



Nicholas A. Toumpas
Commissioner

José Thier Montero
Director

STATE OF NEW HAMPSHIRE
DEPARTMENT OF HEALTH AND HUMAN SERVICES

29 HAZEN DRIVE, CONCORD, NH 03301-6503
603-271-4612 1-800-852-3345 Ext. 4612
Fax: 603-271-4827 TDD Access: 1-800-735-2964



45A MJT

March 27, 2014

Her Excellency, Governor Margaret Wood Hassan
and the Honorable Council
State House
Concord, New Hampshire 03301

Retroactive

REQUESTED ACTION

100% Other funds

1. Authorize the Department of Health and Human Services, Division of Public Health Services, Bureau of Public Health Protection, Radiological Health Section to enter into an agreement with the U.S. Food and Drug Administration (FDA), 5630 Fishers Lane, Rockville, MD, in an amount not to exceed \$33,740, for the Division to perform inspections on certified mammography facilities within New Hampshire, **retroactive** to September 30, 2013, effective the date of Governor and Council approval, through September 29, 2014.
2. Effective upon approval of Requested Action #1, authorize the Department of Health and Human Services, Division of Public Health Services, Bureau of Public Health Protection, Radiological Health Section, to accept and expend federal funds in the amount of \$3,814.00 from the U.S. Food and Drug Administration (FDA) to fund training to certify a Radiation Health Physicist III as an inspector for certified mammography facilities within New Hampshire, effective upon date of approval by the Governor and Council, through September 29, 2014, and further authorize the funds to be allocated as follows.

05-95-90-901510-53910000 HEALTH AND SOCIAL SERVICES, DEPARTMENT OF HEALTH AND HUMAN SVS, HHS: DIVISION OF PUBLIC HEALTH SERVICES, BUREAU OF PUBLIC HEALTH PROTECTION, RADIOLOGICAL HEALTH.

SFY 2014

Class/Object	Class Title	Current Modified Budget	Increase (Decrease) Amount	Revised Modified Amount
000-406763	Federal Funds	\$0	\$3,814	\$3,814
001-405608	Transfer From Other Agency	\$82,623	\$0	\$82,623
009-403119	Radiological Fees	\$957,662	\$0	\$957,662
Total Revenue		\$1,040,285	\$3,814	\$1,044,099

010-500100	Personal Services Permanent	\$595,047	\$0	\$595,047
018-500106	Overtime	\$11,999	\$0	\$11,999
019-500105	Holiday Pay	\$360	\$0	\$360
020-500215	Current Expenses	\$16,000	\$0	\$16,000
021 500211	Food Institutions	\$1,700	\$0	\$1,700
022-500225	Rents-Leases Other Than Sta	\$2,095	\$0	\$2,095
024-500225	Maintenance Other than Bldg	\$9,000	\$0	\$9,000
026-500251	Organizational Dues	\$1,500	\$0	\$1,500
030-500300	Equipment	\$39,570	\$0	\$39,570
039-500190	Telecommunications	\$6,000	\$0	\$6,000
050-500109	Personal Service Temp	\$14,889	\$0	\$14,889
057-500531	Books Periodicals Subscript	\$500	\$0	\$500
060-500601	Benefits	\$324,025	\$0	\$324,025
066-500543	Employee Training	\$600	\$0	\$600
070-500704	In State Travel	\$5,000	\$0	\$5,000
080-500714	Out of State Travel	\$7,000	\$3,814	\$10,814
102-500731	Contracts for Program Svcs	\$5,000	\$0	\$5,000
Total Expenses		\$1,040,285	\$3,814	\$1,044,099

EXPLANATION

This request is **retroactive**. The NH Division of Public Health Services signed the agreement in September, 2013, however, due to an oversight regarding the source of funds, the Division neglected to move forward with this request in a timely fashion. Therefore, the Department respectfully requests that this be accepted as a retroactive request.

