

SOLICITATION, OFFER AND AWARD

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 7900)

RATING

PAGE 1 OF PAGES 35

2. CONTRACT NUMBER	3. SOLICITATION NUMBER FDA-12-Devices	4. TYPE OF SOLICITATION <input type="checkbox"/> SEALED BID (IFB) <input checked="" type="checkbox"/> NEGOTIATED (RFP)	5. DATE ISSUED	6. REQUISITION/PURCHASE NUMBER
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7. ISSUED BY DHHS/FDA/OAGS/DASG/State Contracts and Compliance 5630 Fishers Lane, Room 2129, HFA-500	CODE	8. ADDRESS OFFER TO (If other than item 7)
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NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder".

SOLICITATION

9. Sealed offers in original and 1 copies for furnishings the supplies or services in the Schedule will be received at the place specified in item 8, or if hand carried, in the depository located in 5630 Fishers Lane, Rm 2129, Rockville, MD 20857 until _____ local time _____ (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.

10. FOR INFORMATION CALL:	A. NAME Yared Girmai	B. TELEPHONE (NO COLLECT CALLS) AREA CODE 301 NUMBER 8277117 EXT.	C. E-MAIL ADDRESS yared.girmai@fda.hhs.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 set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT (See Section I, Clause No. 52.232-8)	10 CALENDAR DAYS (%)	20 CALENDAR DAYS (%)	30 CALENDAR DAYS (%)	CALENDAR DAYS(%)
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14. ACKNOWLEDGMENT OF AMENDMENTS (The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated):	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR	CODE	FACILITY	16. NAME AND THE TITLE OF PERSON AUTHORIZED TO SIGN OFFER (Type or print) Kathryn C. Perkins, RN, MBA Assistant Commissioner, Division for Regulatory Services Texas Department of State Health Services
Texas Department of State Health Services 1100 W 49th St. Austin, TX 78756			

15B. TELEPHONE NUMBER AREA CODE NUMBER EXT.	<input type="checkbox"/> 15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE <i>Kathryn C. Perkins</i>	18. OFFER DATE 8/15/12
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AWARD (To be completed by Government)

19. ACCEPTED AS TO ITEMS	20. AMOUNT 81,685.16	21. ACCOUNTING AND APPROPRIATION
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22. AUTHORITY FOR USING OTHER THAN FULL 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 (4 copies unless otherwise specified)	ITEM RFP Section G-3
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24. ADMINISTERED BY (If other than Item 7)	25. PAYMENT WILL BE MADE BY CODE Office of Financial Services/Food and Drug Administration 10903 New Hampshire Ave/ WO32 - Second Floor/MAIL HUB 2145 Silver Spring, MD 20993
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26. NAME OF CONTRACTING OFFICER (Type or print) Yared Girmai (Signature of Contracting Officer)	27. UNITED STATES OF AMERICA	28. AWARD DATE 9-4-2012
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IMPORTANT - Award will be made on this Form, or on Standard Form 26, or by other authorized official written notice.

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is unusable**STANDARD FORM 33** (REV. 9-97)
Prescribed by GSA - Far (48 CFR) 53.214 (c)

SOLICITATION, OFFER AND AWARD		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES 1 26	
2. CONTRACT NUMBER HHSF223201210171C		3. SOLICITATION NUMBER FDA-12-DEVICES		4. TYPE OF SOLICITATION <input type="checkbox"/> SEALED BID (IFB) <input type="checkbox"/> NEGOTIATED (RFP)	5. DATE ISSUED
7. ISSUED BY DHHS/FDA/OAGS/DASG ATTN: YARED GIRMAI 5630 FISHERS LANE ROOM 2129, HFA-500 ROCKVILLE MD 20857		CODE DCSC	8. ADDRESS OFFER TO (If other than Item 7)		
6. REQUISITION/PURCHASE NUMBER 1108667					

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 hand carried, in the depository located in _____ until _____ local time _____ (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.

10. FOR INFORMATION CALL:	A. NAME YARED T GIRMAI	B. TELEPHONE (NO COLLECT CALLS)		C. E-MAIL ADDRESS yared.girmai@fda.hhs.gov
		AREA CODE 301	NUMBER 827-7117	EXT.

11. TABLE OF CONTENTS

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<input checked="" type="checkbox"/>	B	SUPPLIES OR SERVICES AND PRICES/COSTS	3-5	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
<input checked="" type="checkbox"/>	C	DESCRIPTION/SPECS./WORK STATEMENT	5-8	<input checked="" type="checkbox"/>	J	LIST OF ATTACHMENTS	26
<input checked="" type="checkbox"/>	D	PACKAGING AND MARKING	9	PART IV - REPRESENTATIONS AND INSTRUCTIONS			
<input checked="" type="checkbox"/>	E	INSPECTION AND ACCEPTANCE	9	<input type="checkbox"/>	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
<input checked="" type="checkbox"/>	F	DELIVERIES OR PERFORMANCE	9-12	<input type="checkbox"/>	L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
<input checked="" type="checkbox"/>	G	CONTRACT ADMINISTRATION DATA	12-16	<input type="checkbox"/>	M	EVALUATION FACTORS FOR AWARD	
<input checked="" type="checkbox"/>	H	SPECIAL CONTRACT REQUIREMENTS	16-21				

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 (See Section I, Clause No. 52.232.8)	<input type="checkbox"/> 10 CALENDAR DAYS (%)	<input type="checkbox"/> 20 CALENDAR DAYS (%)	<input type="checkbox"/> 30 CALENDAR DAYS (%)	<input type="checkbox"/> CALENDAR DAYS (%)
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14. ACKNOWLEDGEMENT OF AMENDMENTS (The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated):	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR	CODE 382153	FACILITY	16. NAME AND TITLE OF PERSON AUTHORIZED TO SIGN OFFER (Type or print)
TEXAS DEPARTMENT OF STATE HEALTH SERVICES 382153 STATE HEALTH SERVICES, TEXAS DEPART 100 WEST 49TH STREET AUSTIN TX 78756-3101			

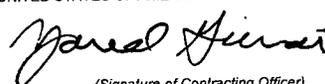
15B. TELEPHONE NUMBER		15C. CHECK IF REMITTANCE ADDRESS <input type="checkbox"/> IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE	18. OFFER DATE
AREA CODE	NUMBER			

