifications include: [insert relevant, project-specific requirements].

## Minimum qualifications for Contractor Project Chemist

The Contractor Project Chemist must have a Bachelor's degree in chemical, environmental, biological sciences, physical sciences or engineering, with at least 30 semester hours in chemistry, supplemented by course work in mathematics through differential and integral calculus, at least 6 semester hours of physics, and at least 2 years of experience in areas of environmental sampling and analytical testing relevant to the project. An advanced degree in one of the above disciplines may be substituted for equivalent experience. As applicable to the specific project, the Project Chemist must also have knowledge of environmental analytical chemistry methodologies, remedial process chemistry, chemical fate and transport, and experience in the sampling and analysis of toxic/hazardous chemicals in environmental matrices. Specific qualifications include: [insert relevant, project-specific requirements].

## Attachment 3

# Declaration of Conformance to the Department of Defense Quality Systems Manual for **Environmental Laboratories Version 3 (DoD QSM)**

Environmental laboratories performing services for the Department of Defense must possess any required state or host nation certification and/or be accredited for each applicable test method by a nationally recognized laboratory accreditation body (e.g. NELAP) compliant with ISO/IEC 17011:2004. The laboratory must demonstrate the ability to generate acceptable results from the analysis of proficiency-testing (PT) sample(s), subject to availability, using each applicable method in the specified matrix. Upon request, laboratories must make available, to the Department of Defense, the results of all PT samples analyzed by the laboratory during the contract-specified period of performance. Laboratories must have an established and documented laboratory quality system that conforms to ISO/IEC 17025 as implemented by the DoD Quality Systems Manual for Environmental Laboratories, insert appropriate version number. [This document may be downloaded free of charge at

https://www.denix.osd.mil/denix/Public/Library/Compliance/EDQW/admin.html. The laboratory must declare conformance to the DoD OSM using this form and must submit a copy of its laboratory quality manual (however named) to an authorized representative of the Department of Defense. All laboratories are subject to on-site assessments by authorized representatives of the Department of Defense. The laboratory must notify the Department of Defense, in writing, of any change in laboratory certification or accreditation status within 30 calendar days of the change.

# **Laboratory Information** Laboratory Name: Address: Point of Contact: Title: Email: Phone: Fax: Title, date of laboratory quality manual

List analytes/analyte groups, matrices, methods for which this declaration applies:

Identify laboratory standard operating procedures (SOPs) for which this declaration applies (include number, title and date of last revision):

# 1. Quality System

- a. Does the laboratory quality manual meet the requirements of DoD QSM Sections 4.2.2, 4.2.3, and 4.2.4?
- b. Do laboratory SOPs meet the requirements of DoD QSM Section 5.4.1?
- c. Are laboratory records controlled in accordance with the requirements of DoD QSM Section 4.12?
- d. Do your laboratory personnel structure and lines of responsibility meet the requirements of DoD QSM Section 4.1.5?
- e. Does your laboratory Quality Manager meet requirements of DoD QSM Section 4.1.5(i)?
- f. Does your laboratory perform internal audits, management reviews, and corrective action in accordance with DoD QSM Sections 4.13, 4.14, and 4.10?

# 2. Training and Ethics

- a. Does your laboratory's technical training program meet the requirements of DoD QSM Section 5.2.6?
- b. Does your laboratory ethics program comply with the requirements of DoD QSM Section 5.2.7?

## 3. Proficiency Testing

a. List all proficiency testing programs (e.g. UST, DMRQA) in which your laboratory participates that are relevant to the analytes/analyte groups, matrices, and methods included in the scope of this declaration:

#### 4. Resources

- a. Does your laboratory have adequate personnel, facilities, equipment, instrumentation, and other resources available, as required in DoD QSM Sections 5.2.1, 5.3.1, and 5.5, to perform the tests specified in this declaration?
- 5. Please list any concerns/comments regarding conformance to the DoD QSM:

The undersigned acknowledge the accuracy and correctness of this declaration. The undersigned acknowledge that laboratory engagement in any prohibited practice identified in Attachment 3a will be considered material non-compliance, which may result in contract termination or other remedies as appropriate.

Laboratory Quality Manager:	
Signature:	
Date:	
Laboratory's Authorized Contract Representative:	
Signature:	
Date:	

## Attachment 3a

# Prohibited Practices (Involving Environmental Sampling and Testing Activities)

The following prohibited practices will be considered material non-compliance, which may result in contract termination or other remedies as appropriate.

- Fabrication, falsification, or misrepresentation of data
  - o Creating data for an analysis that was not performed
  - o Creating information for a sample that was not collected
  - Using external analysts, equipment and/or laboratories to perform analyses when not allowed by contract
- Improper clock setting (time traveling) or improper date/time recording
  - Resetting the internal clock on an instrument to make it appear that a sample was analyzed within holding time when in fact it was not
  - O Changing the actual time or recording a false time to make it appear that holding times were met, or changing the times for sample collection, extractions or other steps to make it appear that holding times were met
- Unwarranted manipulation of samples, software, or analytical conditions
  - Unjustified dilution of samples
  - Manipulating GC/MS tuning data to produce an ion abundance result that appears to meet specific QC criteria
  - Changing the instrument conditions for sample analysis from the conditions used for standard analysis (e.g., changing EM voltage)
  - O Unwarranted manipulation of computer software, e.g. forcing calibration or QC data to meet criteria, removing computer operational codes such as the "M" flag, inappropriately subtracting background, or improperly manipulating the chromatographic baseline
  - Turning off, or otherwise disabling, electronic instrument audit/tracking functions
- Misrepresenting or misreporting QC samples
  - o Representing spiked samples as being digested or extracted when this has not been done
  - O Substituting previously generated runs for a non-compliant calibration or QC run to make it appear that an acceptable run was performed
  - o Failing to prepare or analyze method blanks and LCS in the same manner that samples were prepared or analyzed
  - o Tampering with QC samples and results, including over spiking and adding surrogates after sample extraction
  - Performing multiple calibrations or QC runs (including CCVs, LCSs, spikes, duplicates and blanks) until one meets criteria, rather than taking needed corrective action, and not documenting or retaining data for the other unacceptable data
  - O Deleting or failing to record non-compliant QC data to conceal the fact that calibration or other QC analyses were non-compliant
- Improper calibrations
  - o Discarding points in the initial calibration to force the calibration to be acceptable
  - Discarding points from an MDL study to force the calculated MDL to be higher or lower than the actual value
  - Using an initial calibration that does not correspond to the actual run sequence to make continuing calibration data look acceptable when in fact it was not
  - Performing improper manual integrations, including peak shaving, peak enhancing, or baseline manipulation to achieve QC criteria or to avoid corrective action
- Concealing a known analytical or sample problem
- Concealing a known improper or unethical behavior or action
- Failing to report the occurrence of a prohibited practice or known improper or unethical act to the appropriate laboratory or contract representative, or to an appropriate government official.

# **Attachment 4 Laboratory Non-Conformance Report Submitter Information** Organization: Name: Email Address: Date prepared: Address: Phone: **Laboratory Information** Name: Address: Phone: POC: POC Phone: POC Email Address: **Description of Non-conformance:** Source of Laboratory Specifications (e.g. Title of QAPP) Contract No.: Requirement (include specific reference from requirements document): Description of Problem: Summary of discussion with the laboratory POC about this issue: Requested Resolution: