

<b>SOLICITATION, OFFER AND AWARD</b>		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) <span style="float: right;">▶</span>		RATING	PAGE 1 OF PAGES 59
2. CONTRACT NO.	3. SOLICITATION NO. 2012-N-14359	4. TYPE OF SOLICITATION <input type="checkbox"/> SEALED BID (IFB) <input checked="" type="checkbox"/> NEGOTIATED (RFP)		5. DATE ISSUED	6. REQUISITION/PURCHASE NO. 000HCPCG-2012-46432
7. ISSUED BY Centers for Disease Control and Prevention (CDC) Procurement and Grants Office (PGO) 2920 Brandywine Road Atlanta, GA 30341-5539		CODE 8219	8. ADDRESS OFFER TO (If other than Item 7)		
Approved as to Form and Legality: _____					

**NOTE:** In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder."

**SOLICITATION**

9. Sealed offers in original and \_\_\_\_\_ copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if handcarried, in the depository located in (electronic copies only sent to mbartkevicius@cdc.gov) until 2:00 local time 07/26/2012  
(Hour) (Date)

CAUTION -- LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

<b>10. FOR INFORMATION CALL:</b> ▶	A. NAME Marie Francoise. Bartkevicius	B. TELEPHONE (NO COLLECT CALLS) AREA CODE NUMBER: EXT: (770) 488-8493	C. E-MAIL ADDRESS mbartkevicius@cdc.gov
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**OFFER (Must be fully completed by offeror)**

**NOTE:** Item 12 does not apply if the solicitation includes the provisions at 52.214-16. Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within \_\_\_\_\_ calendar days (60 calendar days unless a different period is inserted by the offeror) from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT <small>(See Section I, Clause No. 52-232-8)</small>	▶ 10 CALENDAR DAYS	20 CALENDAR DAYS	30 CALENDAR DAYS	CALENDAR DAYS
	%	%	%	%

14. ACKNOWLEDGMENT OF AMENDMENTS <small>(The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated:</small>	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR	CODE	FACILITY	16. NAME AND ADDRESS OF PERSON AUTHORIZED TO SIGN OFFER <small>(Type or Print)</small>
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15B. TELEPHONE NO. AREA CODE NUMBER EXT.	<input type="checkbox"/>	15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE	18. OFFER DATE
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**AWARD (To be completed by Government)**

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION	
22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304(c)( ) <input type="checkbox"/> 41 U.S.C. 253(c)( )		23. SUBMIT INVOICES TO ADDRESS SHOWN IN <small>(4 copies unless otherwise specified)</small>	ITEM
24. ADMINISTERED BY (If other than Item 7) CODE 8219 Centers for Disease Control and Prevention (CDC) Procurement and Grants Office (PGO) 2920 Brandywine Road Atlanta, GA 30341-5539		25. PAYMENT WILL BE MADE BY CODE 434 Centers for Disease Control and Prevention (FMO) PO Box 15580 404-718-8100 Atlanta, GA 30333-0080	
26. NAME OF CONTRACTING OFFICER (Type or print)		27. UNITED STATES OF AMERICA  <small>(Signature of Contracting Officer)</small>	28. AWARD DATE

**IMPORTANT -- Award will be made on this form, or on Standard Form 26, or by other authorized official written notice.**

## Section B - Supplies Or Services And Prices/Costs

### Period of Six (6) Months

<b>CLIN 0001 – Fluoride Water and Fluoride Plasma</b>				
	<b>Lab Measurements</b>	<b>QTY</b>	<b>Unit Price</b>	<b>Extended Price</b>
<b>CLIN 0001-01</b>	Fluoride, water	Min: 0 Max: 250		
<b>CLIN 0001-02</b>	Fluoride, plasma	Min: 0 Max: 250		
<b>TOTAL</b>				

### Period of Twelve (12) Months

<b>CLIN 0002 – Fluoride Water and Fluoride Plasma</b>				
	<b>Lab Measurements</b>	<b>QTY</b>	<b>Unit Price</b>	<b>Extended Price</b>
<b>CLIN 0002-01</b>	Fluoride, water	Min: 0 Max: 660		
<b>CLIN 0002-02</b>	Fluoride, plasma	Min: 0 Max: 1360		
<b>TOTAL</b>				

### Period of Twelve (12)

<b>CLIN 0003 – Fluoride Water and Fluoride Plasma</b>				
	<b>Lab Measurements</b>	<b>QTY</b>	<b>Unit Price</b>	<b>Extended Price</b>
<b>CLIN 0003-01</b>	Fluoride, water	Min: 0 Max: 660		
<b>CLIN 0003-02</b>	Fluoride, plasma	Min: 0 Max: 1360		
<b>TOTAL</b>				

### Period of Twelve (12) Months

<b>CLIN 0004 - Fluoride Water and Fluoride Plasma</b>				
	<b>Lab Measurements</b>	<b>QTY</b>	<b>Unit Price</b>	<b>Extended Price</b>
<b>CLIN 0004-01</b>	Fluoride, water	Min: 0 Max: 660		
<b>CLIN 0004-02</b>	Fluoride, plasma	Min: 0 Max: 1360		
<b>TOTAL</b>				

**Period of Twelve (12)**

<b>CLIN 0005 - Fluoride Water and Fluoride Plasma</b>				
	<b>Lab Measurements</b>	<b>QTY</b>	<b>Unit Price</b>	<b>Extended Price</b>
<b>CLIN 0005-01</b>	Fluoride, water	Min: 0 Max: 660		
<b>CLIN 0005-02</b>	Fluoride, plasma	Min: 0 Max: 1360		
<b>TOTAL</b>				

**Period of Six (6) Months**

<b>CLIN 0006 - Fluoride Water and Fluoride Plasma</b>				
	<b>Lab Measurements</b>	<b>QTY</b>	<b>Unit Price</b>	<b>Extended Price</b>
<b>CLIN 0006-01</b>	Fluoride, water	Min: 0 Max: 66		
<b>CLIN 0006-02</b>	Fluoride, plasma	Min: 0 Max: 135		
<b>TOTAL</b>				

<b>TOTAL CONTRACT AMOUNT</b>		
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## Section C - Description/Specification/Performance Work Statement

### Performance-Based Work Statement Laboratory Fluoride Analyses for NHANES 2012-2017

#### C.1 GENERAL

##### C.1.1 Background

The National Health and Nutrition Examination Surveys (NHANES) are a series of cross-sectional surveys conducted by the National Center for Health Statistics (NCHS) designed to provide national statistics on the health and nutritional status of the civilian, non-institutionalized U.S. population through household interviews, standardized physical examinations, and the collection of biologic samples in special mobile examination centers. The surveys oversample the two largest race/ethnic minority groups, non-Hispanic blacks and Mexican-Americans, along with other subgroups of the population.

This performance-based work statement (PBWS) seeks to obtain laboratories for laboratory measurements on water and plasma specimens for fluoride testing from the base year 2012-2017. The contractor shall provide any and all labor, equipment, supplies, services, permits, and licenses necessary to perform these measurements. A single award may result from this solicitation, with fixed-price contract(s) anticipated. These tests must be batched as a single award.

A water sample will be collected at the household and processed in the examination center (MEC). Since fasting is not a requirement for fluoride plasma measurements this test will be measured on all participants in all sessions in the MEC. These tests will be performed on participants aged 6 to 19 years.

##### C.1.2 Objective and Scope

###### C.1.2.1 Objective:

The objective of this PBWS firm-fixed price competitive negotiated contract is to seek laboratories to measure fluoride testing from water and plasma specimens collected at the NHANES home and MEC, and develop a laboratory manual comprised of the following three (3) tasks.

**Task 1 (base period):** Water and plasma fluoride testing of 100-250 samples for a period of six months (2012-2013). Task 1 (base period) will be completed within six months after the delivery of specimens.

Ion Specific Electrode is the method of choice for water. The test involves combining the specimen with an equal volume of ionic buffer solution and then placing in a suitable beaker that can submerge the electrode element.

The fluoride electrode is the method of choice for plasma. Plasma typically has an F concentration near or actually below the sensitivity limit of the electrode so a preparatory method that transfers the F to a smaller volume should be used. The preferred method is the HMDS-facilitated diffusion method, which is considered to be the "gold standard."

**Task 2 (5 periods):** Fluoride testing of 1000–1320 plasma and 300 – 1000 water samples from NHANES, 2013-2017. Task 2 will be completed within six month after final delivery of specimens.

Ion Specific Electrode is the method of choice for water. The test involves combining the specimen with an equal volume of ionic buffer solution and then placing in a suitable beaker that can submerge the electrode element.

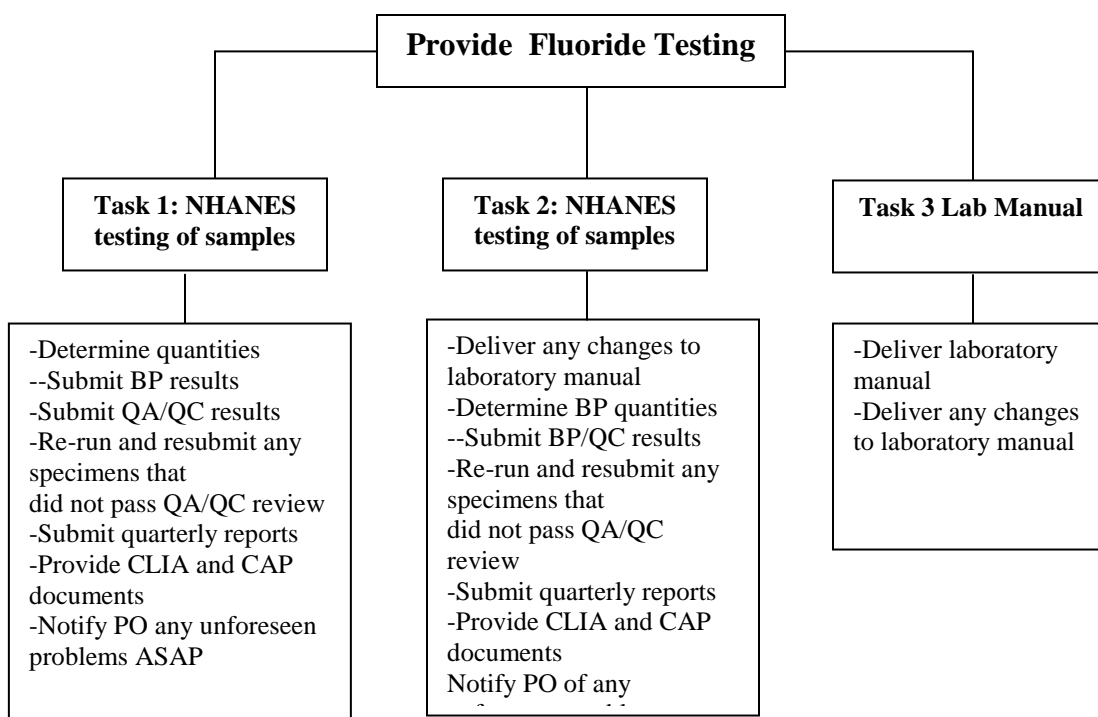
The fluoride electrode is the method of choice for plasma. Plasma typically has an F concentration near or actually below the sensitivity limit of the electrode so a preparatory method that transfers the F to a smaller volume should be used. The preferred method is the HMDS-facilitated diffusion method, which is considered to be the "gold standard."

**Task 3: Laboratory Manual** - The manual is to be developed in accordance with the instructions found at Paragraph f. of Section 3.2.1.3 and delivered by the date outlined under DELIVERABLES. Any subsequent changes to the manual from NHANES 2012-2017 must be submitted as they occur.

### C.1.2.2 Scope:

This technical approach involves three (3) primary tasks for a base period and 5 periods. This work will provide laboratory measurements for fluoride testing. Specifically, this effort will allow the CDC to post the data available via a web site for public use. The technical approach for this phase involves the following:

### C.1.2.3 Work Breakdown Structure



**The technical approach for this phase involves the following three (3) tasks:**

**Task 1 (base period)** will provide high-throughput fluorosis testing for 100-250 samples for a period of six months (2012-2013). Task 1 (base period) will be completed within six months after the delivery of specimens. Task 1 will only be exercised if a new contract is awarded. If the existing contractor is awarded this work then task 1 won't be exercised.

Ion Specific Electrode is the method of choice for water. The test involves combining the specimen with an equal volume of ionic buffer solution and then placing in a suitable beaker that can submerge the electrode element.

The fluoride electrode is the method of choice for plasma. Plasma typically has an F concentration near or actually below the sensitivity limit of the electrode so a preparatory method that transfers the F to a smaller volume should

be used. The preferred method is the HMDS-facilitated diffusion method, which is considered to be the "gold standard."

The assays must be stable and available as was used for Task 1 to Task 2.

Test results and quality control results must be supplied in machine-readable format no later than three weeks (3) after receipt of specimens. Offerors must have a well-established quality assurance program. Data should be transmitted to NHANES in electronic data files in a format stipulated by NHANES.

**Task 2 (5 periods)** will provide high-throughput 1000–1320 plasma and 300 – 1000 water samples from 2013-2017.

Ion Specific Electrode is the method of choice for water. The test involves combining the specimen with an equal volume of ionic buffer solution and then placing in a suitable beaker that can submerge the electrode element.

The fluoride electrode is the method of choice for plasma. Plasma typically has an F concentration near or actually below the sensitivity limit of the electrode so a preparatory method that transfers the F to a smaller volume should be used. The preferred method is the HMDS-facilitated diffusion method, which is considered to be the "gold standard."