AWARD (To be completed by government)

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT \$81,685.24	21. ACCOUNTING AND APPROPRIATION 2012.6990914.256E.28390NMEDI12TX0
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22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304 (c) () <input checked="" type="checkbox"/> 41 U.S.C. 253 (c) (5)	23. SUBMIT INVOICES TO ADDRESS SHOWN IN (4 copies unless otherwise specified)	ITEM G-3
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24. ADMINISTERED BY (If other than Item 7) See Schedule G	CODE DCSC	25. PAYMENT WILL BE MADE BY See Schedule G	CODE FDA PAYMENT SVCS
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26. NAME OF CONTRACTING OFFICER (Type or print) YARED T. GIRMAI	27. UNITED STATES OF AMERICA  (Signature of Contracting Officer)	28. AWARD DATE 9-4-2012
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CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
HHSF223201210171C

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NAME OF OFFEROR OR CONTRACTOR
TEXAS DEPARTMENT OF STATE HEALTH SERVICES 382153

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 32-0113643 DUNS Number: 807391511 Delivery: 09/29/2013 Admin Office: DHHS/FDA/OAGS/DASG ATTN: YARED GIRMAI 5630 FISHERS LANE ROOM 2129, HFA-500 ROCKVILLE MD 20857 Delivery Location Code: PKLN 12420 Parklawn Drive ROCKVILLE MD 20857 US Payment: FDA PAYMENT SVCS Attn: Vendor Payments, OFS FDA 10903 New Hampshire Avenue Bldg 32, Rm 2162, Mail Hub 2145 Silver Spring MD 20993-0002 Appr. Yr.: 2012 CAN: 6990914 Object Class: 256E CenterTag: 28390NMEDI12TX0 FOB: Destination Period of Performance: 09/30/2012 to 09/29/2013				
1	QSIT Level 1 Inspections Obligated Amount: \$19,622.80	8	EA	2,452.85	19,622.80
2	QSIT Level 2 Inspections Obligated Amount: \$43,556.88	12	EA	3,629.74	43,556.88
3	Joint Inspections Obligated Amount: \$6,409.56	6	EA	1,068.26	6,409.56
4	Training Obligated Amount: \$12,096.00	12096	EA	1.00	12,096.00
The total amount of award: \$81,685.24. The obligation for this award is shown in box 20.					

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

B-1 – Background and Objectives

In performing the work as described in detail in Section C, C-1, entitled "Scope of Work", the contractor shall consider the following:

a. Background Information

Section 510 (h) of the Federal, Food, Drug and Cosmetic Act states, "Every establishment in any state registered with the Secretary pursuant to this section shall be subject to inspection pursuant to Section 704 and every such establishment engaged in the manufacture, propagation, compounding or processing of a drug or drugs or of a device or devices classified in Class II or III shall be so inspected by one or more officers or employees duly designated by the secretary at least once in the two-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive two-year period thereafter."

In 1978, when Section 510 (h) was amended to include medical devices, the Food and Drug Administration (FDA) established its current policy that the biennial inspection requirements of Section 510(h) will be satisfied only by the conduct of Good Manufacturing Practice (GMP) inspections. This policy was established because it was believed that the intent of Congress was that all 510(h) inspections were to entail an in-depth coverage of the inspection processes.

In October 1996, the final rule for the new Quality System (QS)/GMP Regulation was promulgated. This final rule revised the requirements in Part 820 of Title 21 of the Code of Federal Regulations. The requirements of this new regulation now include a detailed design control sub-system that has added to the complexity of the inspection process and the need for a reengineered inspection approach. This new approach known as the Quality System Inspection Technique (QSIT) was implemented at the beginning of Fiscal Year 2000. Under the QSIT approach to inspections, two different levels of inspection, Level 1 and Level 2, can be performed.

b. Objectives

Because of the large number of Class I and II firms in FDA's Official Establishment Inventory (OEI), the purpose of this contract will be to obtain state assistance in the inspection of Class I and Class II medical devices manufacturers to determine compliance with the QSIT/GMP regulations.

B-2 – Compensation

- a. As consideration for full performance of the work stated in Part I, Section C, C-1 – Scope of Work, the Government shall pay the contractor the firm fixed price of \$19,622.80 for QSIT Level 1 medical device inspections, \$43,556.88 for QSIT

Level 2 medical device inspections, \$6,409.56 for 6 joint inspections, and not to exceed \$12,096.00 for cost reimbursement travel for training, for a total contract amount of \$81,685.24.

The period of performance will be from September 30, 2012 through September 29, 2013. (12 months)

- b. Payment up to the full amount of this contract shall be contingent upon receipt and acceptance by the Government of inspection reports and proper invoices as required by Part I, Section F, F-1 – Reports / Deliverables and Section G, G-3, Invoice Submission and in accordance with the following schedule:

Base Period	Period of Performance : From 9/30/2012 To 9/29/2013		
Inspection Type	Inspection #	Unit Price	Total
QSIT Level 1	8	\$2,452.85	\$19,622.80
QSIT Level 2	12	\$3,629.74	\$43,556.88
Joint	6	\$1,068.26	\$6,409.56
		Training	\$12,096.00
		Period Total	\$81,685.24

Option 1	Period of Performance : From 9/30/2013 To 9/29/2014		
Inspection Type	Inspection #	Unit Price	Total
QSIT Level 1	8	\$2,452.85	\$19,622.80
QSIT Level 2	12	\$3,629.74	\$43,556.88
Joint	6	\$1,068.26	\$6,409.56
		Training	\$12,096.00
		Period Total	\$81,685.24

Option 2	Period of Performance : From 9/30/2014 To 9/29/2015		
Inspection Type	Inspection #	Unit Price	Total
QSIT Level 1	8	\$2,452.85	\$19,622.80
QSIT Level 2	12	\$3,629.74	\$43,556.88
Joint	6	\$1,068.26	\$6,409.56
		Training	\$12,096.00
		Period Total	\$81,685.24