The New Hampshire Division of Public Health Services has agreed to perform inspections of mammography facilities in New Hampshire as part of the Mammography Quality Standards Act of 1992 (MQSA), which was signed into law on October 27, 1992. The intent of the Act is to ensure that women receive high quality mammography for early breast cancer detection by requiring the establishment of a

federal certification and inspection program for mammography facilities. The Act authorizes the U.S. Food and Drug Administration (FDA) to obtain state and local assistance in enforcing the MQSA requirements including annual inspections of all certified mammography facilities. Upon the enactment of the law, the Radiological Health Section employed a certified staff member to perform these inspections, but terminated the program when the staff member left State service prior to SFY1999. On September 3, 2013, the State applied and was approved for funding from the Food and Drug Administration (FDA) to perform inspections of mammography facilities, and the FDA directly funded training for the Section Chief. The current Base Period of performance is from September 30, 2013 through September 29, 2014, with an option to renew through September 29, 2017. The agreement is based on a fixed price per facility and allowance for continuing education every three years. A modification to the agreement was issued on March 26, 2014, to include additional funding for MQSA Inspector Training for a recently hired Radiation Health Physicist III, whose duties include inspections of mammography facilities in the State.

The funds are to be budgeted as follows:

Funds in class 080 are needed to pay for out-of-state travel for a Radiation Health Physicist II to attend the MQSA Inspector Certification Course III in Maryland.

Area served: statewide.

Source of funds: These funds are 100% Federal from the U.S. Food and Drug Administration (FDA) to fund training to certify a Radiation Health Physicist III as an inspector for certified mammography facilities.

Attached is the Agreement and Amendment. Notice of these funds was received on September 3, 2013. They were not added to the operating budget because these are new funds recently granted to the State and were not anticipated at the time the budget was developed.

In the event that these Federal Funds become no longer available, General Funds will not be requested to support this program.

Respectfully submitted,



José Thier Montero, MD, MHCDS
Director

Approved by:



Nicholas A. Toumpas
Commissioner

JTM/nrm

2. AMENDMENT/MODIFICATION NO. 0001	3. EFFECTIVE DATE 03/26/2014	4. REQUISITION/PURCHASE REQ. NO. 1131983	5. PROJECT NO. (If applicable)
6. ISSUED BY CODE DCSC DHHS/FDA/OAGS/DASG ATTN: Yared Girmai 5630 FISHERS LANE ROOM 2129, HFA-500 ROCKVILLE MD 20857		7. ADMINISTERED BY (If other than Item 6) CODE DCSC DHHS/FDA/OAGS/DASG ATTN: Yared Girmai 5630 FISHERS LANE ROOM 2129, HFA-500 ROCKVILLE MD 20857	

8. NAME AND ADDRESS OF CONTRACTOR (No. , street, county, State and ZIP Code) STATE OF NEW HAMPSHIRE 1371435 HEALTH AND HUMAN SERVICES, NEW HAMP 129 PLEASANT ST CONCORD NH 033013852 CODE 1371435 FACILITY CODE	9A. AMENDMENT OF SOLICITATION NO. 9B. DATED (SEE ITEM 11) X 10A. MODIFICATION OF CONTRACT/ORDER NO. HHSF223201310086C 10B. DATED (SEE ITEM 13) 09/03/2013
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11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended. is not extended.
 Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required) ..2014.6999BAA.256E...11513MQSA10086C	Net Increase:	\$3,814.70
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13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER (Specify type of modification and authority) FAR 52.243-1 - Changes - Fixed-Price, Alternate I (Apr 1984)

E. IMPORTANT: Contractor is not. is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible)

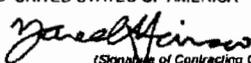
Tax ID Number: 02-6000618
 DUNS Number: 011040545
 The purpose of this modification is to include funding for new MQSA inspector training.