Test results and quality control results must be supplied in machine-readable format no later than three weeks (3) after receipt of whole blood specimens. Offerors must have a well-established quality assurance program. Data should be transmitted to NHANES in electronic data files in a format stipulated by NHANES.

The assays must be stable and available as was used for Task 1 to Task 2.

**Task 3: Laboratory Manual** – The manual is to be developed in accordance with the instructions found at Paragraph f. of Section 3.2.1.3 and delivered by the date outlined under DELIVERABLES. Any subsequent changes to the manual from NHANES 2012-2017 must be submitted as they occur.

**C.2 CONTRACTOR FURNISHED.** All required staffing, equipment, supplies, services, permits, and licenses necessary to perform the contract.

## **C.4 Project Identification & Purpose**

### **C.4.1 Background and Need**

#### **C.4.1.1 BACKGROUND**

It is estimated that approximately 20,000 individuals ages one and older will be examined during the period of performance of this contract. This sample size for each analyte may be altered by changes in fund availability. The number of specimens for each laboratory analyses will vary due to different age targets for each assay.

#### **C.4.1.2 PROJECT FUNDING**

This is a fixed-price, requirements-type contract. Under this contract, services may be ordered on an as needed basis. Payment for these services shall be in accordance with the prices set forth herein not to exceed the current funding. Funds may be increased or decreased unilaterally by the Contracting Officer by modification to the contract. The Contractor shall not accept orders in excess of funds allotted to this contract. Funds allotted to this contract do not constitute an obligation of the Government to place orders in value up to such amounts. The obligation of the Government is only to the extent of the orders issued under this contract.

### C.4.1.3 NHANES BACKGROUND

Data collection for the 2012-2017 survey will begin on the date of award in 2012 and conclude in 2017. Prior to the commencement of data collection, all data management, programming, quality control and reporting system changes must be developed. This will occur during the five months from contract award until data collection commencement. Approximately 5,000 individuals are expected to be examined per year. This contract will cover laboratory testing of samples collected during the 2012 to 2017 data collection.

For approximately eleven months of the year (with breaks of about two weeks during the holiday season at the end of the calendar year and about two weeks in the summer), specimens will be collected and shipped to the contracting laboratory.

The contractor shall use an automated system for data handling and transmittal as specified by NCHS. This will be developed prior to the commencement of specimen collection and shipping.

### C.5 PERFORMANCE SCHEDULE

On average two shipments of specimens (approximately 50 specimens per shipment) will arrive at the laboratory each week. The specimens are not collected during a 2 week summer vacation and the last 2 weeks of December. The shipping schedule and the type of shipment (dry ice, freezer packs, or ambient temperature) will be agreed upon by the Project Officer and the Contractor.

2012	Conference call to discuss requirements of contract
2012	Test data and test quality control (QC) data transmitted to NHANES data collection contractor
2012	Test scenarios for early and routine report of findings conducted
2012	Draft laboratory manual delivered.
2013	First results transmitted to NHANES data collection contractor.
2017	Last results transmitted to NHANES data collection contractor.
2017	All outstanding results, Quality Control (QC), required reports, and final laboratory manual delivered to NCHS.

### C.6 SPECIFIC REQUIREMENTS FOR ALL LABORATORY ANALYSES

**C.6.1 Performance-based Outputs and Standards.** See Paragraph 10 - Performance-based Matrix for specific outputs and standards.

#### C.6.2 Technical Services.

**C.6.2.1** In preparation for the performance of the samples obtained from participants examined in the National Health and Nutrition Examination Surveys NHANES 2012-2017:

### C.7 GENERAL REQUIREMENTS FOR ALL FLUORIDE ANALYSES

In preparation for the performance of the laboratory analyses on individuals examined in the National Health and Nutrition Examination 2012-2017, the Contractor specifically shall:

1. Maintain an adequate storage facility (-70 degrees C ) for specimens upon receipt and for any excess specimen remaining in vials after analyzing the samples. Excess samples will be packed on dry ice and shipped by an overnight shipper to SriSai (NHANES Surplus Repository) in Germantown, MD. The timetable for sending these samples to the Germantown repository will be determined by the Project Officer and the Contractor. The Contractor

should be able to store specimens for at least one year. The government will pay for shipment of samples to SriSai's Repository.

2. Accept delivery of specimens on a predetermined schedule supplied by the National Center for Health Statistics (NCHS).
3. Prepare a laboratory manual with the Project Officer's approval, which will include detailed information on techniques and materials to be used in the assay and the quality control procedures to be used. Normal ranges for laboratory values will also be included along with published documentation to support the choice of the ranges. The manual must be delivered as a Microsoft Word file. The Project Officer will provide the format of the manual.
4. Maintain records for reporting results and document quality control information, which at a minimum will include the following (all results must be linked to the sample person's identification number):
  - a. Quality control information relevant to this project. The specifications for data output of these data will be provided by the Government (see Information Technology Section, Section B).
  - b. A laboratory log containing a record of the status of all vials upon arrival, date of receipt, deviations from protocol or good laboratory practice, i.e. proper labeling and packaging, and an account of all vials.
  - c. A laboratory log containing a record of all handling, storage, and manipulation of specimens, which might affect the quantitative results reported (e.g., freezing, thawing of plasma or water, spilled, contaminated).
  - d. A quality assurance system by which random or systematic errors may be detected and monitored.
5. All sample person values must be linked to:
  - a. Analytic batch and date of analysis.
  - b. Quality control values measured as part of the batch, expected control values, lot number of the controls and the manufacturer and date of expiration of control materials. If control materials are prepared in house, a description of the procedure, data, and the date must be included.
  - c. Standard reference materials used to provide long-term comparability of values.
  - d. Reagents by batch, reagent's expiration dates, and date of change of reagents. Reagents should be identified by lot number and manufacturer.
  - e. All repeated values and reasons for test repeats should be recorded. Repeat tests for abnormal ranges, 2% random repeats, or for specimens that have been compromised in the shipping process will be done at the cost of the Government. All other repeats will be done at the cost of the Contractor.
6. Proficiency testing through independent laboratories such as the College of American Pathologists or a comparable program shall be done and results reported to the Project Officer for biological specimens.
7. The laboratory must be CLIA-certified or equivalent certification. Provide copy of CLIA certification. If CLIA-exempt, provide supporting documentation.
8. Critical call or life-threatening results will be electronically transmitted to the NCHS data collection contractor.
9. For quality control assessment, the laboratory should apply the Westgard rules if applicable to the test method. The Offeror should provide quality control rules for biochemistry profile.
10. All laboratory staff must follow the guidelines outlined by the Centers for Disease Control (MMWR 36; 2S, 1987) for the prevention of HIV transmission in health-care settings if they are performing testing.
11. Provide list of possible comment codes associated with the laboratory results that might be required.



## **C.8 SPECIFIC REQUIREMENTS**

Throughout the course of NHANES 2012-2017, the Contractor shall:

1. Repeat a 2% random sample of the specimens tested to monitor the reproducibility of results.
2. Notify the Project Officer immediately of any current or foreseeable problems with the data collection and/or preparation. The need for modification in procedures shall be determined by the mutual agreement of the Contractor and the Project Officer. All modifications shall be documented in the laboratory manual as to how and why they were imposed.
3. Submit a progress report quarterly, beginning three months after the start of data collection, to the Project Officer including; 1) a summary of the status of all specimens including date of arrival, deviations from protocol, handling, storage, and manipulation of vials and all laboratory procedures used; 2) a description of any major problems such as missing data, out of range values or inconsistent data and what was done to overcome them, and plotted graphs of each level of control. The format of the report will be decided between the Contractor and NCHS Project Officer.
4. Submit results electronically to The NHANES Survey Contractor on a flow basis. All results shall be submitted within three (3) weeks after specimen receipt.
5. Three months after the start of the Contract, the Contractor shall deliver a laboratory manual that includes detailed information on techniques and materials to be used in the assay and the quality control procedures (see section A3). This manual must be reviewed and updated on a periodic basis throughout the study. All updates must be delivered to the Project Officer. This manual must be delivered in an electronic format using Microsoft Word.

## **C.9 REQUIREMENTS FOR EACH LABORATORY ANALYSIS**

Ion Specific Electrode is the method of choice for water. The test involves combining the specimen with an equal volume of ionic buffer solution and then placing in a suitable beaker that can submerge the electrode element.

The fluoride electrode is the method of choice for plasma. Plasma typically has an F concentration near or actually below the sensitivity limit of the electrode so a preparatory method that transfers the F to a smaller volume should be used. The preferred method is the HMDS-facilitated diffusion method, which is considered to be the "gold standard."

Test results and quality control results must be supplied in machine-readable format no later than three weeks (3) after receipt of plasma and water specimens. The contractor must have at least 24 months continuous experience in conducting analysis of biochemistry profile. Offerors must have a well-established quality assurance program. Data should be transmitted to NHANES in electronic data files in a format stipulated by NHANES.

## **C.10 INFORMATION TECHNOLOGY REQUIREMENTS**

### **1. Contract Laboratory Functions**

The contractor shall use an automated system for data handling and transmittal

The samples will be appropriately packaged in the field, labeled with a bar coded sample identification number, and shipped via Federal Express to the laboratory for analysis. Tracking data will be forwarded to the NHANES Survey Contractor's Home Office for follow-up with the contract laboratories. The contract laboratory will be responsible for utilizing an automated system for performing the following functions:

- a. Importing sample transmittal information into the system;
- b. Tracking samples in process;

- c. Entering analysis results: The final or best result will be entered in the results field. If abnormal or out-of-range results are re-tested the final data will be flagged with an appropriate comment code for the re-test;
- d. Flagging abnormal or out of range results;
- e. Entering quality control data: Entering quality control data including running bench quality control tests, and 2% random repeats;
- f. Provide detailed auditing information: Provide detailed auditing information including date, time, and technician identification for each major activity;
- g. Generate quarterly reports to NCHS: An electronic version of this report in Word is preferred.
- h. Generate an electronic file of the results and quality control data: Generate an electronic file of the results and quality control data in a government specified format. Column delimited data files generated by software such as Excel is one possible method of the data transmission format. The final format will be negotiated by the contractor and the Project Officer.

### **C.11 OVERVIEW OF PROCESSING REQUIREMENTS**

The Federal Express Air bill number will be used as the Shipment identifier for acknowledgment of receipt and tracking of shipment information. A transmittal file listing the contents of the shipment and any relevant sample information (e.g. age, gender) that is required will also be provided. Transmittal information will be transmitted electronically to the contract laboratory.

Strict control of the sample at the lab is critical. The contractor should have in place an automated process for tracking receipt and processing of the samples from time of receipt in the lab to output of the analysis data. The contractor should have the ability to track the date of receipt, the date and run number of testing, and the technologist who completed these tasks.

### **C.12 ELECTRONIC PROCESSING CAPABILITIES**

Electronic transmission of files will be transmitted by e-mail as the method of communication with the contract laboratories. The government will establish a toll-free 800 number for receipt and transmission of electronic files. The choice of the method of transmission of data will be negotiated between the Contractor and the Project Officer.

### **C.13 RECORD STORAGE**

Labs should maintain historical records/archives of transmissions and results to support resolution of questions or issues regarding particular samples throughout the course of the study.

### **C.14 Additional Information to be Addressed as Applicable:**

#### **Systems Security and Safeguards**

Federal Information Systems Management Act (FISMA) of 2002 (P.L. 107-347) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor (including subcontractor), or other source. FISMA requires agencies to provide information security protections commensurate with the security risks to federal information collected or maintained for the agency and information systems used or operated on behalf of an agency by a contractor.

The National Institute of Standards and Technology (NIST) has issued publications that provide guidance in the establishment of minimum security controls for management, operational and technical safeguards needed to protect the confidentiality, integrity and availability of a Federal Information system and its information.

Pursuant to Federal and Department of Health and Human Services (HHS) Information Security Program policies, the contractor and any subcontractor performing under this contract shall comply with the following requirements:

- The contractor shall ensure the confidentiality, integrity, and availability of sensitive federal information and/or federal information systems, including development of an IT Security Plan..... (see FAR 7.103(u), 7.105(b)(17), and 39.101).
- The contractor shall develop and maintain the software product in compliance with information system security regulatory requirements, while ensuring the application functions and performs in accordance with the business needs, objectives, and operational specifications agreed upon in this contract.
- The contractor will take appropriate action to mitigate security risks and vulnerabilities and ensure compliance with HHS and CDC policies as defined in FISMA and NIST security guidance.
- The contractor shall ensure information and system security requirements are considered and implemented, and complied with in all phases or stages of product during the period of performance of the contract.
- If new or unanticipated threats or vulnerabilities are discovered by either the Government or the Contractor, or if existing safeguards have ceased to function, the discoverer shall immediately bring the situation to the attention of the other party for appropriate resolution and action.
- The contractor shall not publish or disclose in any manner, without the Contracting Officer's written consent, the details of any safeguards either designed or developed by the Contractor under this contract or otherwise provided by the Government.
- The contractor shall afford the Government access to the Contractor's facilities, installations, technical capabilities, operations, documentation, records, and databases to the extent required to carry out a program of inspection to safeguard against threats and hazards to the security, integrity, and confidentiality of Government data.
- The certification and accreditation (C&A) process remains the primary standard by which system security is evaluated. Consistent with Departmental requirements, security documentation to include the constituent parts of the C&A package must be maintained and reviewed for each system reported under FISMA, including contractor systems. A contractor system is defined as any general support system, major application, or minor application hosted or maintained by contractor staff including information system used or operated by a contractor of an agency or other organization on behalf of CDC. This includes all systems physically or logically located within the boundaries of the contractor facilities and systems which reside within CDC boundaries but the primary support for which is delivered by contractor staff. NIST and Departmental guidance provide minimum documentation standards for C&A packages. C&A packages typically consist of the following:

- Risk Assessment
- System Security Plan
- Baseline Security Requirements
- Contingency Plan and Contingency Plan Test Plan and Results
- ST&E Plan and Security Assessment Report
- Plan of Action and Milestones
- Self Assessment

While CDC personnel are responsible for the review, approval, implementation, and annual evaluation of the C&A package and the SSP, the initial responsibility for the development of the required documentation may be assigned to the contractor.