Option 3	Period of Performance : From 9/30/2015 To 9/29/2016		
Inspection Type	Inspection #	Unit Price	Total
QSIT Level 1	8	\$2,452.85	\$19,622.80
QSIT Level 2	12	\$3,629.74	\$43,556.88
Joint	6	\$1,068.26	\$6,409.56
		Training	\$12,096.00
		Period Total	\$81,685.24

Option 4	Period of Performance : From 9/30/2016 To 9/29/2017		
Inspection Type	Inspection #	Unit Price	Total
QSIT Level 1	8	\$2,452.85	\$19,622.80
QSIT Level 2	12	\$3,629.74	\$43,556.88
Joint	6	\$1,068.26	\$6,409.56
		Training	\$12,096.00
		Period Total	\$81,685.24

Contract Total (base plus options):

\$408,426.20

- c. **Training:** Total expenditures for domestic travel (transportation, lodging, meals, and incidental expenses) and other allowable costs associated with Government approved training not to exceed \$12,096.00 incurred in direct performance of this contract shall be allowed based on the contractor's travel policy. The estimated cost for travel associated with training under this contract shall be subject to the FAR provisions of the Limitation of Cost (APR 1984) and Allowable Cost and Payment (FEB 2002).

SECTION C – DESCRIPTION / SPECIFICATIONS / WORK STATEMENT

C-1 - Scope of Work

Independently and not as an agent of the Government, the contractor shall furnish the necessary personnel, materials, services, facilities, except as provided in the schedule, and otherwise do all things necessary for or incident to the performance of the work described below:

Identification of Inspection Obligations

1. Upon award of this contract, the appropriate FDA District Office's Co-Contracting Officer Representative (COR) shall supply to the contractor a list of Class I and /or Class II medical device manufacturers. This list will identify the level of inspection to be performed at each manufacturer's location. These manufacturers, other than manufacturers of critical devices and significant risk devices identified in the QS/GMP Compliance Program, are those that FDA believes are active and suitable for inspection under this contract. Questions regarding the guidance contained in the Compliance Program may be discussed with the FDA Contracting Officer Representative (COR) and Field Co-COR.
2. Prior to conducting QSIT inspections, the contractor shall follow the pre-announced inspection procedures set forth in the FDA Investigations Operations Manual (IOM), "510 Pre-Inspectional Activities", website address: http://www.fda.gov/ora/inspect_ref/iom/) and annotation of observations on the List of Inspectional Observations, Form FDA-483 in accordance with IOM

512.3, Annotation of the FDA 483 at website address:

<http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm115029>

3. If the pre-announcement procedure indicates that the firm may no longer be active, the contractor shall notify the Field Co-COR in writing or e-mail as soon as possible and await further guidance.
4. From among the list of verified and active Class I and Class II finished medical device manufacturers; the FDA shall direct the contractor to perform QSIT Level I or QSIT Level 2 inspections.

Inspection Coverage

1. The contractor shall conduct Level 1 QSIT inspections and Level 2 QSIT inspections of verified, active, Class I / Class II finished device manufacturers selected from the list provided to the contractor by the FDA Field Co-COR.
2. During the inspection, the Contractor shall determine manufacturer compliance with the Medical Device Reporting (MDR) Regulation, 21 CFR, Part 803. Instructions for the inspection procedures are contained in the program entitled: "Inspection of Medical Device Manufacturers" which is located at website:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm244266.htm>
3. The contractor shall conduct inspections of these establishments using state officials who have been commissioned as officers of the U.S. Department of Health and Human Services, Food and Drug Administration, under the authority of the Federal Food, Drug, and Cosmetic Act. Under commission, conformance with the procedural requirements of the act is required, including use of credentials, issuance of Notice of Inspection (FDA-482), Inspection Observations (FDA-483), and Receipt for Sample (FDA-484) forms. These forms will be provided by the Co-COR. Each FDA-483 form will include the following statements: "The observations noted in this form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements." This statement is contained in FDA Compliance CP 7382.845 located at website: (http://www.fda.gov/ora/inspect_ref/igs/qsit/QSITGUIDE.PDF)
4. Note: *FDA maintains the right to decommission contractor personnel in performance of this contract at any time.*
5. The Contractor shall verify registration and product listing information submitted by the manufacturer and submit any corrected information to the FDA Field Co-COR with the inspection report. Verification and product listing will be verified in accordance with FDA Compliance Program (CP7382.845) entitled: "Inspection of Medical Device Manufacturers", located at website:

http://www.fda.gov/ora/inspect_ref/igs/qsit/QSITGUIDE.PDF as either a Level 1 or Level 2 inspection.

6. The Contractor shall determine manufacturer compliance with the Corrections and Removals (CAR) Regulation in accordance with 21 CFR, Part 806 and FDA Compliance Program (CP7382.845) entitled: "Inspection of Medical Device Manufacturers." located at website:
http://www.fda.gov/ora/inspect_ref/igs/qsit/QSITGUIDE.PDF Instructions for quality audit procedures are contained in the program entitled: "Inspection of Medical Device Manufacturers" located under "Quality Audits" at website:
<http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm114945.htm#9.%20Quality>".
7. The contractor shall complete an Establishment Inspection Report (EIR) for each establishment inspected in accordance with IOM 510 – Narrative Report, located at website:
<http://www.fda.gov/ICECI/Inspections/ForeignInspections/ucm113573.htm> along with related FDA-supplied forms.
8. Compliance actions are not provided for under this contract. However, any contractor may wish to pursue any necessary compliance follow-up to volatile conditions under the State's jurisdiction. Any State actions taken as a result of a contract inspection shall be coordinated with the FDA COR and Field Co-COR.

Performance Standard: All inspection requirements shall be completed no later than 30 days prior to the end of the contractual period of performance. Accurately completed Establishment Inspection Reports shall be forwarded to the appropriate FDA Field Co-COR no later than 10 working days after completion of the inspection. Reports will be considered to be accurate and complete if FDA staff can enter all data from the reports into its QSIT database. All contractor inspectors shall be audited at least once every three (3) years.

Within 12 months of contract award, the contractor shall complete all inspections referenced in Section B, B-2, paragraph b.