Section B-2 Compensation, is modified as follows:

A. As consideration for full performance of the work stated in Part I, Section C - Scope of Work, the Government shall pay the contractor a total fixed price of \$29,925.49 for inspections, \$3,814.70 for new inspector training, and not to exceed \$0.00 for Continuing Education Units, for a total contract amount of \$33,740.19. The period of performance will be from 9/30/2013 through 9/29/2014. (12 months)

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) YARED T. GIRMAI
15B. CONTRACTOR/OFFEROR <small>(Signature of person authorized to sign)</small>	15C. DATE SIGNED
	16B. UNITED STATES OF AMERICA  <small>(Signature of Contracting Officer)</small>
	16C. DATE SIGNED 3-26-2014

NAME OF OFFEROR OR CONTRACTOR
STATE OF NEW HAMPSHIRE 1371435

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	<p>D. Training and Travel:</p> <p>For training/travel, the total expenditures for domestic travel (transportation, lodging, meals, and incidental expenses) not to exceed \$3,814.70 incurred in direct performance of this contract shall be allowed based on the contractor's travel policy.</p> <p>The domestic travel allowance for training under this contract shall be paid on a cost reimbursement basis. The estimated travel and training costs are subject to FAR clause 52.216-7 "Allowable Cost and Payment" and FAR clause 52.232-20 "Limitation of Cost." These FAR clauses are included by reference in Section I of the contract.</p> <p>All other terms and conditions remain the same. 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.: 2014 CAN: 6999BAA Object Class: 256E CenterTag: 11513MQSA10086C FOB: Destination Period of Performance: 09/30/2013 to 09/29/2014</p> <p>Add Item 6 as follows:</p>				
6	MQSA New Inspector Training Obligated Amount: \$3,814.70	3814.7	EA	1.00	3,814.70

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES 1 / 31
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2. CONTRACT (Proc. Inst. Ident.) NO. HHSF223201310086C	3. EFFECTIVE DATE See Block 20C	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 1124918
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5. ISSUED BY DHHS/FDA/OAGS/DASG ATTN: Yared Girmai 5630 FISHERS LANE ROOM 2129, HFA-500 ROCKVILLE MD 20857	CODE DCSC	6. ADMINISTERED BY (If other than Item 5) DHHS/FDA/OAGS/DASG ATTN: Yared Girmai 5630 FISHERS LANE ROOM 2129, HFA-500 ROCKVILLE MD 20857	CODE DCSC
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7. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, Country, State and ZIP Code) STATE OF NEW HAMPSHIRE 1371435 HEALTH AND HUMAN SERVICES, NEW HAMP 129 PLEASANT ST CONCORD NH 033013852	8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input checked="" type="checkbox"/> OTHER (See below)
	9. DISCOUNT FOR PROMPT PAYMENT

10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN	ITEM G-3
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11. SHIP TO/MARK FOR 5600 FISHERS LANE 5600 FISHERS LANE ROCKVILLE MD 20857	CODE PMLN	12. PAYMENT WILL BE MADE BY FDA PAYMENT SVCS Attn: Vendor Payments, OFS FDA 10903 New Hampshire Avenue Bldg 32, Rm 2162, Mail Hub 2145 Silver Spring MD 20993-0002	CODE FDA PAYMENT SVCS
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13. 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. 263 (a) (5)	14. ACCOUNTING AND APPROPRIATION DATA See Schedule
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15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
Continued					

15G. TOTAL AMOUNT OF CONTRACT	\$29,925.49
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16. TABLE OF CONTENTS							
(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES			
X	A	SOLICITATION/CONTRACT FORM	1-2	X	I	CONTRACT CLAUSES	26-30
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	3-4	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
X	C	DESCRIPTION/SPECS./WORK STATEMENT	5-13	X	J	LIST OF ATTACHMENTS	31
X	D	PACKAGING AND MARKING	14	PART IV - REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTANCE	14	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS		
X	F	DELIVERIES OR PERFORMANCE	15-17	L	INSTR., CONDS. AND NOTICES TO OFFERORS		
X	G	CONTRACT ADMINISTRATION DATA	17-23	M	EVALUATION FACTORS FOR AWARD		
X	H	SPECIAL CONTRACT REQUIREMENTS	23-26				

CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. <input checked="" type="checkbox"/> CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return <u>1</u> copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)	18. <input type="checkbox"/> SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 16 should be checked only when awarding a sealed-bid contract.)
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19A. NAME AND TITLE OF SIGNER (Type or print) Dr. Jose Montero, Director - DPRS	20A. NAME OF CONTRACTING OFFICER YARED T. GIRMAI
19B. NAME OF CONTRACTOR	20B. UNITED STATES OF AMERICA
19C. DATE SIGNED 8/29/13	20C. DATE SIGNED 9/3/2013

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES 1 31
2. CONTRACT (Proc. Inst. Ident.) NO. HHSF223201310086C		3. EFFECTIVE DATE See Block 20C	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 1124918	
5. ISSUED BY DHHS/FDA/OAGS/DASG ATTN: Yared Girmai 5630 FISHERS LANE ROOM 2129, HFA-500 ROCKVILLE MD 20857	CODE DCSC	6. ADMINISTERED BY (If other than Item 5) DHHS/FDA/OAGS/DASG ATTN: Yared Girmai 5630 FISHERS LANE ROOM 2129, HFA-500 ROCKVILLE MD 20857		CODE DCSC

7. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, Country, State and ZIP Code) STATE OF NEW HAMPSHIRE 1371435 HEALTH AND HUMAN SERVICES, NEW HAMP 129 PLEASANT ST CONCORD NH 033013852		8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input checked="" type="checkbox"/> OTHER (See below)
		9. DISCOUNT FOR PROMPT PAYMENT
		10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN ITEM G-3

CODE 1371435	FACILITY CODE
11. SHIP TO/MARK FOR 5600 FISHERS LANE 5600 FISHERS LANE ROCKVILLE MD 20857	CODE PKLN
12. PAYMENT WILL BE MADE BY FDA PAYMENT SVCS Attn: Vendor Payments, OFS FDA 10903 New Hampshire Avenue Bldg 32, Rm 2162, Mail Hub 2145 Silver Spring MD 20993-0002	

13. 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)	14. ACCOUNTING AND APPROPRIATION DATA See Schedule
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15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
Continued					

15G. TOTAL AMOUNT OF CONTRACT **\$29,925.49**

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
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X	F	DELIVERIES OR PERFORMANCE	15-17	L	INSTRS., CONDS. AND NOTICES TO OFFERORS		
X	G	CONTRACT ADMINISTRATION DATA	17-23	M	EVALUATION FACTORS FOR AWARD		
X	H	SPECIAL CONTRACT REQUIREMENTS	23-26				

CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 1 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18. SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

18A. NAME AND TITLE OF SIGNER (Type or print)	19A. NAME OF CONTRACTOR	19C. DATE SIGNED	20A. NAME OF CONTRACTING OFFICER YARED T. GIRMAI	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED 9/3/2013
BY (Signature of person authorized to sign)		BY <i>Yared Girmai</i> (Signature of the Contracting Officer)			

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
HHSF223201310086C

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2 31

NAME OF OFFEROR OR CONTRACTOR
STATE OF NEW HAMPSHIRE 1371435

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 02-6000618 DUNS Number: 011040545 Delivery: 09/29/2014 FOB: Destination Period of Performance: 09/30/2013 to 09/29/2014				
1	41 MQSA inspections @ \$729.89 each Obligated Amount: \$29,925.49 Quantity: 27232.2 Accounting Info: ..2013.6999BAA.256E....11438MQSAnewNH2 Appr. Yr.: 2013 CAN: 6999BAA Object Class: 256E CenterTag: 11438MQSAnewNH2 Funded: \$27,232.20 Quantity: 2693.29 Accounting Info: ..2013.6999BBM.256E....11438MQSAnewNH2 Appr. Yr.: 2013 CAN: 6999BBM Object Class: 256E CenterTag: 11438MQSAnewNH2 Funded: \$2,693.29	29925.49	EA	1.00	29,925.49
2	Option 1 Amount: \$30,524.50 (Option Line Item) 09/30/2014	41	EA	744.50	0.00
3	Option 1 - MEU Amount: \$1,300.00 (Option Line Item) 09/30/2014	1300	EA	1.00	0.00
4	Option 2 Amount: \$31,134.58 (Option Line Item) 09/30/2015	41	EA	759.38	0.00
5	Option 3 Amount: \$31,756.96 (Option Line Item) 09/30/2016 The total amount of award: \$124,641.53. The obligation for this award is shown in box 15G.	41	EA	774.56	0.00