References for adherence:

- (1) Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. Law 107-347  
<http://csrc.nist.gov/policies/FISMA-final.pdf>
- (2) NIST SP 800-18, *Guide for Developing Security Plans for Federal Information Systems*  
<http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf>
- (3) NIST SP 800-53 Rev2, *Recommended Security Controls for Federal Information Systems*  
<http://csrc.nist.gov/publications/nistpubs/800-53-Rev2/sp800-53-rev2-final.pdf>  
*Annex 1, Low Impact Baseline*  
<http://csrc.nist.gov/publications/nistpubs/800-53-Rev2/sp800-53-rev2-annex1.pdf>  
*Annex 2, Moderate Impact Baseline*  
<http://csrc.nist.gov/publications/nistpubs/800-53-Rev2/sp800-53-rev2-annex2.pdf>  
*Annex 3, High-Impact Baseline*  
<http://csrc.nist.gov/publications/nistpubs/800-53-Rev2/sp800-53-rev2-annex3.pdf>
- (4) NIST SP 800-64 Rev2, *Security Considerations in System Development Life Cycle*  
<http://csrc.nist.gov/publications/nistpubs/800-64-Rev2/SP800-64-Revision2.pdf>
- (5) NIST SP 800-37 Rev 1, *DRAFT Guide for Security Authorization of Federal Information Systems: a Security Lifecycle Approach*  
<http://csrc.nist.gov/publications/PubsDrafts.html#SP-800-37-Rev.%201>
- (6) *NIST SP 800-37, Guide for the Security Certification & Accreditation of Federal Information Systems*  
<http://csrc.nist.gov/publications/nistpubs/800-37/SP800-37-final.pdf>
- (7) NIST SP 800-60 (Volume I), *Guide for Mapping Types of Information and Information Systems to Security Categories.*  
[http://csrc.nist.gov/publications/nistpubs/800-60-rev1/SP800-60\\_Vol1-Rev1.pdf](http://csrc.nist.gov/publications/nistpubs/800-60-rev1/SP800-60_Vol1-Rev1.pdf)  
Volume II, *Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories*  
[http://csrc.nist.gov/publications/nistpubs/800-60-rev1/SP800-60\\_Vol2-Rev1.pdf](http://csrc.nist.gov/publications/nistpubs/800-60-rev1/SP800-60_Vol2-Rev1.pdf)
- (8) FIPS PUB 199, *Standards for Security Categorization of Federal Information and Information Systems*  
<http://csrc.nist.gov/publications/fips/fips199/FIPS-PUB-199-final.pdf>

(9) FIPS PUB 200, *Minimum Security Requirements for Federal Information and Information Systems*  
<http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf>

(10) FAR 52.239-1, *Privacy or Security Safeguards*  
<http://www.acquisition.gov/far/current/html/FARTOCP52.html#wp340130>

C.15

## Water and Plasma Fluoride Testing for NHANES 2012-2017

## PERFORMANCE-BASED MATRIX TO QASP

Desired End Result	Feature(s) of end result to be surveilled (Indicator).	The required performance level for each feature (Standard).	Quality Assurance	Incentives/Payment-Quality Link
Contractor shall produce "Project Progress Reports"	Timeliness; completeness	Due quarterly; satisfactory completeness and accuracy. Monitored by Project Officer	.Surveillance system will be primarily by POs review.	<p><b>1. Positive incentives:</b> a. Payment of contract labor rate for satisfactory service b. Contractor performance evaluated using the automated Contractor Performance Assessment Reporting System (CPARS). The evaluation will be considered when future AGENCY contract selections are made.</p> <p><b>2. Payment is linked to quality through FAR 52.246-4 Inspection of Services - Fixed Price (Aug 1996)</b> a) <i>Definition.</i> "Services," as used in this clause, includes services performed, workmanship, and material furnished or utilized in the performance of services. (b) The Contractor shall provide and maintain an inspection system acceptable to the Government covering the services under this contract. Complete records of all inspection work performed by the Contractor shall be maintained and made available to the Government during contract performance and for as long afterwards as the contract requires. (c) The Government has the right to inspect and test all services called for by the contract, to the extent practicable at all times and places during the term of the contract. The Government shall perform inspections and tests in a manner that will not unduly delay the work. (d) If the Government performs inspections or tests on the premises of the Contractor or a subcontractor, the Contractor shall furnish, and shall require subcontractors to furnish, at no increase in contract price, all reasonable facilities and assistance for the safe and convenient performance of these duties. (e) If any of the services do not conform</p>
The Contractor shall provide QC and Results to Westat electronically within 3 weeks of each run.	Accuracy & timeliness	Due 3 weeks after receipt of samples; satisfactory completeness and accuracy. Monitored by Project Officer .	Surveillance system will be primarily by POs and review of lab and QA/QC of data.	
Re-run/resubmit any specimens that don't pass QA/QC review	Accuracy & timeliness	Due 3 weeks after receipt of samples; satisfactory completeness and accuracy. Monitored by Project Officer	If fault of Contractor, they will retest at their expense.	
Contractor shall notify the PO of any unforeseen or foreseen problems with the testing or delivery of data.	Accuracy & timeliness	Due within 3 days after identification of technical problems. Monitored by Project Officer	The contractor will keep the PO apprised of the status and rectification of the problems	
Contractor must maintain QC statistics	Accuracy & timeliness	Maintain throughout the contract performance period. Monitored by Project Officer	Surveillance system will be primarily site inspections by POs and review of lab and QA/QC of data	
The vendor will follow Westgaard QC rules	Accuracy & timeliness	Maintain throughout the contract performance period. Monitored by Project Officer	Surveillance system will be primarily site inspections by POs and review of lab and QA/QC of data	

			<p>with contract requirements, the Government may require the Contractor to perform the services again in conformity with contract requirements, at no increase in contract amount. When the defects in services cannot be corrected by reperformance, the Government may—</p> <p>(1) Require the Contractor to take necessary action to ensure that future performance conforms to contract requirements; and</p> <p>(2) Reduce the contract price to reflect the reduced value of the services performed.</p> <p>(f) If the Contractor fails to promptly perform the services again or to take the necessary action to ensure future performance in conformity with contract requirements, the Government may—</p> <p>(1) By contract or otherwise, perform the services and charge to the Contractor any cost incurred by the Government that is directly related to the performance of such service; or</p> <p>(2) Terminate the contract for default.</p>
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**Section D - Packaging And Marking**

There are no clauses/provisions included in this section.



## Section E - Inspection And Acceptance

FAR SOURCE	TITLE AND DATE
52.246-4	Inspection of Services – Fixed Price (Aug 1996)

### E.1 Inspection and Acceptance (Jul 1999)

Inspection and acceptance of the articles, services, and documentation called for herein shall be accomplished by the Contracting Officer, or his duly authorized representative (who for the purposes of this contract shall be the Contracting Officer's Representative - COR) at the destination of the articles, services or documentation.

(End of Clause)

### E.2 Acceptance

Final acceptance will be based on the completion of each delivery/task order.

(End of Clause)

## Section F - Deliveries Or Performance

### F.1 Deliverable(s) Schedule (Jul 1999)

Delivery Schedule, Number of Copies, and Delivery Date

**a. Laboratory Test Results:**

Submit results and QC files electronically to The NHANES Survey Contractor on a flow basis. Delivery Date: On a flow, basis three (3) weeks after the specimens are received.

**b. Progress Reports**

Include a) a summary of the status of all specimens including date of arrival, deviations from protocol, handling, storage, and manipulation of vials, and all laboratory procedures used; b) a description of any major problems such as missing data, out of range values or inconsistent data and what was done to overcome them; internal and external quality control for runs containing NHANES specimens; instrument calibration and repairs; reagent lots and dates of use. The laboratory should provide an overview of their existing capabilities to meet this requirement. Delivery Date: Quarterly, delivered electronically by E-mail to the Project Officer three months after the start of data collection.

**c. Laboratory Manual**

Submit results and QC files electronically to The NHANES Survey Contractor on a flow basis. Delivery Date: On a flow, basis three (3) weeks after the specimens are received.

<b>Deliverables</b>	<b>Due Date</b>
Laboratory Test Results	On a flow, basis three (3) weeks after the specimens are received.
Progress Reports	Quarterly, delivered electronically by E-mail to the Contracting Officer's Representative three months after the start of data collection.
Laboratory Manual	Three months after the start of the contract. This manual must be reviewed and updated on a periodic basis throughout the study.

### F.2 Period of Performance (Jul 1999)

(a) Contract: The period of performance of this contract shall not exceed 66 months. The effective date of the contract is shown on the face page of the contract.

(b) Task Orders: The time for completion for each task or delivery order shall be determined under each individual task or delivery order through the mutual agreement of the parties involved. Task/delivery orders under this contract may be awarded by the Contracting Officer at any time within the contract period. The actual performance of the work may extend beyond the contract period.

(c) The period of performance is from 8/15/2012 to 6/14/2017. A six (6) month startup period, two (2) two- year cycles are necessary for the data collection and six (6) months is needed at the end of the survey for data clean up and possible repeat analysis of test results. All laboratory data must be comparable throughout the survey with the same laboratory and methods used. (End of Clause)

### F.3 Place(s) of Performance (Jul 1999)

The Contractor shall perform all work under this contract at the contractor's location. (End of Clause)

#### F.4 PERFORMANCE SCHEDULE

On average, two shipments of specimens (approximately 50 specimens for each analyte per shipment) will arrive at the laboratory each week. The specimens are not collected during a 2 week summer vacation and the last 2 weeks of December. The shipping schedule and the type of shipment (dry ice, freezer packs, or ambient temperature) will be agreed upon by the Project Officer and the Contractor.

2012	Conference call to discuss requirements of contract
2012	Test data and test quality control (QC) data transmitted to NHANES data collection contractor
2012	Test scenarios for early and routine report of findings conducted
2012	Draft laboratory manual delivered.
2013	First results transmitted to NHANES data collection contractor.
2017	Last results transmitted to NHANES data collection contractor.
2017	all outstanding results, Quality Control (QC), required reports, and final laboratory manual delivered to NCHS.

#### F.5 DELIVERABLES FOR THE REQUEST FOR CONTRACT

1. Copies of Proficiency testing through independent laboratories such as the College of American Pathologists or a comparable program for 2011 and 2012.
2. Provide copy of CLIA certification. If CLIA-exempt, provide supporting documentation.
3. A summary of the analytical procedure.
4. Hazards for the procedure and special safety precautions for handling and disposal of hazardous materials are to be clearly stated. Specify any protective clothing and safety equipment required (e.g., barriers, safety glasses, gloves, clip-on monitors, etc.) and type of spill kit to use if necessary.
5. Specimen collection, storage, and handling procedures; criteria for specimen rejection
  - a. Specify specimen type and requirements.
  - b. Indicate amount of specimen required, include both optimum and minimum. Assays that require a smaller amount of blood are encouraged.
  - c. List acceptable containers, anticoagulants, preservatives, and sterility requirements as well as prohibited containers, anticoagulants, etc., which may create significant analytical interference and compromise test results. If appropriate, the Contractor may screen any blood drawing equipment, collection and storage containers that may cause analytical interference and compromise test results.
  - d. Clearly state specimen stability and storage requirements.
  - f. List specimen characteristics that may compromise test results, e.g., cloudy, lipemia, etc. Describe criteria for determining unacceptable specimens and action to be taken in handling and reporting unacceptable specimens.
  - g. Specify specimen handling conditions including timing of collection, transport, and special equipment.
  - h. Specify the limits of detection (LOD) for each assay and explain how LOD was determined. Indicate if zero is a reportable value.
6. Preparation of reagents, calibrators (standards), controls, and all other materials; equipment and instrumentation:

- a. List the reagents and standard materials, supplies, and equipment used in the procedure. Include statement of any special health or safety information associated with the reagent, supplies, equipment or materials used in the procedure.
- b. Clearly state directions for preparation of each reagent or standard material (stock and working solutions).
- c. Identify and describe special equipment and instruments; include operating parameters.
- d. Clearly state if specimens should be run singly or in duplicate.

#### 7. Calibration Verification Procedures

- a. Include number, type, and concentration of calibration materials, the acceptable limits for calibration, and the frequency of calibration. Indicate traceability of calibration materials to a reference method or reference material (standard) of known value.
- b. All equipment used in the study must be calibrated on a regular basis. The rationale for the selected time period must be documented. Documentation of calibration must be made on the quality control record. Periodic preventive maintenance and documentation that the instruments are maintaining a previously determined performance at each check shall be done.

#### 8. Procedure operating instructions; calculations; interpretation of results

- a. Specify key criteria for instrument operation. For example, for photometric measurements, include type of instrument, wavelength, cuvette size, solution used as a blank, linearity, how the raw data are read (absorbance, etc.), allowable time interval between preparation and reading of the solution, any stopping points in the methodology, and stability of the final solution.
- b. Professional judgment is often used in reviewing sample test results. Document specific situations that require such review and interpretation in the procedure. Include cross-references of tests as appropriate.
- c. Review of Test Results. Indicate what results are reviewed and by whom. Describe any corrective actions or follow up procedures.