Performance Measurement: Contractor performance will be evaluated by the FDA throughout the contract period of performance. FDA will review reports, conduct joint State/Federal inspections (included as contract inspections) or independent re-inspections. Independent re-inspections (audits) are made by FDA to evaluate the overall performance of the contractor. Findings of the independent FDA re-inspections will be provided to the Contractor for review and information. Inspection reports will be reviewed by FDA to verify that the required data and information are accurate and complete. Inaccurate or incomplete forms will be considered unacceptable and returned to the Contractor for correction and re-submission. All contractor inspectors must successfully pass joint audit requirements with an overall "acceptable" rating.

Deduction: If FDA finds an inspection report or form to be unacceptable, the Contractor shall correct or submit a new inspection report. Each instance whereby the Contractor fails to submit or correct the required report shall result in withholding of invoice payment until the Contractor submits or corrects the required report. All contractor inspectors who receive an overall score of "needs improvement" shall receive remedial training in deficient areas or as agreed upon by the FDA COR and Co-COR prior to resuming inspection duties.

Training

1. The FDA will provide training for medical device inspections to state investigators having 30 credit hours of college-level courses in the natural sciences (e.g., biology, chemistry, physics, etc) or engineering and having conducted inspections and issued notices of findings in the medical device area. State inspectors shall participate in one (1) Level 1 and one (1) Level 2 QSIT joint inspections of manufacturers of Class I/II devices with FDA investigators within that State, prior to conducting any independent inspections called for by this contract. The Contractor shall bear the cost of training additional personnel beyond the needs of this contract. If significant changes are made in the FDA medical device regulations, FDA will provide any necessary training on the changes for State contract personnel.
2. The initial, formal training course for new inspectors will be extensive and thorough. FDA shall present guidelines consisting of detailed information on requirements of the GMP, MDR, CAR and other FDA regulations pertinent to this contract; associated procedures and reporting requirements; information regarding liaison activities with appropriate FDA Field Co-CORs and familiarization with applicable FDA forms, manuals. QSIT training will be computer based. Successful completion of the computer based QSIT training course and Update Video on Quality Auditing is a prerequisite to conduct inspections under this contract. A follow-up training course will be scheduled as needed. (Note: The FDA will reimburse contractors only for personnel who successfully complete training courses.)

Samples

1. Routine physical samples will not be collected during inspections, except as noted in the relevant Compliance Program. In the event samples are indicated, the contractor shall contact the FDA-Field COR for guidance. FDA will bear the cost of sample shipment to an FDA laboratory.

SECTION D - PACKAGING AND MARKING

This section is not applicable to this contract.

SECTION E - INSPECTION AND ACCEPTANCE

E-1 – FAR 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):

<https://www.acquisition.gov/far/>

E-2 – Inspection and Acceptance

Pursuant to the appropriate inspection clause as provided below, final inspection and acceptance of all items called for by this contract shall be made by the FDA Contracting Officer at the Food and Drug Administration, State Contracts and Compliance, HFA-500, 5630 Fishers Lane, Room 2117, Rockville, Maryland 20857.

FAR 52.246-4, Inspection of Services – Fixed Price. (AUG 1996)

SECTION F – DELIVERIES OR PERFORMANCE

F-1 – Reports/Deliverables

The contractor shall submit the following reports/deliverables:

a. Quarterly Reports

Quarterly Reports shall be submitted to the FDA Contract Office, FDA COR and FDA Field Co-COR via e-mail, fax, or mail. QSIT Quarterly Reports and any submitted supporting documentation shall be submitted no later than 90, 180 and 360 days after award of the contract.

The QSIT Quarterly Reports shall include the following information:

1. Facilities Inspected – A list of the facilities inspected during the reporting period, including:
 - Facility Name
 - Facility Identification Number
 - Date of Inspection
 - Level of QSIT inspection performed (Level 1 or Level 2)
 - Inspector Name
 - Date Inspection Submitted to FDA
 - Summary of Findings
2. Cumulative Inspection Performed – a cumulative total of the number of

inspection performed since the beginning of the contract period of performance.

3. Facility Status Changes- A list of the facilities with status or address changes discovered by the Contractor, including:
 - Facility name
 - Address
 - Facility Identification
 - Date inspected
 - Inspector
 - Change
4. State Adverse Actions – The contractor shall report any actions taken at the state level against facilities for medical device violations. If there was no adverse action taken, the contractor shall check “none”.

The following information for each medical device facility shall be transmitted in the QSIT Quarterly Report:

- Name and address of the medical device facility,
 - Facility Identification Number
 - Summary of the problems that initiated the State action, including the date of inspection(s), violations cited, and other pertinent information.
 - Description of the State action (including copies of orders or letters) to the facility that were used to inform them of the action.
5. Inspections / Work To Be Performed – A brief description of the inspections and work to be scheduled and performed during the next 90 days.
 6. Changes to Point of Contact / Inspector Information – A brief description of changes in Point of Contact / Inspector status, business phone numbers, business mailing addresses, e-mail addresses, and/or names.
 7. Current Problems – Provide a brief synopsis of problems being encountered (or were encountered) proposed corrective action, as well as point of contact and e-mail address or telephone number.

QSIT Quarterly Reports shall be prepared and submitted via e-mail, Facsimile, or mailed to the FDA COR, FDA Co-COR and FDA Contract Specialist every 90 days while the contract is effect.

- b. Establishment Inspection Reports shall be forwarded to the appropriate FDA Co-COR no later than 10 working days after completion of the inspection.
- c. Property Inventory shall be submitted annually if applicable.

d. Confidentiality/Security Requirements

Pursuant to the clauses set forth in Section H, the Contractor shall submit to the Contracting Officer any changes or updates to its security plan accepted by FDA. The Contractor shall also submit the State's approved confidentiality form (Attachment 1) Form FDA 3398, for any new inspectors under the contract during the period of performance.