SECTION B - SUPPLIES OR SERVICES AND PRICE/COST

B-1 - Background and Objectives

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

A. Background Information

The Mammography Quality Standards Act of 1992,(MQSA) was signed into law on 27 October 1992. The intent of the Act is to ensure that women receive high quality mammography for early breast cancer detection by requiring the establishment of a federal certification and inspection program for mammography facilities. The Act authorizes FDA to obtain state and local assistance in enforcing the MQSA requirements including annual inspections of all certified mammography facilities. NOTE: Interim regulations were published on 30 September 1994 and 03 April 1996. On 28 October 1997, the U.S. Food and Drug Administration (FDA) published final MQSA regulations in the Federal Register. These regulations took effect on 28 April 1999.

B. Objective

This project is designed to obtain State and local assistance in the inspection of certified non-federal mammography facilities.

B-2 - Compensation

- A. As consideration for full performance of the work stated in Part I, Section C - Scope of Work, the Government shall pay the contractor a total fixed price of \$29,925.49 for inspections, and not to exceed \$0.00 for Continuing Education Units, for a total contract amount of \$29,925.49. The period of performance will be from 9/30/2013 through 9/29/2014. (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:
- C. Continuing Education for MQSA Inspectors

Total expenditures for each certified inspector to acquire 15 Mammography Continuing Education Units (MEUs) (strictly limited to registration and tuition fees, course materials, and if necessary, appropriate travel expenses) shall not exceed the fixed allotment of \$1,300 within any three year certification period.

Funds in the amount of \$0.00 to be billed separately for 0 inspectors are allotted for MEUs

under this contract.

Note: Salary costs are not reimbursable expenditures while receiving Continuing Education.

D. Training and Travel:

For training/travel, the total expenditures for domestic travel (transportation, lodging, meals, and incidental expenses) not to exceed \$0.00 incurred in direct performance of this contract shall be allowed based on the contractor's travel policy.

The domestic travel allowance for training under this contract shall be paid on a cost reimbursement basis. The estimated travel and training costs are subject to FAR clause 52.216-7 "Allowable Cost and Payment" and FAR clause 52.232-20 "Limitation of Cost". These FAR clauses are included by reference in Section I of the contract.

E. Schedule

Base Period	Period of Performance : From 9/30/2013 To 9/29/2014			
# of Inspections	Unit Price	MEU	Training	Total
41	\$729.89	\$0.00	\$0.00	\$29,925.49

Option 1	Period of Performance : From 9/30/2014 To 9/29/2015			
# of Inspections	Unit Price	MEU	Training	Total
41	\$744.50	\$1,300.00	\$0.00	\$31,824.50

Option 2	Period of Performance : From 9/30/2015 To 9/29/2016			
# of Inspections	Unit Price	MEU	Training	Total
41	\$759.38	\$0.00	\$0.00	\$31,134.58

Option 3	Period of Performance : From 9/30/2016 To 9/29/2017			
# of Inspections	Unit Price	MEU	Training	Total
41	\$774.56	\$0.00	\$0.00	\$31,756.96

F. As consideration for the full performance of the work (base period and all option years), stated in Part I, Section C - Scope of Work, the Government shall pay the contractor a total fixed price of \$123,341.53 for inspections, \$0.00 for training, and not to exceed \$1,300.00 for Mammography Education Units, for a total contract amount of \$124,641.53.

SECTION C - DESCRIPTION/SPECIFICATION/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, and otherwise do all things necessary for or incident to the performance of the work as described below:

I. Annual Inspections of Certified Mammography Facilities

The contractor shall inspect non-federal mammography facilities that have been certified by the Food and Drug Administration (FDA) to perform mammography under the Mammography Quality Standards Act of 1992 (MQSA).