#### 9. Reporting of Results

The normal ranges for each determination shall be specified with the reference for the criteria used. Where applicable, the results should be reported in traditional and SI units. For certain methods, values are reported only in SI units. Please include the maximum number of significant decimals for each assay.

Include the mechanism for repeating of out of range results. Example: Are the original and repeated results averaged, or if repeated results are within limits of original value, is the original result reported?

##### a. Reportable Range of Test Results

State reportable range of test results according to reliability of test system. Provide performance characteristics of test procedure; include linearity limits, accuracy, precision, specificity, and sensitivity.

##### b. Reference Range (Normal Values)

Reference ranges are to be stated, including range of values for each type of sample, demographic variables (if applicable), and confidence limits used to establish the range. Indicate the source(s) of reference range.

- c. Critical Call Results ("Panic Values" – if applicable): The procedure for handling critical call or life-threatening results if applicable will be developed by the Project Officer and the Contractor in order to provide this information to the participant in an expedited fashion, though most critical results will be

electronically transmitted to the NCHS data collection contractor. Please discuss if the assay proposed has the possibility of having critical or panic values and the ability of the Contractor to respond by providing the results in an expedited manner. Include the earliest time period after the specimen is received and tested that a critical result might be obtained.

#### 10. Quality Control (QC) Procedures

Identify the materials to be used and give instructions for preparation and handling. Describe number of QC materials, frequency of control runs (including position in analytical run) and documentation and storage of QC data. State how tolerance limits for controls are established.

Describe the composition and order of the test runs. Describe the number and level of each control per assay. Indicate the order and position of standards, unknowns, and control materials in each run. Indicate if standards and controls are run at the beginning of each run, in the middle of runs, and/or end of each run.

Indicate how changes in instrument performance or environment, which might occur during one run, will be detected.

Indicate if supplemental methods of quality control are used in conjunction with the primary quality control program to eliminate any bias. Examples are use of "blind controls", split samples, or testing a specimen a day later to compare results.

Indicate any relationships the assays may have to each other.

The Contractor shall make provisions for detecting errors outside pre-determined limits.

The Contractor shall make provisions for documenting daily bench performance and for detecting drifts over time.

Quality control pools for each assay must be characterized, summary statistics characterized and standardized prior to testing of NHANES 2012-2017 samples.

Checks shall be made of consecutive series of runs where the run mean value is above or below an expected range of mean values. A protocol to detect trends from the target mean shall be set up.

Criteria shall be set up for "in-control" and "out-of control" values.

Plots of daily quality control information shall be monitored and corrective actions documented for reference by the Project Officer.

Provisions must be made for controls and standards for each assay performed. If possible one standard set of materials should be used for the length of the survey. In the event that stock standards do change, a comparability study of at least 100 specimens shall be done at the Contractor's expense to demonstrate the relationship of the values before and after the change in standards. Controls and standards shall be identified by lot number, manufacturer, and date of expiration. Confirmatory studies of commercial standards and controls performed as a routine monitoring of the laboratory's performance of the specified testing shall be recorded and results be made available. If standards are prepared and used only by the contracting laboratory, this should be documented.

The staff analyzing the samples must be identifiable by a lab ID. This identification will also apply to sample preparation if it is a separate step or series of steps.

If this assay is the result of a new procedure, provide supporting data on how the procedure was developed and validated. This documentation should include, if indicated:

- a. addition of known quantities of a constituent to a matrix with recovery calculated;
- b. analysis of constituent at low, normal and high concentrations;

- b. Plasma, or water matrix pools analyzed by a reference method or “generally accepted method;”
- d. summary statistics comparisons to show within-run or within-day precision among-runs;
- e. provide quality control data for at least one year at introduction of new procedure;

#### 11. Remedial Action if Calibration or QC Systems Fail to Meet Acceptable Criteria

List corrective actions to be taken if calibration or QC procedures fail to meet acceptable performance criteria. Indicate acceptable alternatives if no quality control materials are available. Document the procedure to be followed when quality control material results are not within acceptable limits. Include documentation of cases in which decisions about repeat sample testing is made based on relative analytical significance of the analyte in question (e.g. a QC value is out of range by a factor which is not significant analytically, so the decision is made not to repeat samples tested prior to the sample). Indicate the individuals who have the authority to make such decisions (e.g. bench tech, team leader, and supervisor); document all decisions. If the QC data indicates that the run is “out-of-control”, the specimens included in that run will be re-tested at the Contractor’s expense.

#### 12. Limitations of method; interfering substances and conditions

- a. Indicate range of linearity and limit of detection (LOD).
- b. Specify known sources of potential bias including interfering substances. Include both in vitro (preservatives, hemolysis, etc.) and in vivo (medications) interferences.

#### 13. Specimen storage and handling during testing

Indicate proper storage or handling of specimens during testing to insure specimen integrity. Example: Refrigerate specimens between steps 2 and 3; or suspend specimen tubes in ice bath while adding reagent A.

#### 14. Alternative methods for performing test or storing specimens if test system fails or becomes inoperable

Indicate acceptable alternative methods or analytical test systems (backup instrumentation) and recommended storage conditions including optimal and maximum storage time for sample retention.

#### 15. Automation of comments fields

There will be no text field for entering free-form comments associated with the tests results. Please give careful consideration to all possible comments associated with each assay. NCHS will create fields in the automation system to accommodate repeat results, conditions of sample, etc. Please list possible comment codes that might be needed.

#### 16. Evaluation of the performance of each assay method

Performance of a method must be judged on both the practicality and reliability of the methods. In evaluating the practicality of a method, speed, cost, technical skill required, dependability and safety must be considered.

To judge these factors, provide the following:

- a. time needed for analysis of one specimen alone;
- b. number of samples which can be analyzed per unit of time under routine conditions; and
- c. time in hours’ use for preventive maintenance, reagent preparation, calibration, trouble shooting, and total operating time.

## **Section G - Contract Administration Data**

### **G.1 Contracting Officer's Representative - COR (Jul 1999)**

Performance of the work hereunder shall be subject to the technical directions of the designated Contracting Officer's Representative for this contract.

As used herein, technical directions are directions to the Contractor which fill in details, suggests possible lines of inquiry, or otherwise completes the general scope of work set forth herein. These technical directions must be within the general scope of work, and may not alter the scope of work or cause changes of such a nature as to justify an adjustment in the stated contract price/cost, or any stated limitation thereof. In the event that the Contractor feels that full implementation of any of these directions may exceed the scope of the contract, he or she shall notify the originator of the technical direction and the Contracting Officer in a letter separate of any required report(s) within two (2) weeks of the date of receipt of the technical direction and no action shall be taken pursuant to the direction. If the Contractor fails to provide the required notification within the said two (2) week period that any technical direction exceeds the scope of the contract, then it shall be deemed for purposes of this contract that the technical direction was within the scope. No technical direction, nor its fulfillment, shall alter or abrogate the rights and obligations fixed in this contract.

The Government Contracting Officer's Representative is not authorized to change any of the terms and conditions of this contract. Changes shall be made only by the Contracting Officer by properly written modification(s) to the contract.

The Government will provide the Contractor with a copy of the delegation memorandum for the Contracting Officer's Representative. Any changes in Contracting Officer's Representative delegation will be made by the Contracting Officer in writing with a copy being furnished to the Contractor.  
(End of Clause)

### **G.2 Payment by Electronic Funds Transfer (Mar 2004)**

(a) The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer – Central Contractor Registration, in Section I, requires the contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

(b) The contractor shall make the designation by submitting the form titled "ACH Vendor/Miscellaneous Payment Enrollment Form" to the address indicated below. Note: The form is either attached to this contract (see Section J, List of Attachments) or may be obtained by contacting the Contracting Officer or the CDC Financial Management Office at (404) 498-4050.

(c) In cases where the contractor has previously provided such designation, i.e., pursuant to a prior contract/order, and been enrolled in the program, the form is not required.

(d) The completed form shall be mailed after award, but no later than 14 calendar days before an invoice is submitted, to the following address:

Centers for Disease Control and Prevention (FMO)  
PO Box 15580 404-498-4050 1-800-335-2455  
Atlanta, GA 30333-  
(End of Clause)

### G.3 Extent of Obligation

The Government is obligated only to the extent of authorized purchases made via issuance of delivery/task orders under this contract. No monies are actually obligated under this contract, but obligated through delivery/task orders issued against this contract.

(End of Clause)

### G.4 Invoice Submission - part 1 (Mar 2006)

(a) The Contractor shall submit the original contract invoice/voucher at the end of each month to the shown below:  
The Centers for Disease Control and Prevention  
Financial Management Office (FMO)  
P.O. Box 15580  
Atlanta, GA 3033

(b) Please do not forget to submit a copy of each invoice directly to the Contracting Officer's Representative and Contracting Officer or Contract Administrator *concurrently* with submission to the Financial Management Office (FMO). It saves time, postage, and speeds up the payment processing by emailing the invoices to the 3 listed email addresses below:

Financial Management Office (FMO):  
Email: [FMOAPINV@CDC.GOV](mailto:FMOAPINV@CDC.GOV)  
Fax: 404-638-5324  
Phone #: 404-498-4050

Contract Administrator: Marie F. Bartkevicius, [mbartkevicius@cdc.gov](mailto:mbartkevicius@cdc.gov)

Contracting Officer's Representative: Brenda Lewis, [blewis@cdc.gov](mailto:blewis@cdc.gov)

- (c) The Contractor is required to submit a copy of each invoice directly to the Contracting Officer's Representative concurrently with submission to the Contracting Officer.
- (d) In accordance with 5 CFR part 1315 (Prompt Payment), CDC's Financial Management Office is the designated billing office for the purpose of determining the payment due date under FAR 32.904.
- (e) The Contractor shall include (as a minimum) the following information on each invoice:
- (1) Contractor's Name & Address
  - (2) Contractor's Tax Identification Number (TIN)
  - (3) Purchase Order/Contract Number and Task Order Number, if Appropriate
  - (4) Invoice Number
  - (5) Invoice Date
  - (6) Contract Line Item Number and Description of Item
  - (7) Quantity
  - (8) Unit Price & Extended Amount for each line item
  - (9) Shipping and Payment Terms
  - (10) Total Amount of Invoice
  - (11) Name, title and telephone number of person to be notified in the event of a defective invoice
  - (12) Payment Address, if different from the information in (c)(1).
  - (13) DUNS + 4 Number

(End of Clause)



## **G.5 Evaluation of Contractor Performance (Service) (Jan 2000)**

### (a) Purpose

In accordance with FAR 42.1502, the Contractor's performance will be periodically evaluated by the Government, in order to provide current information for source selection purposes. These evaluations will therefore be marked "Source Selection Information."

### (b) Performance Evaluation Period

The Contractor's performance will be evaluated at least annually.

### (c) Evaluators

The performance evaluation will be completed jointly by the Contracting Officer's Representative and the Contracting officer.

### (d) Performance Evaluation Factors

The contractor's performance will be evaluated in accordance with the attachment listed in Section J titled Performance Evaluation Report.

### (e) Contractor Review

A copy of the evaluation will be provided to the contractor as soon as practicable after completion of the evaluation. The contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within 30 calendar days after receipt of the evaluation.

### (f) Resolving Disagreements Between the Government and the Contractor

Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, contractor's response, and review comments, if any, will be retained as part of the evaluation.

### (g) Release of Contractor Performance Evaluation Information

The completed evaluation will not be released to other than Government personnel and the contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the contractor being evaluated as well as impede the efficiency of Government operations.

### (h) Source Selection Information

Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.

### (i) Retention Period

The agency will retain past performance information for a maximum period of three years after completion of contract performance for the purpose of providing source selection information for future contract awards.

(End of Clause)

**G.6 Criminal Liability (Jan 2000)**

It is understood that disclosures of information relating to the work or services hereunder to any person not entitled to receive it, or failure to safeguard any classified information as defined in Executive Order 11652 that may come to the Contractor or any person under the Contractor's control in connection with the work under this contract, may subject the Contractor, his agents or employees to criminal liability under Title 18, Section 793, 794 and 798 of the United States Code.

(End of Clause)

**G.7 Contracting Officer (Jul 1999)**

(a) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.

(b) No information, other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

(End of Clause)

**G.8 Contract Communications/Correspondence (Jul 1999)**

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting thereon the contract number found in Block 2 of the face page the contract.

(End of Clause)

## **Section H - Special Contract Requirements**

### **H.1 Privacy Act (Apr 2000)**

(a) Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. (45 CFR Part 5b)

(b) The Contracting Officer's Representative is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

(c) The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act system notice provided in Section J, List of Attachments.

(End of Clause)

### **H.2 Laboratory License Requirements (May 1998)**

The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended). This requirement shall also be included in any subcontract for services under the contract.

(End of Clause)

### **H.3 Dissemination of Information (May 1998)**

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the Contracting Officer's Representative.

(End of Clause)

### **H.4 Identification of Data (May 1998)**

The Contractor shall identify the technical data delivered to the Government as required by this contract with the number of the contract and the name and address of the Contractor or subcontractor that generated the data.

(End of Clause)

### **H.5 Identification and Disposition of Data**

The Contractor guarantees that it will not tabulate, analyze, release or use the data without prior written approval of the Contracting Office and the Contracting Officer's Representative. The Contractor will release all tabulations and reports solely to the Contracting Officer's Representative or their designee. Copies of quality control data may be maintained in the contracting laboratory. If method development is done as part of this project, the Contractor may keep that data. All biologic specimens must be returned to the Contracting Officer's Representative and may not be used for other purposes unless approved by the Contracting Officer's Representative.