Quarterly progress reports shall be prepared and submitted via email, fax, or mail within fifteen (15) working days after each quarter. Quarterly progress reports shall be submitted to the Co-COR/RRHR, designated on the contract award letter, with a copy to each of the following two (2) points of contact:

1. COR

Food and Drug Administration
ORA/Division of Federal-State Relations
Attn: Mei-Ying Li
12420 Parklawn Drive
ELEM-3019
Rockville, MD 20857

Fax: 301-827-9221
E-mail: MeiYing.Li@fda.hhs.gov
POC: 301-796-5903

2. FDA Contracts Office

Food and Drug Administration
State Contracts and Compliance, HFA-500
Attn: Contract Specialist
5630 Fishers Lane, Room 2136
Rockville, Maryland 20857

Fax: 301-827-7106
E-mail: yared.girmai@fda.hhs.gov
POC: Yared Girmai

***IMPORTANT NOTE: Vouchers/Invoices shall not be approved without QSIT Quarterly Reports. Therefore, timely submission is critical to expedite voucher/invoice processing.**

F-2 – Period of Performance

The period of performance is 12 months for the base year with four 12 month option years. The total period of performance inclusive of options is 60 months.

SECTION G - CONTRACT ADMINISTRATION DATA**G-1 - Administrative/Technical Personnel**

- a. The Government administrative and technical personnel assigned responsibilities for this contract are as follows:

COR: Mei-Ying Li
301-796-5903
MeiYing.Li@fda.hhs.gov

Co-COR: Graham N. Giesen
214-253-5265
graham.giesen@fda.hhs.gov

- b. The COR and Co-COR are authorized to correspond and hold conferences with the Contractor on matters of a technical nature, conduct inspections, perform evaluations permitted by the contract, approve technical data required by the contract, and maintain the official technical file.

The CORs are responsible for monitoring the contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in the requirement. Action taken by the COR and Co-COR to resolve technical problems encountered during performance of the contract shall be documented and a copy of the documentation shall be furnished to the Contracting Officer. This documentation also includes site visit reports and minutes of all meetings held in connection with this contract. The Contracting Officer shall also be notified in advance of all meetings or any site visit to the Contractor's facility.

The COR or Co-COR are not empowered to issue or approve changes, enter into any agreement or contract modifications or any other matter which may affect the cost, period of performance, terms or conditions of the contract.

G-2 - Project Director

The performance of the work required by this contract will be conducted for the State under the direction of:

Name: Tom Brinck

Title: Manager, Drugs and Medical Devices Group

Email Address: tom.brinck@dshs.state.tx.us

Telephone: (512) 834-6755 x2388

G-3 - Invoice Submission

Fixed Price - Quarterly

FDA TWO-WAY-MATCHING INVOICE CLAUSE

A. THE CONTRACTOR SHALL SUBMIT ALL INVOICES TO ALL ADDRESSEES IN THE MANNER SPECIFIED BELOW:

(I) ONE ORIGINAL AND ONE COPY TO THE APPROVING OFFICIAL:

U.S. FOOD AND DRUG ADMINISTRATION
OFFICE OF ACQUISITIONS AND GRANTS SERVICES
ATTN: Yared Girmai, CS
5630 FISHERS LANE
ROOM 2136, HFA-500
ROCKVILLE, MARYLAND 20857
E-mail: yared.girmai@fda.hhs.gov

(II) ONE COPY TO THE CONTRACTING OFFICER REPRESENTATIVE (COR) OR OTHER PROGRAM CENTER/OFFICE DESIGNEE, CLEARLY MARKED "COURTESY COPY ONLY":

U.S. FOOD AND DRUG ADMINISTRATION
Mei-Ying Li
CDR, USPHS
FDA/ORR/DFSR
12420 Parklawn Dr. RM 3019
Rockville, MD 20857
(301) 796-5903 (Ph)
(301) 827-9221 (F)
meiying.li@fda.hhs.gov

B. INVOICES SUBMITTED UNDER THIS CONTRACT MUST COMPLY WITH THE REQUIREMENTS SET FORTH IN FAR CLAUSES 52.232-25 (PROMPT PAYMENT) AND 52.232-33 (PAYMENT BY ELECTRONIC FUNDS TRANSFER – CENTRAL CONTRACTOR REGISTRATION) AND/OR OTHER APPLICABLE FAR CLAUSES SPECIFIED HEREIN. TO CONSTITUTE A PROPER INVOICE, THE INVOICE MUST BE SUBMITTED ON COMPANY LETTERHEAD AND INCLUDE EACH OF THE FOLLOWING:

(I) NAME AND ADDRESS OF THE CONTRACTOR;

(II) INVOICE DATE AND INVOICE NUMBER;

(III) PURCHASE ORDER/AWARD NUMBER;

(IV) DESCRIPTION, QUANTITY, UNIT OF MEASURE, UNIT PRICE, AND EXTENDED PRICE SUPPLIES DELIVERED OR SERVICES PERFORMED, INCLUDING:

(a) PERIOD OF PERFORMANCE FOR WHICH COSTS ARE CLAIMED;

(b) ITEMIZED TRAVEL COSTS, INCLUDING ORIGIN AND DESTINATION;

(c) ANY OTHER SUPPORTING INFORMATION NECESSARY TO CLARIFY QUESTIONABLE EXPENDITURES;

(V) SHIPPING NUMBER AND DATE OF SHIPMENT, INCLUDING THE BILL OF LADING NUMBER AND WEIGHT OF SHIPMENT IF SHIPPED ON GOVERNMENT BILL OF LADING;

(VI) TERMS OF ANY DISCOUNT FOR PROMPT PAYMENT OFFERED;

(VII) NAME AND ADDRESS OF OFFICIAL TO WHOM PAYMENT IS TO BE SENT (MUST BE THE SAME AS THAT IN THE PURCHASE ORDER/AWARD, OR IN A PROPER NOTICE OF ASSIGNMENT);

(VIII) NAME, TITLE, AND PHONE NUMBER OF PERSON TO NOTIFY IN EVENT OF DEFECTIVE INVOICE;

(IX) TAXPAYER IDENTIFICATION NUMBER (TIN);

(X) ELECTRONIC FUNDS TRANSFER (EFT) BANKING INFORMATION, INCLUDING ROUTING TRANSIT NUMBER OF THE FINANCIAL INSTITUTION RECEIVING PAYMENT AND THE NUMBER OF THE ACCOUNT INTO WHICH FUNDS ARE TO BE DEPOSITED;

(XI) NAME AND TELEPHONE NUMBER OF THE FDA CONTRACTING OFFICER TECHNICAL REPRESENTATIVE (COR) OR OTHER PROGRAM CENTER/OFFICE POINT OF CONTACT, AS REFERENCED ON THE PURCHASE ORDER;

(XII) ANY OTHER INFORMATION OR DOCUMENTATION REQUIRED BY THE PURCHASE ORDER/AWARD.