The following shall be accomplished:

a. Inspections

Inspections shall be performed at certified non-federal facilities performing mammography. The State Facility Listing Report is available on-line. Questions concerning access to the report should be directed to FDA/Division of Mammography Quality Standards (DMQS), Computer Support at (301) 796-6633 or via email to computersupport@cdrh.fda.gov

An inspection means the completion of the procedures in the documents entitled "Mammography Quality Standard Act (MQSA) - Facility Inspection Procedures" (a copy provided to all State Program Directors and MQSA Inspectors via email whenever updated) and "FDA Compliance Program 7385.014, Mammography Facility Inspections", and any subsequent revisions.

The types of inspections that shall be conducted include the following:

- Annual Inspection - this is a routine inspection conducted annually. To assure compliance with MQSA, the inspection shall be conducted no sooner than 10 months, and no later than 14 months from the last routine annual inspection at a facility.
- Follow-up inspection - conducted to determine whether the facility has complied with the terms of their corrective action plan, based upon the deficiencies found during a previous inspection. These inspections will normally be conducted by FDA.
- Joint Audit Inspection - an inspection conducted by a certified inspector under the observation of an FDA auditor to assure that inspections are conducted properly. Audits will normally be conducted during an annual inspection and are required for each inspector once during the course of the federal fiscal year (01 October through 30 September).

b. Facilities

All of the inspections conducted by the Contractor shall be of non-federal facilities that are certified by the FDA. Below is a listing of the various types of facility certification.

Fully Certified Facilities - A fully certified facility is one that had initially applied for and met accreditation standards under a six-month provisional certification status from an FDA-approved Accreditation Body or has successfully completed the re-accreditation process, and subsequently became fully certified for three years. Issuance of the FDA three-year Mammography Facility Certificate means that the FDA: Acknowledges the facility's accreditation by an FDA-approved Accreditation Body; certifies a facility as a mammography facility that can lawfully provide mammography services; will make the facility name and address available to members of the public as a facility certified under MQSA; and shall perform an annual MQSA inspection of the facility.

Provisionally Certified Facilities - A provisionally certified facility is one that has been issued a six-month provisional certificate based on information received by FDA from an approved accreditation body indicating that the facility's application is still in process, but sufficiently complete to allow initial certification. A provisional certificate allows a facility to legally perform mammography services for up to six months while completing the accreditation process. Once FDA is notified of the full accreditation of a facility, FDA issues a certificate fully certifying the facility for three (3) years.

Inspection of new provisionally certified facilities should be avoided unless there is a compelling reason to do so. In these cases, the contractor shall consult with and obtain the concurrence of the Regional Radiological Health Representative (RRHR) before scheduling an inspection of one of these facilities.

Provisionally Reinstated Facilities - A provisionally reinstated facility is one that is currently undergoing accreditation body review for re-accreditation after it had been denied accreditation. This means that the facility is certified by the FDA to lawfully provide mammography services for up to six months while completing the re-accreditation process. Once the FDA is notified of the full reinstatement of the facility, FDA will issue a three-year certificate to the facility.

Provisionally reinstated facilities are subject to inspection and may, in cases of a history of problems preventing accreditation, be considered as a higher priority for inspection than fully certified facilities. States should consult Section 2.1.2, Routine Annual Facility Inspections, "When Should a Facility Be Inspected?" of the MQSA inspection procedures to determine when facilities should be scheduled for their annual inspection.

Facility Notification - The Contractor shall provide the facility sufficient time to prepare for the inspection. Unless authorized by the RRHR or DMQS to inspect the facility without prior notice, it is recommended that notification be no less than five (5) working days prior to the inspection. Notification shall be provided to the facility in writing

(preferably by facsimile) unless the facility waives the need for a written notice.