## **H.6 Data Subject to Confidentiality Requirements (May 1998)**

The type(s) of data subject to the clause at 352.224-70, Confidentiality of Information, which has been incorporated by reference in Section I, are as follows:

All data generated by this procurement, including personally identifying information.

Following are the requirements for handling these data:

The Contractor guarantees that it will not tabulate, analyze, release or use the data without prior written approval of the Contracting Officer and the Contracting Officer's Representative. The Contractor will release all tabulations and reports solely to the Contracting Officer's Representatives or their designee. All data collected, records, data tapes or files (interim and final), and tables remaining in the custody of the Contractor at the close of this contract shall be returned to the custody of the responsible Contracting Officer's Representatives or their designee, and no copies (either preliminary, interim or final) shall be maintained by the Contractor. Copies of quality control data may be maintained in the contracting laboratory. If method development is done as part of this project, the Contractor may keep that data. All biologic specimens must be returned to the Contracting Officer's Representative and may not be used for other purposes unless approved by the Contracting Officer's Representative.

(End of Clause)

## **H.7 Review and Comment (May 1998)**

All materials developed or information of whatever nature resulting from work performed under this contract shall be submitted to the Contracting Officer's Representative for review and comment prior to publication or dissemination.

(End of Clause)

## **H.8 Issuance of Task/Delivery Orders**

Although the Contractor may not be required to conduct all of the tasks set forth in this Statement of Work, the Contractor shall be capable of providing the staff necessary to conduct the required work. The timing, magnitude, and scope of each requirement cannot be predicted until the Government determines the specific work to be performed. The Contractor should expect a fluctuating workload throughout the performance period of this contract and will provide the technical, professional, managerial, and clerical support required to complete the task order successfully. The technical monitor, Contracting Officer's Representative, or designee may accompany the Contractor to each site for the purpose of monitoring the Contractors startup activities and may elect to remain at the site to monitor Contractor activities.

Performance hereunder shall be accomplished by task orders issued under this contract in accordance with the following procedure:

As the Government identifies specific requirements for work to be performed under this contract, a Task/Delivery Order will be issued unilaterally. The Order will detail the requirements and associated funding. The NCHS program official will subsequently provide a predetermined delivery schedule for those requirements. If the Contractor does not accept the Task/Delivery Order and cannot reach agreement on an individual task order basis, it shall be considered a dispute and handled according to the provision of the contract in Section I, FAR 52.233-01 "Disputes – Alternate I" (Oct 1995) (End of Clause)

## **H.9 Task Order Clause Applicability**

Some or all of the following special provisions are applicable only to the extent indicated in individual Task/Delivery orders:

Data Collection Approval  
HHSAR 352.280-1(b), Protection of Human Subjects  
HHSAR 352.280-2(b), Care of Live Vertebrate Animals  
Printing Restrictions  
Inclusion of Women and Racial and Ethnic Minorities in Research  
Automated Information Systems (AIS) Security

(End of Clause)

## **H.10 Remarks**

Depending on the requirements of the task(s) created under this IDIQ contract, the contractor may be required to submit privacy clearances, IRB clearances, and identify system of record numbers for studies and data systems created or maintained. The contractor must protect the confidentiality of proprietary, sensitive, and Personally Identifiable Information (PII).

Contractor performance and resulting deliverables must adhere to all federal, HHS, and/or CDC IT security policies and procedures. Based upon the scope of this contract, the SOW must include the following HHSAR IT Security clauses: **352.239-70** Standard for Security Configurations; **352.239-71** Standard for Encryption Language; **352.239-72** Security requirements for Federal Information Technology Resources. Contractor performance and resulting deliverables must adhere to all federal, HHS, and/or CDC IT security policies and procedures.

## Section I - Contract Clauses

### I.1 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

<http://www.acqnet.gov>

<http://farsite.hill.af.mil/>

*[Insert one or more Internet addresses]*

(End of Clause)

<b>FAR SOURCE</b>	<b>TITLE AND DATE</b>
52.202-1	Definitions (Jan 2012)
52.203-3	Gratuities (Apr 1984)
52.203-5	Covenant against Contingent Fees (Apr 1984)
52.203-6	Restrictions on Subcontractor Sales to the Government (Sep 2006)
52.203-7	Anti-Kickback Procedures (Oct 2010)
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Jan 1997)
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (Jan 1997)
52.203-12	Limitation on Payments to Influence Certain Federal Transactions (Oct 2010)
52.204-4	Printed or Copied Double-Sided on Recycled Paper (May 2011)
52.204-7	Central Contractor Registration (Feb 2012)
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards (Feb 2012)
52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Dec 2010)
52.215-2	Audit and Records - Negotiation (Oct 2010)
52.215-8	Order of Precedence - Uniform Contract Format (Oct 1997)
52.219-8	Utilization of Small Business Concerns (Jan 2011)
52.222-3	Convict Labor (Jun 2003)
52.222-21	Prohibition of Segregated Facilities (Feb 1999)
52.222-26	Equal Opportunity (Mar 2007)
52.222-35	Equal Opportunity for Veterans (Sep 2010)
52.222-36	Affirmative Action for Workers With Disabilities (Oct 2010)
52.222-37	Employment Reports Veterans (Sep 2010)
52.222-50	Combating Trafficking in Persons (Feb 2009)
52.222-54	Employment Eligibility Verification (Jan 2009)
52.223-6	Drug-Free Workplace (May 2001)
52.223-18	Encouraging Contractor Policies to Ban Text Messaging While Driving (Aug 2011)

52.225-13	Restrictions on Certain Foreign Purchases (June 2008)
52.227-1	Authorization and Consent (Dec 2007)
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement (Dec 2007)
52.227-14	Rights in Data—General (Dec 2007)
52.229-3	Federal, State, and Local Taxes (Apr 2003)
52.232-1	Payments (Apr 1984)
52.232-8	Discounts for Prompt Payment (Feb 2002)
52.232-9	Limitation on Withholding of Payments (Apr 1984)
52.232-11	Extras (Apr 1984)
52.232-17	Interest (Oct 2010)
52.232-18	Availability of Funds (Apr 1984)
52.232-23	Assignment of Claims (Jan 1986)
52.232-25	Prompt Payment (Oct 2008)
52.232-33	Payment by Electronic Funds Transfer - Central Contractor Registration (Oct 2003)
52.233-1	Disputes (Jul 2002)
52.233-3	Protest after Award (Aug 1996)
52.233-4	Applicable Law for Breach of Contract Claim (Oct 2004)
52.239-1	Privacy or Security Safeguards (Aug 1996)
52.242-13	Bankruptcy (Jul 1995)
52.242-15	Stop-Work Order (Aug 1989)
52.243-1 Alternate I	Changes - Fixed Price - Alternate I (Apr 1984)
52.246-25	Limitation of Liability – Services (Feb 1997)
52.249-4	Termination for Convenience of the Government (Services) (Short Form) (Apr 1984)
52.249-8	Default (Fixed-Price Supply and Service) (Apr 1984)
52.253-1	Computer Generated Forms (Jan 1991)
<b>HHSAR SOURCE</b>	<b>TITLE AND DATE</b>
352.201-70	Paperwork Reduction Act (Jan 2006)
352.202-1	Definitions (Jan 2006)
352.203-70	Anti-Lobbying (Jan 2006)
352.227-70	Publications and Publicity (Jan 2006)
352.231.71	Pricing of Adjustments (Jan 2001)
352.242-73	Withholding of Contract Payments (Jan 2006)

## Section I-2 - Clauses Incorporated In Full Text

### I.1 In accordance with FAR Part 32.703-1 (b) Incremental Funding

This contract shall be incrementally funded. Subject to the availability of funds, the Government contemplates that funds for this contract shall be allotted to the Contractor for the planned Fiscal Years (FY) in the amounts set forth in Section B. It is further contemplated that each total planned FY allotment may be allotted incrementally within each FY.

### I.2 FAR 52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 10 days prior to the end of the period of performance.

(End of Clause)

### I.3 52.215-2 Audit and Records—Negotiation (June 1999)

As prescribed in [15.209\(b\)](#), insert the following clause:

(a) As used in this clause, “records” includes books, documents, accounting procedures and practices, and other data, regardless of type and regardless of whether such items are in written form, in the form of computer data, or in any other form.

(b) *Examination of costs.* If this is a cost-reimbursement, incentive, time-and-materials, labor-hour, or price re-determinable contract, or any combination of these, the Contractor shall maintain and the Contracting Officer, or an authorized representative of the Contracting Officer, shall have the right to examine and audit all records and other evidence sufficient to reflect properly all costs claimed to have been incurred or anticipated to be incurred directly or indirectly in performance of this contract. This right of examination shall include inspection at all reasonable times of the Contractor’s plants, or parts of them, engaged in performing the contract.

(c) *Cost or pricing data.* If the Contractor has been required to submit cost or pricing data in connection with any pricing action relating to this contract, the Contracting Officer, or an authorized representative of the Contracting Officer, in order to evaluate the accuracy, completeness, and currency of the cost or pricing data, shall have the right to examine and audit all of the Contractor’s records, including computations and projections, related to—

- (1) The proposal for the contract, subcontract, or modification;
- (2) The discussions conducted on the proposal(s), including those related to negotiating;
- (3) Pricing of the contract, subcontract, or modification; or
- (4) Performance of the contract, subcontract or modification.

(d) Comptroller General—

(1) The Comptroller General of the United States, or an authorized representative, shall have access to and the right to examine any of the Contractor’s directly pertinent records involving transactions related to this contract or a subcontract hereunder.

(2) This paragraph may not be construed to require the Contractor or subcontractor to create or maintain any record that the Contractor or subcontractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e) *Reports.* If the Contractor is required to furnish cost, funding, or performance reports, the Contracting Officer or an authorized representative of the Contracting Officer shall have the right to examine and audit the supporting records and materials, for the purpose of evaluating—



(1) The effectiveness of the Contractor's policies and procedures to produce data compatible with the objectives of these reports; and

(2) The data reported.

(f) *Availability*. The Contractor shall make available at its office at all reasonable times the records, materials, and other evidence described in paragraphs (a), (b), (c), (d), and (e) of this clause, for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in [Subpart 4.7](#), Contractor Records Retention, of the Federal Acquisition Regulation (FAR), or for any longer period required by statute or by other clauses of this contract. In addition—

(1) If this contract is completely or partially terminated, the Contractor shall make available the records relating to the work terminated until 3 years after any resulting final termination settlement; and

(2) The Contractor shall make available records relating to appeals under the Disputes clause or to litigation or the settlement of claims arising under or relating to this contract until such appeals, litigation, or claims are finally resolved.

(g) The Contractor shall insert a clause containing all the terms of this clause, including this paragraph (g), in all subcontracts under this contract that exceed the simplified acquisition threshold, and—

(1) That are cost-reimbursement, incentive, time-and-materials, labor-hour, or price-redeterminable type or any combination of these;

(2) For which cost or pricing data are required; or

(3) That require the subcontractor to furnish reports as discussed in paragraph (e) of this clause.

The clause may be altered only as necessary to identify properly the contracting parties and the Contracting Officer under the Government prime contract.

(End of clause)

#### **I.4 FAR 52.216-18 Ordering (Oct 1995)**

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from date of award through the performance period.

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c) If mailed, a delivery order or task order is considered “issued” when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

(End of Clause)

#### **I.5 FAR 52.216-19 Order Limitations (Oct 1995)**

(a) *Minimum order*. When the Government requires supplies or services covered by this contract in an amount of less than \$\_\_\_\_\_, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) *Maximum order*. The Contractor is not obligated to honor –

(1) Any order for a single item in excess of maximum annual amount; \$

(2) Any order for a combination of items in excess of the maximum annual amount; or \$

(3) A series of orders from the same ordering office within 30 days that together call for quantities exceeding the limitation in subparagraph (b)(1) or (2) of this section.

(c) If this is a requirements contract (*i.e.*, includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) of this section.

(d) Notwithstanding paragraphs (b) and (c) of this section, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within 7 days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

(End of Clause)

#### **I.6 HHSAR 352.224-70 Privacy Act (Jan 2006)**

This contract requires the Contractor to perform one or more of the following:

(a) design; (b) develop; or (c) operate a federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) [[5 U.S.C. 552a\(m\)\(1\)](#)] and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties [[5 U.S.C. 552a\(i\)](#)]. The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records [[5 U.S.C. 552a\(m\)\(1\)](#)]. The contract work statement: (a) identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and (b) specifies the disposition to be made of such records upon completion of contract performance. (End of clause)

#### **I.7 HHSAR 352.233-71 Litigation and Claims (Jan 2006)**

a) The Contractor shall provide written notification immediately to the Contracting Officer of any action, including any proceeding before an administrative agency, filed against the Contractor arising out of the performance of this contract, including, but not limited to the performance of any subcontract hereunder; and any claim against the Contractor the cost and expense of which is allowable under the clause entitled "Allowable Cost and Payment."

(b) Except as otherwise directed by the Contracting Officer, the Contractor shall furnish immediately to the Contracting Officer copies of all pertinent papers received by the Contractor with respect to such action or claim. To the extent not in conflict with any applicable policy of insurance, the Contractor may, with the Contracting Officer's approval, settle any such action or claim. If required by the Contracting Officer, the Contractor shall effect an assignment and subrogation in favor of the Government of all the Contractor's rights and claims (except those against the Government) arising out of any such action or claim against the Contractor; and authorize representatives of the Government to settle or defend any such action or claim and to represent the Contractor in, or to take charge of, any action.