(XIII) CONTRACTOR IS IS NOT REQUIRED TO ATTACH AN INVOICE LOG ADDENDUM TO EACH INVOICE WHICH SHALL INCLUDE, AT A MINIMUM, THE FOLLOWING INFORMATION FOR CONTRACT ADMINISTRATION AND RECONCILIATION PURPOSES:

(a) LIST OF ALL INVOICES SUBMITTED TO DATE UNDER THE SUBJECT AWARD, INCLUDING THE FOLLOWING:

(1) INVOICE NUMBER, AMOUNT, & DATE SUBMITTED

(2) CORRESPONDING PAYMENT AMOUNT & DATE
RECEIVED
(b) TOTAL AMOUNT OF ALL PAYMENTS RECEIVED TO DATE
UNDER THE SUBJECT CONTRACT OR ORDER
(c) AND, FOR DEFINITIZED CONTRACTS OR ORDERS ONLY,
TOTAL ESTIMATED AMOUNTS YET TO BE INVOICED FOR THE
CURRENT, ACTIVE PERIOD OF PERFORMANCE

C. AN ELECTRONIC INVOICE IS ACCEPTABLE IF SUBMITTED IN ADOBE ACROBAT (PDF) FORMAT. ALL ITEMS LISTED IN (I) THROUGH (XII) OF THIS CLAUSE MUST BE INCLUDED IN THE ELECTRONIC INVOICE. ELECTRONIC INVOICES MUST BE ON COMPANY LETTERHEAD AND MUST CONTAIN NO INK CHANGES AND BE LEGIBLE FOR PRINTING.

D. QUESTIONS REGARDING INVOICE PAYMENTS SHOULD BE DIRECTED TO THE FDA PAYMENT OFFICE AT:

Office of Financial Services
Food and Drug Administration
10903 New Hampshire Ave
WO32 - Second Floor
MAIL HUB 2145
Silver Spring, MD 20993-0002
Attn: Vendor Payments

G-4 – Government Furnished Materials

All reporting forms required for use in the performance of the services required hereunder will be furnished by the Government. Delivery will be made in a timely manner to the Contractor's facility, such that the required services can be performed within the effective dates of the contract.

G-5 – Post Award Evaluation of Contractor Performance

A. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted annually.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

B. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through the Contractor Performance Assessment Reporting System (CPARS) web site, which is managed by the Department of Defense (DOD). Details regarding CPARS training and on-line registration can be found at <http://www.cpars.csd.disa.mil/>.

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact who will be responsible for notifying the FDA contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The clauses below are mandatory to ensure compliance with information disclosure laws.

H-1 – Confidentiality Definitions

Confidential Commercial Information. Confidential commercial information is valuable data or information which is used in one's business and, if voluntarily submitted by the information's owner to FDA, is of a type customarily not disclosed to the public by the person to whom the information belongs or, if not voluntarily submitted, is information which, if disclosed by FDA would be likely to cause substantial harm to the competitive position of the person to whom the information belongs or impair the agency's ability to obtain similar data in the future. Examples of records that may fall within the definition of confidential commercial information either in part or in their entirety include information in an application to market an unapproved product, or in an Establishment Inspection Report containing the results of an inspection of a regulated company.

Disclosure. Disclosure means releasing, transferring, providing access to, or otherwise divulging to the public nonpublic information by any means of communication--including photographic, written, oral, electronic (including databases), or mechanical.

Nonpublic information. Nonpublic information includes but is not limited to trade secret, confidential commercial, predecisional, or other information, such as personal privacy information about an individual, information provided by a confidential informant, techniques and procedures for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to

risk circumvention of the law, information that could reasonably be expected to endanger the life or physical safety of an individual, or information, which if disclosed, could reasonably be expected to interfere with enforcement proceedings ("open investigatory"). Information includes oral information, documents, photographs, data, and other records, in written (paper) or electronic form or other medium, that are either created or obtained by FDA and under FDA's control at the time the information is shared with the Contractor.

Contractor. For purposes of this Contract, the term "Contractor" means a state or local government organization and includes an employee of the Contractor.

Personal privacy information. Information about an individual, which, if disclosed, would constitute a clearly unwarranted invasion of personal privacy.

Predecisional information. Predecisional information refers to information that is created by FDA in the course of its decision-making process and is not available to the general public. Predecisional information includes non-factual information contained in inter- or intra-agency records prepared during the process of FDA's deliberations and proposed policies before final adoption. A document that FDA considers to be predecisional may include confidential commercial or trade secret information.

Sponsor/submitter. A sponsor/submitter is an individual, partnership, corporation, or association that owns or submitted the nonpublic confidential commercial or trade secret information that is submitted to FDA. (Often a sponsor/submitter is the manufacturer of a product.)

Trade secret information. A trade secret is information that may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process. Trade secret information might be found in the same records that contain confidential commercial information.

H-2 - FDA 1350 Access To Non-Public Information

All contractor and subcontractor employees are required to sign the Contractor's Commitment to Protect Non-Public Information Agreement form provided as an attachment to this contract (Attachment 1). If a person who has signed this agreement resigns, is dismissed, or is otherwise no longer working on this contract, the contractor shall notify the FDA COR (P.O.) and Contracting Officer. Any new contractor and subcontractor employees assigned to this contract shall sign the form, and the contractor shall hand-deliver it (ten (10) days prior to commencement of work) to the Contracting Officer.

The prime contractor, subcontractors, and consultants shall not be provided nor possess non-public information in any form unless written approval and a facility clearance have been granted.

Briefings

A FDA representative (typically, the COR) will conduct an orientation briefing for the contractor/contractor employees. The briefing will stress: (1) the importance of protecting non-public information; (2) specified computer/ADP requirements as outlined in the DHHS Automated Information Systems Security Program Handbook; and (3) the consequences of unauthorized disclosure of non-public information. Briefing updates will be conducted annually.

The contractor shall brief all contractor employees, subcontractors and consultants regarding the sensitivity of the information to be handled under the contract and of the responsibility to protect it. The briefing shall stress that the information is non-public and shall not be disclosed to any unauthorized source. The contractor shall conduct an updated briefing annually and shall submit a report to the FDA COR within ten (10) days after the briefing which includes: an outline of the briefing, a copy of any briefing materials, date briefing was conducted and the names of the attendees.