Facility Status Changes - The Contractor shall advise the FDA of changes in facility status in its Progress Report (e.g., closure, change in name or address, or if a facility is discovered to be performing mammography without a certificate provided by the FDA or by a State approved as a certification body by the FDA). Upon notification of a change in facility status, the Contractor shall direct the facility to their respective Accreditation Body to effect the official change.

Patient Data - No patient name, addresses, or any other information that can be used to identify an individual, shall be collected from facilities inspected under this contract. If copies of patient records are collected, patient identification shall be removed and a code used to identify the records.

c. Inspection Procedures

Copies of the inspection procedures and compliance program 7385.014 will be provided to the Contractor. FDA will also provide training in the use of these procedures for all personnel performing MQSA inspections. Additionally, inspection guidance is available in the following areas:

- Policy Guidance Help System (accessible via inspector's laptop and MQSA website).
- Inspector HelpDesk (accessible via email at MQSAhotline@HCMSLLC.com or telephone at 800-838-7715 or fax at 410-290-6351).
- All Hands Inspector E-Mails.
- Course I-III Training Notebooks (provided to inspectors at MQSA Inspector certification training).

d. Inspection Record/Reports

A computer-generated inspection record shall be generated for each inspection, using the latest version of the Field Inspection Support System (FISS) software. The specific inspection data shall be recorded on a portable computer system supplied by the FDA (or a FDA-approved contractor owned system - reference Attachment 1, entitled "Computer Equipment Specifications for MQSA Inspections") and uploaded into FDA's Mammography Program Reporting and Information System (MPRIS) via telecommunication within five (5) business days of the facility inspection. Instructions for completing the computer generated inspection record are contained in the MQSA Facility Inspection Procedures.

e. Inspection Observations

The Contractor shall notify the FDA Regional and District offices within five (5) working days when the inspection results indicate a level 1 (serious) or repeat level 2 observation. A facsimile copy of the MQSA Facility Inspection Report shall be sent to the designated FDA contact as soon as possible. If it is not possible to send a facsimile within five (5) working days, the

Contractor shall notify the FDA RRHR field office contact by telephone or email.

If there is a disagreement between the inspection observation and the State supervisors, it is recommended that the contractor contact the RRHR and DMQS (Rachel Evans, 240-402-5126).

Level 1 Observations and Repeat Level 1 and 2 Observations - When serious observations are made during an inspection, this will warrant a written response from the facility (within fifteen (15) working days) to FDA with a copy to the Contractor. The FDA will contact the contractor if FDA requires any input on the response from the facility.

Level 2 Observations and Repeat Level 3 Observations - When found during an inspection, this will warrant a written response (within thirty (30) working days) from the facility to FDA with a copy to the Contractor. The FDA will contact the contractor if FDA requires any input on the response from the facility.

Documentation for Inspection Observations – Whenever Level 1 or 2 observations are made, inspectors must copy facility records that document the observations. When needed, inspectors also must include remarks in the inspection software to provide further information on inspection observations. See Section 2.8.10, Copying Records during Inspections and Using Remarks in the MQSA inspection procedures for more information.

f. Performance Standards

Inspection Performance Standard: In accordance with contract requirements, the contractor shall conduct an annual inspection of all designated, non-Federal mammography facilities within the state.

Inspection Performance Measurement: The Government will measure compliance with contract inspection requirements by reviewing inspection records and conducting joint State-Federal inspections (audit inspections). Results of all FDA quality assurance reviews will be furnished to the contractor. A sample of inspection records will be reviewed by FDA to verify that the required data and information are complete and accurate. During each twelve (12) month period, the FDA Regional or District office will request the Contractor to send a minimum of two inspection reports with all inspection films for each certified inspector. The reports will be selected at random by the FDA and all records and films will be returned to the Contractor at the completion of the audit.

Action: If FDA finds an inspection record to be unacceptable, the Contractor will be advised and given an opportunity to correct or submit a new inspection record. Each instance whereby the Contractor fails to submit or correct the required result report shall result in withholding of invoice payment until the Contractor submits or corrects the required reports.