(c) If the Government undertakes a settlement or defense of an action or claim, the Contractor shall furnish all reasonable assistance in effecting a settlement or asserting a defense. Where an action against the Contractor is not covered by a policy of insurance, the Contractor shall, with the approval of the Contracting Officer, proceed with the defense of the action in good faith. The Government shall not be liable for the expense of defending any action or for any costs resulting from the loss thereof to the extent that the Contractor would have been compensated by insurance which was required by law or regulation or by written direction of the Contracting Officer, but which the Contractor failed to secure through its own fault or negligence. In any event, unless otherwise expressly provided in this contract, the Government shall not reimburse or indemnify the Contractor for any liability loss, cost, or expense, which the Contractor may incur or be subject to by reason of any loss, injury or damage, to the person or to real or

personal property of any third parties as may accrue during, or arise from, the performance of this contract. (End of clause)

**I.8 HSSAR 352.242-70 Key Personnel (Jan 2006)**

The key personnel cited below are considered essential to the work performed under the contract. If these individuals leave the Contractor’s employ or are reassigned to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. The Contractor shall not replace or divert any key personnel without the written consent of the Contracting Officer. If a suitability determination of the approved substituted key personnel is required, the contractor shall comply with the instructions in clause titled “Suitability Determination Requirements (Nov 2002)” to obtain the determination.

The persons who perform the testing without direct supervision must have as a minimum an associate’s degree in a laboratory science or a four-year degree from a medical technology school. Individuals with this level of education are called Medical Technologists and are not covered by the Service Contract Act. A Medical Laboratory Technician, covered by the Service Contract Act, is not an appropriate person to be conducting the assays included in this Contract.

Project investigators should be MDs or PhDs

Lab team: medical technologists, preferred; acceptable: chemists, medical laboratory technician.

Important: Lab must be CLIA certified. (End of Clause)

Personnel	Title

**HHSAR 352.239-70 Standard for Security Configurations (January 2010)**

(a) The Contractor shall configure its computers that contain HHS data with the applicable Federal Desktop Core Configuration (FDCC) (see <http://nvd.nist.gov/fdcc/index.cfm>) and ensure that its computers have and maintain the latest operating system patch level and anti-virus software level. (Note: FDCC is applicable to all computing systems using Windows XP™ and Windows Vista™, including desktops and laptops—regardless of function—but not including servers.)

(b) The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply:

(NOTE: The Contracting Officer shall specify applicable security configuration requirements in solicitations and contracts based on information provided by the Project Officer, who shall consult with the OPDIV/STAFFDIV Chief Information Security Officer.)

(c) The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)-validated tools with FDCC Scanner capability to ensure its products operate correctly with FDCC configurations and do not alter FDCC settings – see <http://scap.nist.gov/validation/>. The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products meet the latest FDCC major version and subsequent major versions.

(d) The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.

(e) The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.

(f) The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (see <http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf>), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with **FAR Subpart 4.13**, Personal Identity Verification.

(g) The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

(End of clause)

### **HHSAR 352.239-71 Standard for Encryption Language (January 2010)**

(a) The Contractor shall use **Federal Information Processing Standard (FIPS) 140-2**-(PDF) compliant encryption (Security Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (Note: The Government has determined that HHS information under this contract is considered “sensitive” in accordance with **FIPS 199, Standards for Security Categorization of Federal Information and Information Systems**, dated February 2004.)

(b) The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (see <http://csrc.nist.gov/cryptval/>) to confirm compliance with **FIPS 140-2** (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer’s Technical Representative.

(c) The Contractor shall use the Key Management Key (see **FIPS 201**, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (see <http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf>). The Contractor shall notify the Contracting Officer and the Contracting Officer’s Technical Representative of personnel authorized to decrypt and recover all encrypted information.

(d) The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with **FIPS 140-2** (as amended).

(e) The Contractor shall ensure that this standard is incorporated into the Contractor’s property management/control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.

(f) The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

(End of clause)

**HHSAR 352.239-72 Security Requirements for Federal Information Technology Resources (January 2010)**

(a) Applicability. This clause applies whether the entire contract or order (hereafter “contract”), or portion thereof, includes information technology resources or services in which the Contractor has physical or logical (electronic) access to, or operates a Department of Health and Human Services (HHS) system containing, information that directly supports HHS’ mission. The term “information technology (IT)”, as used in this clause, includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services) and related resources. This clause does not apply to national security systems as defined in FISMA.

(b) Contractor responsibilities. The Contractor is responsible for the following:

(1) Protecting federal information and federal information systems in order to ensure their—

(i) Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;

(ii) Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and.

(iii) Availability, which means ensuring timely and reliable access to and use of information.

(2) Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.

(3) Adopting, and implementing, at a minimum, the policies, procedures, controls, and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of federal information and federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer’s (OCIO) website.

(c) Contractor security deliverables. In accordance with the timeframes specified, the Contractor shall prepare and submit the following security documents to the Contracting Officer for review, comment, and acceptance:

(1) IT Security Plan (IT-SP) – due within 30 days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor’s bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.

(i) The Contractor’s IT-SP shall comply with applicable federal laws that include, but are not limited to, the **Federal Information Security Management Act (FISMA) of 2002** (PDF) (Title III of the E-Government Act of 2002, Public Law 107-347), and the following federal and HHS policies and procedures:

(A) Office of Management and Budget (**OMB Circular A-130**, Management of Federal Information Resources, Appendix III, Security of Federal Automated Information Resources.

(B) National Institute of Standards and Technology (NIST) **Special Publication (SP) 800-18** (PDF), Guide for Developing Security Plans for Federal Information Systems, in form and content, and with any pertinent contract Statement of Work/Performance Work Statement (SOW/PWS) requirements. The IT-SP shall identify and document appropriate IT security controls consistent with the sensitivity of the information and the requirements of **Federal Information Processing Standard (FIPS) 200**, Recommended Security Controls for Federal Information Systems. The Contractor shall review and update the IT-SP in accordance with **NIST SP 800-26**, Security Self-Assessment Guide for Information Technology Systems and FIPS 200, on an annual basis.

(C) **HHS-OCIO Information Systems Security and Privacy Policy**.

(ii) After resolution of any comments provided by the Government on the draft IT-SP, the Contracting Officer shall accept the IT-SP and incorporate the Contractor's final version into the contract for Contractor implementation and maintenance. On an annual basis, the Contractor shall provide to the Contracting Officer verification that the IT-SP remains valid.

(2) IT Risk Assessment (IT-RA) – due within 30 days after contract award. The IT-RA shall be consistent, in form and content, with **NIST SP 800-30**, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy. After resolution of any comments provided by the Government on the draft IT-RA, the Contracting Officer shall accept the IT-RA and incorporate the Contractor's final version into the contract for Contractor implementation and maintenance. The Contractor shall update the IT-RA on an annual basis.

(3) **FIPS 199** Standards for Security Categorization of Federal Information and Information Systems Assessment (FIPS 199 Assessment) – due within 30 days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard. After resolution of any comments by the Government on the draft FIPS 199 Assessment, the Contracting Officer shall accept the FIPS 199 Assessment and incorporate the Contractor's final version into the contract.

(4) IT Security Certification and Accreditation (IT-SC&A) – due within 3 months after contract award. The Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed for applicable information systems – see paragraph (a) of this clause. The Contractor shall perform the IT-SC&A in accordance with the HHS Chief Information Security Officer's Certification and Accreditation Checklist; **NIST SP 800-37**, Guide for the Security Certification and Accreditation of Federal Information Systems; and **NIST SP 800-53**, Recommended Security Controls for Federal Information Systems. An authorized senior management official shall sign the draft IT-SC&A and provide it to the Contracting Officer for review, comment, and acceptance.

(i) After resolution of any comments provided by the Government on the draft IT-SC&A, the Contracting Officer shall accept the IT-SC&A and incorporate the Contractor's final version into the contract as a compliance requirement.

(ii) The Contractor shall also perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid. Evidence of a valid system accreditation includes written results of (A) annual testing of the system contingency plan and (B) the performance of security control testing and evaluation.

(d) Personal identity verification. The Contractor shall identify its employees with access to systems operated by the Contractor for HHS or connected to HHS systems and networks. The Contracting Officer's Technical

Representative (COTR) shall identify, for those identified employees, position sensitivity levels that are commensurate with the responsibilities and risks associated with their assigned positions. The Contractor shall comply with the HSPD-12 requirements contained in “HHS-Controlled Facilities and Information Systems Security” requirements specified in the SOW/PWS of this contract.

(e) Contractor and subcontractor employee training. The Contractor shall ensure that its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and networks. The Contractor shall provide documentation to the COTR evidencing that Contractor employees have completed the required training.

(f) Government access for IT inspection. The Contractor shall afford the Government access to the Contractor’s and subcontractors’ facilities, installations, operations, documentation, databases, and personnel used in performance of this contract to the extent required to carry out a program of IT inspection (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the integrity, confidentiality, and availability, of HHS data or to the protection of information systems operated on behalf of HHS.

(g) Subcontracts. The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of federal information and federal information systems as described in paragraph (a) of this clause, including those subcontracts that—

(1) Have physical or electronic access to HHS’ computer systems, networks, or IT infrastructure; or

(2) Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor’s information system.

(h) Contractor employment notice. The Contractor shall immediately notify the Contracting Officer when an employee either begins or terminates employment (or is no longer assigned to the HHS project under this contract), if that employee has, or had, access to HHS information systems or data.

(i) Document information. The Contractor shall contact the Contracting Officer for any documents, information, or forms necessary to comply with the requirements of this clause.

(j) Contractor responsibilities upon physical completion of the contract. The Contractor shall return all HHS information and IT resources provided to the Contractor during contract performance and certify that all HHS information has been purged from Contractor-owned systems used in contract performance .

(k) Failure to comply. Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause shall be grounds for the Contracting Officer to terminate this contract.

(End of clause)

**Section J - List of Attachments**

- 1) QASP



**Section K - Representations, Certifications, and Other Statements of Offerors**

**K.1 Contact for Negotiation/Administration (May 1998)**

Designate a person we may contact for contract administration in the event your firm receives a contract as a result of this solicitation:

Name: \_\_\_\_\_ Title: \_\_\_\_\_

Address: \_\_\_\_\_  
(Street) (City) (State) (Zip Code)

Area Code: \_\_\_\_\_ Telephone: \_\_\_\_\_

Bidder/Offeror is located in \_\_\_\_\_ Congressional District.

Contract will be performed in \_\_\_\_\_  
(State) (City) (Congressional District)

(End of Clause)

**K.2 Online Representations and Certification Application (ORCA) (Dec 2005)**

- (a) All potential Contractors are required to complete electronic annual representations and certifications at <http://orca.bpn.gov> in conjunction with registration in the Central Contractor Registration (CCR) database per FAR 4.1102 and FAR 4.1201. Certifications in ORCA are required prior to the submission of contract proposals.
- (b) Contractors shall update the representations and certifications submitted to ORCA as necessary, but at least annually, to ensure they are kept current, accurate, and complete. All Contractors with current contracts shall notify the Contracting Officer in writing when changes are made to ORCA. The representations and certifications are effective until one year from date of submission or update to ORCA.

(End of Clause)

## Section L - Instructions, Conditions, And Notices To Offerors

FAR SOURCE	TITLE AND DATE
52.204-6	Data Universal Numbering System (DUNS) Number (Oct 2003)
52.214-34	Submission of Offers in the English Language (Apr 1991)
52.214-35	Submission of Offers in U.S. Currency (Apr 1991)

### L.1 FAR 52.215-1 Instructions to Offerors - Competitive Acquisition (Jan 2004)

(a) *Definitions.* As used in this provision –

“Discussions” are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer’s discretion, result in the offeror being allowed to revise its proposal.”

“In writing,” “writing,” or “written” means any worded or numbered expression which can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

“Proposal modification” is a change made to a proposal before the solicitation’s closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

“Proposal revision” is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

“Time,” if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.*

(1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages

(i) addressed to the office specified in the solicitation, and

(ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show –

(i) The solicitation number;

(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

*(3) Submission, modification, revision, and withdrawal of proposals.*

(i) Offerors are responsible for submitting proposals, and any modification, or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii)(A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and –

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) *Restriction on disclosure and use of data.* Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall –

(1) Mark the title page with the following legend:

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed – in whole or in part – for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of – or in connection with – the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government’s right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [*insert numbers or other identification of sheets*]; and

(2) Mark each sheet of data it wishes to restrict with the following legend:

Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

(f) *Contract award.*

(1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government’s interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror’s initial proposal should contain the offeror’s best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government’s best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.

(ii) The overall evaluated cost or price and technical rating of the successful and the debriefed offeror and past performance information on the debriefed offeror.

(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection.

(iv) A summary of the rationale for award.

(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

## **L.2 Inquiries (May 1998)**

Inquiries concerning the solicitation document should be submitted by email to the issuing office. **Questions** on the scope or performance of work under this solicitation shall be sent to Marie Bartkevicius via email to [mbartkevicius@cdc.gov](mailto:mbartkevicius@cdc.gov) **NO LATER THAN 2:00 p.m. EST on 07/06/2012**. Any additions, deletions, or changes to the solicitation will be made by an amendment. **OFFERORS ARE INSTRUCTED SPECIFICALLY TO CONTACT ONLY THE SOLICITATION CONTRACTING OFFICE IN CONNECTION WITH ANY ASPECT OF THIS REQUIREMENT PRIOR TO CONTRACT AWARD. PROPOSALS AND ALL CORRESPONDENCE RELATING TO THE SOLICITATION DOCUMENT SHALL BE SUBMITTED TO THE CONTRACTING OFFICE.**

(End of Provision)

## **L.3 FAR 52.216-1 Type of Contract (Apr 1984)**

The Government contemplates award of a Firm Fixed Price contract.