If this is an automated data processing/telecommunications (ADP/TC) contract, in addition to the above briefings, the FDA COR and the FDA Center/Office Information Systems Security Officer (ISSO) will brief contractor and subcontractor personnel and consultants on security measures required pertinent to any hardware/software being utilized. Furthermore, appropriate contractor and subcontractor personnel and consultants shall attend training courses as directed by the FDA to fulfill requirements of the Computer Security Act of 1987. These courses are generally one (1) day in length; and attendance at one (1) course is sufficient. This training will be provided at no cost to the contractor.

H-3 - FDA 1354 Physical Security Requirements for Releasing Non-Public Information

Under the provisions of Title 21, United States Code, Section 331(j), the contractor shall establish and maintain comprehensive security measures for controlling access to non-public information released under a contract involving the processing of such information.

The contractor shall be required to submit a physical security plan with their proposal. The plan shall provide written procedures which detail the instructions issued to contract employees on the following:

1. safeguarding material during use;
2. safeguarding material at all other times;
3. accounting for material
 - a. tracking procedures,
 - b. created in-process;

4. storage control;
5. key control;
6. area security;
7. visitor control;
8. receipt and transmittal of material;
9. reproduction of material;
10. destruction of material;
11. recording logs;
12. response to emergency situations;
13. compromise of information; and,
14. administrative controls.

This clause applies to the contractor, any subcontractors, and any consultants. Non-public information will be released to only those persons who will be using the contractor's approved facility unless the off-site facility has been reviewed by the FDA Physical Security Staff and approved in writing by the FDA Physical Security Office.

For transmittal of documents the contractor shall adhere to the following:

- A. Documents to be transmitted internally shall be transmitted on a person-to-person basis between approved employees only.
- B. Documents to be transmitted outside the contractor's facility shall be double-wrapped with the inner wrapping marked "FDA Privileged Information - Access Controlled". The names and addresses of the sender and addressee shall be typed on both the inner and outer wrappings.
- C. Documents to be transmitted back to the FDA or to another address designated by the FDA shall be transmitted by an approved employee or by U. S. Registered mail (return receipt requested). It shall be double-wrapped or wrapped by such a method as specifically approved in writing by the FDA Physical Security Office.
- D. A receipt log shall be maintained for all external transmittals.
- E. The contractor shall follow up all transmittals in order to obtain signed receipt within five (5) working days of transmittal. Failure of recipient to furnish such receipt shall be reported to the FDA Physical Security Office within ten (10) working days of transmittal.

No non-public information will be released to the contractor unless all required security precautions have been met [as demonstrated during an inspection by the Food and Drug Administration (FDA) Physical Security Staff], and written procedures for enforcing them have been provided by the contractor and approved in writing by the Physical Security Staff. The FDA Physical Security Office will notify the contractor of the approval.

When the contractor facilities have a current certification from the Defense Contract Administration Services/Defense Logistics Agency (DCAS/DLA) as a "Secret" or higher classification, such rating will satisfy the FDA security requirements for the contractor's facility. Loss of such certification during the period of the contract will be cause for a possible issuance of a Stop Work Order pending review by the FDA's Physical Security Staff of the contractor's facility. The contractor shall notify the FDA Physical Security Office in the event the DCAS/DLA rating is expected to be terminated.

Pending the outcome of any subsequently required investigation, additional requirements on the contractor shall include, but not be limited to, the following: restrictions on access to data by contractor employees, subcontractor employees, and consultants; special storage requirements; restrictions on transmission and disclosure of information; changes in periods of retention and in methods of destruction of source documents or related material; and disclosure statements for all contractor employees, subcontractor employees, and consultants.

The FDA Physical Security Staff will review the contractor's facility and assess the contractor's compliance. Recommendations for bringing noncompliant areas into compliance will be provided to the contractor by the FDA Physical Security Office.

The Contractor shall make any changes necessary within thirty (30) days after written notice from the FDA Physical Security Office in order to comply with FDA security requirements. When appropriate changes have been made the Contractor shall contact the FDA Physical Security Office to request further review by the FDA. The FDA Physical Security Office will notify the Contractor in writing of the outcome of the second inspection. Failure of the contractor to satisfy FDA security requirements within thirty (30) days after the first written notification from the Contracting Officer may be cause for termination of the contract.

The contractor shall designate a Security Representative to act as liaison between the contractor and the FDA on all security-related matters. This includes personnel changes, personnel terminations, disciplinary actions, etc. The name of the Security Representative shall be provided in the offeror's proposal.

In addition to the above, if this is an automated data processing/telecommunications (ADP/TC) contract, special requirements are necessary. Contractor and subcontractor employees and consultants participating in the design, operation, maintenance or use of FDA automated information systems or ADP/TC resources shall comply with the DHHS Automated Information Systems Security Program Handbook. Chapter VII, entitled, "Personnel Security/Suitability and Training," which establishes criteria for assigning positions to the three (3) computer/ADP position risk levels: Level 6, high risk public trust position; Level 5, moderate risk public trust position; and Level 1, low risk position. Chapter VIII, entitled, "AIS Facilities," requires contractors to meet or exceed the security requirements described therein.

All contractor, subcontractor and consultants assigned to this contract and working in a FDA facility will be provided with Government badges by the FDA COR at the FDA's expense.

H-4 – Commissioning of Inspectors

The Government may require that the Contractor be commissioned by the Government to enable the Contractor to conduct activities under this contract including, but not limited to, undertaking examinations, inspections, and investigations, and related activities to protect the public health in accordance with federal law, such as the provisions of "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Public Law 107-188).

The Government has an established procedure to commission the Contractor's employee to perform certain functions pursuant to the Federal Food, Drug, and Cosmetic Act, such as conducting FDA examinations, inspections, and investigations, collecting and obtaining samples, copying and verifying records, and receiving and reviewing official FDA documents (see Government's Regulatory Procedures Manual, Chapter 3). The Government also has an alternate commissioning process upon which it may rely to commission a Contractor's employee. The alternate process streamlines the routine commissioning process. In the streamlined commissioning process, the Government may rely on the Contractor's agency head certification that the Contractor has determined that the individual being considered for the Government commission: (1) meets the requirements the Contractor has established to credential its own officer to carry out State government regulatory or enforcement responsibilities, (2) has provided the Contractor with a written assurance that the individual understands the importance of maintaining confidentiality of non-public information created or obtained under this contract, and will comply with the above clauses in this section ("Special Contract Requirements") regarding confidentiality, (3) has provided the Contractor with a written assurance that the individual will not use information created or obtained under this contract to further the individual's private interests or the interests of any other person, (4) has provided the Contractor with a written assurance that the individual has no personal financial interest or any other financial or business relationship with any person operating in the specific program area(s) in which the Contractor would grant authority to the official as a credentialed officer and (5) meets the requirements of the Government's commissioning procedures. Upon review of the signed certificate, the Government may grant the commission by signing the "Contractor Certificate and Government Grant of Commission" form. No certification/credential will be issued when using Government Grant of Commission procedure. In those cases where the Government chooses not to rely on the signed certification, the Government is not precluded from considering the commissioning of the individual by FDA's routine commissioning process.

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):

<https://www.acquisition.gov/far/>

A. Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clauses

Reg	Clause	Date	Clause Title
FAR	52.202-1	Jan 2012	Definitions (Over the Simplified Acquisition Threshold)
FAR	52.203-3	Apr 1984	Gratuities (Over the Simplified Acquisition Threshold)
FAR	52.203-5	Apr 1984	Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)
FAR	52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)
FAR	52.203-7	Oct 2010	Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)
FAR	52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
FAR	52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
FAR	52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions (Over \$150,000)
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)
FAR	52.204-7	Feb 2012	Central Contractor Registration
FAR	52.204-9	Jan 2011	Personal Identity Verification of Contractor Personnel
FAR	52.209-6	Dec 2010	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$30,000)
FAR	52.215-2	Oct 2010	Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over

			the Simplified Acquisition Threshold funded exclusively with non-Recovery Act funds.]
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data (Over \$700,000)
FAR	52.215-12	Oct 2010	Subcontractor Cost or Pricing Data (Over \$700,000)
FAR	52.215-15	Oct 2010	Pension Adjustments and Asset Reversions (Over \$700,000)
FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications
FAR	52.216-7	Jun 2011	Allowable Cost and Payment.
FAR	52.219-8	Jan 2011	Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)
FAR	52.222-3	Jun 2003	Convict Labor
FAR	52.222-21	Feb 1999	Prohibition of Segregated Facilities
FAR	52.222-26	Mar 2007	Equal Opportunity
FAR	52.222-35	Sep 2010	Equal Opportunity for Veterans (\$100,000 or more)
FAR	52.222-36	Oct 2010	Affirmative Action for Workers with Disabilities
FAR	52.222-37	Sep 2010	Employment Reports on Veterans (\$100,000 or more)
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)
FAR	52.222-54	Jan 2009	Employment Eligibility Verification (Over the Simplified Acquisition Threshold)
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving
FAR	52.225-1	Feb	Buy American Act - Supplies

		2009	
FAR	52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
FAR	52.227-1	Dec 2007	Authorization and Consent
FAR	52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.229-3	Apr 2003	Federal, State and Local Taxes (Over the Simplified Acquisition Threshold)
FAR	52.232-1	Apr 1984	Payments
FAR	52.232-8	Feb 2002	Discounts for Prompt Payment
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-11	Apr 1984	Extras
FAR	52.232-17	Oct 2010	Interest (Over the Simplified Acquisition Threshold)
FAR	52.232-20	APR 1984	Limitation of Cost
FAR	52.232-23	Jan 1986	Assignment of Claims
FAR	52.232-25	Oct 2008	Prompt Payment
FAR	52.232-33	Oct 2003	Payment by Electronic Funds Transfer--Central Contractor Registration
FAR	52.233-1	Jul 2002	Disputes
FAR	52.233-3	Aug 1996	Protest After Award
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-13	Jul 1995	Bankruptcy (Over the Simplified Acquisition Threshold)
FAR	52.243-1	Aug 1987	Changes - Fixed-Price, Alternate I (Apr 1984)
FAR	52.244-6	Dec 2010	Subcontracts for Commercial Items
FAR	52.245-1	Jun 2007	Government Property
FAR	52.246-25	Feb 1997	Limitation of Liability - Services (Over the Simplified Acquisition Threshold)

FAR	52.249-4	Apr 1984	Termination for Convenience of the Government (Services) (Short Form)
FAR	52.249-8	Apr 1984	Default (Fixed-Price Supply and Service)(Over the Simplified Acquisition Threshold)
FAR	52.253-1	Jan 1991	Computer Generated Forms

2. Department of Health and Human Services Acquisition Regulation (HHSAR) (48 CFR Chapter 3) Clauses

HHSAR	352.202-1	Jan 2006	Definitions
HHSAR	352.203-70	Mar 2012	Anti-Lobbying (Over Simplified Acquisition Threshold)
HHSAR	352.222-70	Jan 2010	Contractor Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.227-70	Jan 2006	Publications and Publicity
HHSAR	352.231-71	Jan 2001	Pricing of Adjustments
HHSAR	352.239-70	Jan 2010	Standard for Security Configurations
HHSAR	352.239-71	Jan 2010	Standard for Encryption Language
HHSAR	352.242-70	Jan 2006	Key Personnel
HHSAR	352.242-73	Jan 2006	Withholding of Contract Payments

I-2 – Clauses in Full Text

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 30 days.

52.217-9 Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days provided that the Government gives the Contractor a

preliminary written notice of its intent to extend at any time before the contract expires. The preliminary notice does not commit the Government to an extension.
(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.
(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 60 months.

352.242-70 Key Personnel (Jan 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the contractor or Government.

See section G-2 for the Key Personnel on this contract.

SECTION J - LIST OF ATTACHMENTS

The following attachments are incorporated into this contract.

Attachment 1 – Form FDA 3398 – Contractor’s Commitment to Protect Non-Public Information (NPI) Agreement

Attachment 2 – Disclosure of Lobbying Activities

NOTE: These attachments will not be reissued with the resultant contract.