(End of Clause)

#### **L.4 General Instructions (Negotiated) (Jan 2000)**

(a) Offerors are invited to submit a proposal in response to this solicitation. All proposals received will become part of the official file.

(b) The following instructions establish the acceptable minimum requirements for the format and content of proposals.

(c) Your proposal must be prepared in separate parts as instructed herein. Each part shall be separate and complete in itself so that evaluation of one may be accomplished independently of evaluation of the other(s). The technical proposal (if required) must not contain reference to cost or price; **however, resource information, such as data concerning labor hours and categories, material, subcontracts, etc., must be contained in the technical proposal so that your understanding of the Statement of Work/Performance Work Statement can be evaluated.** The technical proposal (if required) must disclose your technical approach in sufficient detail to provide a clear and concise presentation that addresses, but is not limited to, the requirements of the technical proposal instructions.

(d) The proposal must be signed by an official authorized to bind your organization. You must submit an electronic copy of your proposals to:

**Attn: Marie Bartkevicius**

**E-Mail: [mbartkevicius@cdc.gov](mailto:mbartkevicius@cdc.gov)**

**Solicitation No. 2012-N-14359**

(e) Offerors are requested to submit proposals, to the maximum extent possible, on high grade white paper which can be recycled.

(f) Facsimile proposals are not authorized unless this solicitation incorporates FAR 52.215-5, Facsimile Proposals, in Section L.

(g) The Government will evaluate proposals in accordance with the evaluation criteria set forth in Section M, Evaluation Factors for Award.

(End of Provision)

#### **L.5 Business Proposal Instructions**

The business proposal shall be comprised of the following elements:

(a) Contract Form and Representation and Certifications

The contract form found in Part I, Section A, the completed Section B, and the Representations and Certifications contained in Part IV, Section K, (accessed at [www.orca.gov](http://www.orca.gov)) of this Request for Proposals must be executed by an official authorized to bind the offeror.

(b) Contract Proposal Cover Sheet

The cover sheet of your Business Proposal must comply with FAR Table 15-2, which requires the following information (as applicable):

Solicitation, contract, or modification number;

Name and address of offeror;  
Name and telephone number of point of contact;  
Date of submission;  
Name, title, and signature of authorized representative.

(c) Cost Data/Price Information

You must submit, as a minimum, a business proposal supported by detailed pricing information. The itemized price and the rationale for significant categories should be furnished as follows:

- (1) Direct Labor: At a minimum, the staffing plan included in the technical proposal shall be included in the business proposal, along with the proposed hourly rate for each proposed labor category.
- (3) Materials and Services: Provide a consolidated priced summary of individual material quantities anticipated to be needed in performance of the contract and the basis for pricing (vendor quotes, invoice prices, etc.).
- (4) Subcontracted Items (if applicable): Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all cost reimbursement type subcontracts. Include these analyses as part of your own cost submissions for subcontracts (see FAR Subpart 44.2 for information required to support a request for subcontract consent);
- (5) Travel: Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for the proposed costs. A copy of your corporate travel policy shall be submitted with your proposal if travel costs have been proposed;
- (6) Other Direct Costs (ODC): Provide a breakdown of all other costs not otherwise included in the categories listed above (e.g. computer services, consultant services, photocopying costs) and provide the basis for these proposed costs;
- (7) Indirect Costs: Provide information regarding any indirect rates, such as G&A, that will be applied to items such as travel and ODCs. Provide a copy of your current approved indirect cost rate agreement, including location and application of indirect cost rates to this proposal (including major subcontracts);

(d) Accounting System

In the event you do not have a Government approved accounting system and/or have never had a Government cost reimbursement contract, the following is required (include major subcontracts) to be submitted with your proposal:

Description of your present accounting system and any changes contemplated as a result of your proposal;  
Make-up or basis for the indirect cost rate(s) you propose in response to this RFP;  
Current financial statement (balance sheet and/or profit and loss statement for the last two years).

(e) Subcontracting Plan *(if applicable)*

The offeror, prior to being awarded a contract, must submit an acceptable subcontracting plan (see FAR 52.219-9) or demonstrate that no subcontracting opportunities exist. (Note: This requirement does not apply to small business concerns or to offers which do not exceed \$500,000.00 (\$1,000,000.00 for construction) or to offers from non-domestic concerns.)

(f) Other Administrative Data

Your proposal must stipulate that it is predicated upon all the terms and conditions of this RFP/RFQ. In addition, it must contain a statement to the effect that it is firm for a period of at least 60 days from the date of receipt by the Government;

List name and telephone number of person to contact regarding your proposed accounting system;

Your proposal must list any current commitments with the Government relating to the work or services and indicate whether these commitments will or will not interfere with the completion of work and services as contemplated under this proposal;

Your proposal must identify any former HHS employee to be utilized on this project by providing the individual's name when employed by HHS, where employed, and the capacity in which employed;

Your proposal must indicate whether you have the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. (If not, indicate the amount required and the anticipated source.);

(End of Clause)

### **L.6 Incurring Costs (May 1998)**

This solicitation does not commit the Government to pay any cost for the preparation and submission of a proposal. In addition, the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition.

(End of Provision)

### **L.7 Incorporation of Technical Proposal (Dec 2005)**

(a) The technical proposal should be in as much detail as you consider necessary to reflect a clear understanding of the nature of the work being undertaken.

(b) The technical proposal must not contain reference to cost or price; however, resource information, such as data concerning labor hours and categories, material, subcontracts, etc., must be contained in the technical proposal so that your understanding of the statement of work can be evaluated.

(End of Provision)

### **L.8 Length of Technical Proposal**

The technical proposal should succinctly address the requirements alone and shall not exceed 20 pages in length. An appendix of resumes or CV to support the staffing plan does not count against the maximum length of 20 pages.

(End of Provision)

Please email the Technical and Business proposals to: [mbartkevicius@cdc.gov](mailto:mbartkevicius@cdc.gov)

**Questions may be submitted until 07/06/2012 by 2:00 p.m.**

**Proposals must be submitted on 07/26/2012 by 2:00 p.m.**



## Section M - Evaluation Factors for Award

### A. Technical Evaluation Criteria/Relative Weighting of a Cost/Price Proposal

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of these parts shall be separate and complete so that evaluation of one may be accomplished independently of evaluation of the other. The technical proposal must not contain any reference to cost; however, resource information such as data concerning labor hours and categories, materials, etc., must be contained in the technical proposal so that the understanding of the scope of work can be evaluated. It must disclose the technical approach in sufficient detail to provide a clear and concise presentation that includes, but is not limited to, the requirements of the technical proposal. The offeror shall submit a copy of the technical and business proposal separately to the Contracts Administrator Marie F. Bartkevicius. Proposals received shall be evaluated initially from a technical standpoint. Proposals, which are technically acceptable, shall then be evaluated with regard to financial and management aspects. This evaluation shall be based upon the completeness and thoroughness of the proposal submitted. The offeror should show that the objectives stated in the proposal are understood and offer a logical program for their achievement.

Offerors are advised that in proposal evaluation paramount consideration shall be given to technical proposals rather than to cost or price unless, as a result of technical evaluations, proposals are judged to be essentially equal, in which case cost or price shall become the determining factor.

Discussions, if held, will be conducted only with those offerors determined to be within the competitive range.

Award shall be made to that responsible offeror submitting the proposal (Technical and Business) determined to be the most advantageous and the best value to the Government as evaluated under the criteria described in this Section.

#### (1) Relative weighting of cost/price and technical proposal

This evaluation shall be based upon the completeness and thoroughness of the proposal submitted. The offeror should show that the objectives stated in the proposal are understood and offer a logical program for their achievement. The following criteria will be used to technically evaluate proposals and will be weighted as indicated in establishing a numerical rating for all technical proposals submitted.

##### **Technical Evaluation**

The technical evaluation factors and evaluation criteria are as follows:

<b>Factors</b>	<b>Weights</b>
Technical Approach	40%
Staffing Plan, Corporate Capability	25%
Similar Experience	35%
Total	100%

Negotiations will be conducted with those offerors determined to have submitted technically acceptable proposals together with a realistic cost estimate. Paramount consideration shall be given to the evaluation of technical proposals rather than cost or price unless, as a result of technical evaluation, proposals are determined to be essentially equal, in which case cost or price shall then become the determining factor. Furthermore, costs/prices will be evaluated on the basis of cost realism, which is defined as the offeror's ability to project costs, which are reasonable and indicate that the offeror understands the nature and extent of the work to be performed.

Awards shall be made to the responsible offeror submitting the proposal (Technical and Business) determined to be most advantageous to the Government as evaluated under the criteria described in this section.

## **(2) Technical proposal instructions**

### **2) Technical proposal instructions**

#### **a. Technical Approach**

The proposed approach to comply with each of the requirements specified in the Statement of Work, including phasing of tasks, methods to be utilized, person hours for key personnel, and scheduling of time and resources. The offeror should specify laboratory equipment, methods and materials for the analysis, and the amount of specimens (serum, plasma, water, whole blood, etc.) required to perform the test and for repeat tests if unusual values are observed. The definition of unusual or out-of-range values will be agreed upon by the Contractor and the Project Officers but should be discussed in the proposal. The Offeror must describe methodology by which all laboratory personnel are made cognizant of the proper laboratory methods and techniques to be used in the study. The Offeror should propose systems for receiving and storing samples, assay calibrations, performing assays, quality control including verification of calibration with available reference materials, and participation in available external proficiency testing programs, and recording and reporting results. The methods to assess day-to-day variability should also be stated. The offerors should participate in external proficiency testing if available. Minimum requirements for reporting results are stated in section C of the scope of work, but these requirements may be waived for offerors who propose alternative methods of accomplishing the project objectives.

#### **b. Staffing plan, corporate capability**

Include a description of the project organization including person-hours for each key individual including bench level staff and curriculum vitae detailing relevant training and experience. Demonstrate for each key person their experience, expertise, and qualifications to perform the duties described in the scope of work. The functions of each key person, therefore, must be described and related to each individual's qualifications. An overall management schedule of critical events also shall be presented indicating expenditure of person-hours.

#### **c. Similar Experience**

A description of the number of years the laboratory has been performing the test(s), equipment, location and space available for performance of the contract analyses. This description will include the capability of transmitting data in a computer readable format for electronic transmission.

## ATTACHMENTS

### QUALITY ASSURANCE SURVEILLANCE PLAN (QASP)

#### Introduction

**1.1** Since this is a Performance-Based Contract, the Government must effectively validate in a timely manner the performance of the Contractor in meeting the services required. This QASP provides a systematic surveillance method for the services, and describes the methodology by which the Contractor's performance will be monitored.

**1.2** The principal focus of the surveillance system is the Contractor's performance in providing the services identified in the Performance-based Matrix. The CPARS contractor performance assessment addresses the following areas: Quality of Product or Services, Schedule, Cost Control, Business Relations, Management of Key Personnel, Utilization of Small Business, and Other Areas. These Other Areas may address the indicators identified in the Performance-Based Matrix at C.15 of the Performance Based Work Statement (PBWS). Therefore, the QASP surveillance standards are identical to those in C.15). See Attachment 1 for a description of CPARS Ratings.

**1.3** The task order will be surveilled with this Quality Assurance Surveillance Plan (QASP).

**1.4** The plan will use the Contractors Performance Assessment Reporting System (CPARS) to electronically process interim and final contractor performance assessments at [www.cpars.gov](http://www.cpars.gov). At a minimum, interim contractor performance assessments will be conducted every 12 months until the end of the contract. Please see attachment Tab 2 for Contractor Performance Report. CPARS allows the Contracting Officer's Representative or Contracting Officer, to report Contractor and subcontractor performance on a national, easily accessible database. It requires the Contracting Officer to review the database prior to approving the use of a Contractor to insure that the Contractor or subcontractor has done a good job in the past. As a result, it is anticipated that CPARS should help motivate the Contractor, wishing future work in the Federal sector, on the current contract toward superior performance.

**1.5** For the purpose of this plan, The Centers for Disease Control and Prevention consider the FAR Clause FAR 52.246-4 Inspection of Services - Fixed Price (Aug 1996).

**1.6** This QASP:

- Identifies the service and products that will be measured.
- Establishes the specific standards of performance for each required output.
- Establishes the responsibilities for performing the measurement.
- Defines the Government role in overseeing the performance.
- Provides for feedback to the Contractor regarding quality, quantity, and timeliness of the service outputs.
- Establishes timeframes for communicating performance improvements

Methods of Surveillance:

**2.1** The Performance-Based Matrix at C.15 (or Tab 1 attachment) lists the services to be monitored and the standards to be applied.

**2.2** This QASP is based on the premise the government desires to maintain a quality standard for publication and dissemination technical support services.

**2.3** The Contractor, and not the government, is responsible for management and quality control actions to meet the terms of the contract. The role of the government is quality assurance to ensure contract standards are achieved.

**2.4** In this contract the Contractor quality control program is the basis for service quality. The Contractor is required to only deliver publication and dissemination technical support services that conform to the requirements of the contract.

### 3.0 Roles and Responsibilities:

**3.1** The Contractor's primary responsibility is to ensure all requirements are met at the required quality level. The Government shall ensure this responsibility has been met before payment is made to the Contractor. The primary Government team members are the Contracting Officers Representative (COR), Technical Monitor (TM), and the Contracting Officer (CO).

**3.2** The CO has the overall responsibility for overseeing the Contractor's performance. The CO is responsible for monitoring Contractor performance in the areas of contract compliance, contract management, and the resolution of all issues relative to the language of the contract.

**3.3** The COR is responsible for directly monitoring, assessing, recording, and reporting on the technical performance of the Contractor. The COR will have primary responsibility for signing off on all invoices and documenting the inspection and evaluation of the Contractor's performance.

**3.4** The COR will work with staff and the Contractor to ensure good communication and resolve any problems not requiring the CO's authority.

**4.0** Surveillance: The COR will evaluate the performance objectives through periodic inspections during each service month. See Attachment Tab 2 for a sample of a COR Monthly Evaluation Report.

The following information will be included:

**4.1.1** Contract paragraph number referencing the requirement.

**4.1.2** A short description of the requirement being surveilled.

**4.1.3** Date, time, and location of surveillance.

**4.1.4** Results of surveillance.

**4.1.5** Signature of individual accomplishing the surveillance.

**4.2** All performance must be documented, whether acceptable or unacceptable. When unacceptable performance is documented, the COR shall take the following actions:

**4.2.1** If government actions caused the unacceptable performance, take steps to prevent it in the future.

**4.2.2** If the Contractor's performance is unacceptable, inform the Contractor's on site representative of the unacceptable performance and the reasons why it is unacceptable.

**4.2.3** If the contractor wants to dispute the results of the surveillance, refer them to the CO for resolution.

**4.3** Performance should not be determined unacceptable until all possible contributing factors have been considered.

**4.4** For required tasks not shown on the Performance-Based Matrix, the government still retains the right to inspect any item included in the contract. These services will be inspected periodically and the results provided to the CO.

**5.0** Standards: All standards in the Performance-Based Matrix must be met. All deliverable dates and other contractual completion dates must also be met. If any of the standards are not met, the Government shall receive consideration from the Contractor for breach of contract.

**5.1** Late performance is un-excusable unless the Contractor can justify all of the following:

**5.1.1** The delay was not the Contractor's fault.

**5.1.2** The delay was not foreseeable.

**5.1.3** It was beyond the Contractor's control to avoid the delay.

**5.2** All work shall be performed in accordance with the PBWS. The COR shall not consider the services complete until all deficiencies have been corrected.

**5.3** The COR shall determine whether the failure was a minor non-conformance or a substantive non-conformance. (See Tab 3 for the decision matrix on non-conforming deliverables.)

**6.0** Procedures: The Government will inspect performance requirements to ensure contractor compliance and record results of inspection, noting the date and time of inspection. Unacceptable performance and complaints shall be

referred to the CO for investigation and validation. The CO will investigate and validate the unacceptable performance and/or customer input. The Contractor shall be given a reasonable amount of time after notification to correct the unacceptable performance and report to the CO that the deficiency has been corrected. If deficiencies are not corrected, the COR will notify the CO and recommend a course of action.

## **7.0 Contract Performance Evaluation**

**7.1** FAR subpart 42.15 – Contractor Performance Information establishes the Government responsibility for recording and maintaining contractor performance information. This requirement does not apply to procedures used in determining incentive awards or other incentive systems, although the two systems should be mutually supporting.

**7.2** FAR subpart 42.1501 – Past Performance Information is relevant information for future source selection purposes, regarding a contractor's actions under previously awarded contracts. It includes, for example, the contractor's record of conforming to contract requirements and to standards of good workmanship; the contractor's record of forecasting and controlling costs; the contractor's adherence to contract schedules, including the administrative aspects of performance; the contractor's history of reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the contractor's business-like concern for the interest of their customers.

**7.3** The general procedures to be used are addressed in the following FAR section. All contractor performance assessments will be initiated and processed through CPARS.

### **42.1503 Procedures:**

- (a) Agency procedures for the past performance evaluation system shall generally provide for input to the evaluations from the technical office, contracting office and, where appropriate, end users of the product or service.
- (b) Agency evaluations of contractor performance prepared under this subpart shall be provided to the contractor as soon as practicable after completion of the evaluation. Contractors shall be given a minimum of 30 days to submit comments, rebutting statements, or additional information. Agencies shall provide for review at a level above the CO to consider disagreements between the parties regarding the evaluation. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, contractor response, and review comments, if any, shall be retained as part of the evaluation. These evaluations may be used to support future award decisions, and should therefore be marked "Source Selection Information".

**7.4** The CPARS contractor performance assessment will be completed at least annually and more frequently if necessary to motivate or reward the contractor.

TAB 1

## Water and Plasma Fluoride Testing for NHANES 2012-2017

## PERFORMANCE-BASED MATRX TO QASP

Desired End Result	Feature(s) of end result to be surveilled (Indicator).	The required performance level for each feature (Standard).	Quality Assurance	Incentives/Payment-Quality Link
Contractor shall produce "Project Progress Reports"	Timeliness; completeness	Due quarterly; satisfactory completeness and accuracy. Monitored by Project Officer	.Surveillance system will be primarily by POs review.	<p><b>1. Positive incentives:</b> a. Payment of contract labor rate for satisfactory service b. Contractor performance evaluated using the automated Contractor Performance Assessment Reporting System (CPARS). The evaluation will be considered when future AGENCY contract selections are made.</p> <p><b>2. Payment is linked to quality through FAR 52.246-4 Inspection of Services - Fixed Price (Aug 1996)a) Definition.</b> "Services," as used in this clause, includes services performed, workmanship, and material furnished or utilized in the performance of services. (b) The Contractor shall provide and maintain an inspection system acceptable to the Government covering the services under this contract. Complete records of all inspection work performed by the Contractor shall be maintained and made available to the Government during contract performance and for as long afterwards as the contract requires. (c) The Government has the right to inspect and test all services called for by the contract, to the extent practicable at all times and places during the term of the contract. The Government shall perform inspections and tests in a manner that will not unduly delay the work. (d) If the Government performs inspections or tests on the premises of the Contractor or a subcontractor, the Contractor shall furnish, and shall require subcontractors to furnish, at no increase in contract price, all</p>
The Contractor shall provide QC and Results to Westat electronically within 3 weeks of each run.	Accuracy & timeliness	Due 3 weeks after receipt of samples; satisfactory completeness and accuracy. Monitored by Project Officer .	Surveillance system will be primarily by POs and review of lab and QA/QC of data.	
Re-run/resubmit any specimens that don't pass QA/QC review	Accuracy & timeliness	Due 3 weeks after receipt of samples; satisfactory completeness and accuracy. Monitored by Project Officer	If fault of Contractor, they will retest at their expense.	
Contractor shall notify the PO of any unforeseen or foreseen problems with the testing or delivery of data.	Accuracy & timeliness	Due within 3 days after identification of technical problems. Monitored by Project Officer	The contractor will keep the PO apprised of the status and rectification of the problems	
Contractor must maintain QC statistics	Accuracy & timeliness	Maintain throughout the contract performance period. Monitored by Project Officer	Surveillance system will be primarily site inspections by POs and review of lab and QA/QC of data	
The vendor will follow Westgaard QC rules	Accuracy & timeliness	Maintain throughout the contract performance period. Monitored by Project	Surveillance system will be primarily site inspections by	

		<p>Officer</p>	<p>POs and review of lab and QA/QC of data</p>	<p>reasonable facilities and assistance for the safe and convenient performance of these duties. (e) If any of the services do not conform with contract requirements, the Government may require the Contractor to perform the services again in conformity with contract requirements, at no increase in contract amount. When the defects in services cannot be corrected by reperformance, the Government may—</p> <p>(1) Require the Contractor to take necessary action to ensure that future performance conforms to contract requirements; and</p> <p>(2) Reduce the contract price to reflect the reduced value of the services performed.</p> <p>(f) If the Contractor fails to promptly perform the services again or to take the necessary action to ensure future performance in conformity with contract requirements, the Government may—</p> <p>(1) By contract or otherwise, perform the services and charge to the Contractor any cost incurred by the Government that is directly related to the performance of such service; or</p> <p>(2) Terminate the contract for default.</p>
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**TAB 2**

<b>CONTRACTOR PERFORMANCE REPORT</b> (OMB No: 9000-0142)	
<input type="checkbox"/> Final <input type="checkbox"/> Interim - Period Report:                      From:                      To	
Contractor Name and Address:	2. Contract Number:  3. Contract Value (Base Plus Option): _____ 4. Contract Award Date: _____ Contract Completion Date: _____
5. Type of Contract: (Check all that apply) <input type="checkbox"/> FP <input type="checkbox"/> FP-EPA <input type="checkbox"/> ID/IQ <input type="checkbox"/> BOA <input type="checkbox"/> Requirements <input type="checkbox"/> Labor Hour <input type="checkbox"/> T&M <input type="checkbox"/> SBSA 8(a) <input type="checkbox"/> SBIR <input type="checkbox"/> Sealed Bid <input type="checkbox"/> Negotiated <input type="checkbox"/> Competitive <input type="checkbox"/> Non-Competitive <input type="checkbox"/> Other (Specify)	
6. Description of Requirement:	
7. Ratings. Summarize contractor performance and circle in the column on the right the number which corresponds to the performance rating for each rating category. Please see page four for explanation of rating scale.	
<b>QUALITY OF PRODUCT OR SERVICE</b> Comments:	0 1 2 3 4 5+___
<b>VALUE</b> Comments:	0 1 2 3 4 5+___
<b>TIMELINESS OF PERFORMANCE</b> Comments:	0 1 2 3 4 5+___
0	



<b>BUSINESS RELATIONS</b> Comments:	1 2 3 4 5+___
<b>TOTAL</b>	
<b>MEAN SCORE</b> (Divide the total rating above by the number of areas rated): _____	
<b>8. KEY PERSONNEL</b>  Project Manager: Name: _____ Comments/Rating: _____  <div style="text-align: right; margin-right: 50px;">Name: _____</div> Comments/Rating: _____  <div style="text-align: right; margin-right: 50px;">Name: _____</div> Comments/Rating: _____  <div style="text-align: right; margin-right: 50px;">Name: _____</div> Comments/Rating: _____	Employment Dates _____  Employment Dates _____  Employment Dates _____  Employment Dates _____
9. Would you select this firm again? Please explain.	
10. Contracting Officer's Representative Name: _____ Date: _____ Signature: _____	
11. <b>CONTRACTORS REVIEW:</b> Were comments, rebuttals, or additional information provided? [ ] No [ ] Yes. Please attach comments.	
12. Contractor Name: _____ Phone: _____ Fax: _____ Internet address: _____	Signature: _____  Date: _____
13. <b>AGENCY REVIEW:</b> Were contractor comments reviewed at a level above the contracting officer? [ ] No [ ] Yes. Comments attached.	

14. **FINAL RATINGS:** Re-assess the Block 7 ratings based on contractor comments and agency review. Validate or revise as appropriate.

Quality \_\_\_\_\_ Value \_\_\_\_\_ Timeliness \_\_\_\_\_ Business Relations \_\_\_\_\_

Mean Score (Add the ratings above and divide by number of areas rated): \_\_\_\_\_

15. Contracting Officer's Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Phone: \_\_\_\_\_

Date: \_\_\_\_\_

FAX#: \_\_\_\_\_

Internet Address: \_\_\_\_\_

### Rating Guidelines

#### Quality of Product or Service

**0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding**

Unsatisfactory	Non-conformances are jeopardizing the achievement of contract requirements, despite use of Agency resources. Recovery is not likely. If performance cannot be substantially corrected, it constitutes a significant impediment in consideration for future awards containing similar requirements.
Poor	Overall compliance requires significant Agency resources to ensure achievement of contract requirements.
Fair	Overall compliance requires minor Agency resources to ensure achievement of contract requirements.
Good	There are no, or very minimal, quality problems, and the Contractor has met the contract requirements.
Excellent	There are no quality issues, and the Contractor has substantially exceeded the contract performance requirements without commensurate additional costs to the Government.
Outstanding	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where contractor performance clearly exceeds the performance levels described as "Excellent".

TAB 3

<b>NONCONFORMING DELIVERABLES – FIXED PRICE</b>		
<b>MINOR NONCONFORMANCE</b>		
<i>If</i>	<i>Then</i>	<i>Consideration</i>
Consideration would be less than the cost of modifying the contract	Accept as is (once)	None
Consideration would be greater than the cost of modifying the contract	Accept as is (once)	Consideration comparable to the value of the loss sustained by the Government
<b>MAJOR NONCONFORMANCE</b>		
<i>If</i>	<i>Then</i>	<i>Consideration</i>
The contractor agrees to correct the deliverable (or reperform the service) within the delivery schedule	Withhold acceptance until receipt of the corrected deliverable	Cost to reinspect or retest
The contractor agrees to correct the deliverable (or reperform the service) but needs an extension of the delivery date	Withhold acceptance until receipt of the corrected deliverable	Cost to reinspect or retest Appropriate consideration for the delay Deduct QC hours
Repair can be accomplished through warranty provisions	Accept as is	None
Acceptance:  •Would not affect safety or performance, and  •Is justified on the basis of economy or urgency	Accept as is	Consideration comparable to the value of the loss sustained by the Government
The contractor refuses to make repair or provide appropriate consideration.	Either: Correct the product or service through other means (contract or in-house), or Terminate for default and reproduce.	Contractor to pay all costs for the correction or reprocurement.