Compliance Actions under State Authority – MQSA Compliance Actions are not provided for

under this contract. However, the Contractor may wish to pursue any necessary compliance follow-up to observations subject to the State's jurisdiction. If the Contractor pursues compliance follow-up under their State's jurisdiction, the following procedures apply:

1. Adverse Action Taken Against a Facility under State Authority

The Contractor shall report to the RRHR or other designated contact, any adverse action taken against a facility under State authority within ten (10) working days of the event in instances where a significant observation has occurred that would result in FDA taking action under MQSA. An adverse action could include, but is not limited to, the following:

- Facility license suspension (temporary or permanent),
- Facility license revocation, restrictions or similar sanctions, fines and penalties (civil or administrative),
- Cease and desist orders,
- Civil money penalties or fines,
- Orders requiring additional mammography review or patient notification (see 21 CFR 900.12(j) for a description),
- Remedial or corrective action plans required by State authorities for serious violations (examples being State violations equivalent to MQSA Level 1 violations or any violations considered serious by the State that would also be MQSA violations),
- Prosecution and convictions under State laws relating to fraud and abuse, false billings or kickbacks, and
- Other State action(identify and provide description).

2. Providing Adverse Action Information (See Attachment 9)

The FDA is required, pursuant to MQSA, to compile certain information about mammography facilities, and make it available to physicians and the general public (42 U.S.C. 263b(1)), who should find this information useful in evaluating the performance of mammography facilities. The report, submitted to Congress annually, will include explanatory information necessary to help in the interpretation of the information provided. One such required category of information is a list of mammography facilities against which States have taken adverse actions. In addition, FDA is also seeking information about which States have instituted a patient notification rule applicable to mammography.

Contractors shall report, in the progress report, both adverse actions and patient notification information taken under State or MQSA authority.

The information for each cited mammography facility should include the following items:

- a. Name and address of the mammography facility.
- b. MQSA facility identification number if known.
- c. Current status of the facility.
- d. Summary of the problems that initiated the State action, including dates of inspections, violations cited, and other pertinent information. When applicable,

use “reason for action” codes at the bottom of the adverse actions report form.
e. Description of the State action (include copies of orders or letters to the facility that were used to inform them of the action).

Performance Standard: The contractor shall report to the RRHR or other designated contact any adverse action taken against a facility under State authority within ten (10) working days of the event in instances where a significant finding has occurred that would result in FDA taking action under MQSA.

Performance Measurement: The Government will measure compliance by reviewing the completeness of monthly reports.

Action: Each instance whereby the Contractor fails to meet the contract standards for adverse action reporting requirements shall result in withholding of invoice approval until the standards are met.

Inspector Certification Training - All inspections under this contract shall be conducted by personnel who are fully certified by the FDA to perform inspections under MQSA. The training for inspector certification will consist of courses taught under the auspices of the FDA and shall require the inspector to pass specific examinations. All new inspectors shall meet the educational requirements for new MQSA inspectors outlined in the “MQSA Inspector Initial Training-Qualification Process” document (Attachment 2) and the “MQSA Inspector Training” chart (Attachment 3) before taking the MQSA training courses.

In determining a State’s need for a trained inspector, FDA shall reference the “DMQS’ State Contract Policy for Training MQSA Inspectors and Assigning Inspection Equipment” (Attachment 4).

NOTE 1: Unless notified and agreed upon otherwise, all mentoring shall be completed within 90 days after completion of course III.

NOTE 2: The contractor shall ensure that newly certified inspectors complete a minimum of 24 inspections within 24 months.

NOTE 3: The contractor is responsible to ensure that their inspector trainees put forth due diligence and effort in completing the Inspector Training courses. FDA may exercise the right to withhold Inspector Trainee course payments for failed efforts in completing portions of the course.

Maintaining Certification of MQSA Inspectors

MQSA Inspector Certification is granted by the FDA. To maintain their certification, MQSA inspectors shall fulfill the following:

1. Mammography Education Units - Inspectors shall participate in continuing education activities. The current requirement is for each certified inspector to teach or earn a minimum of fifteen (15) mammography education units (MEUs) during a 36-month period in accordance with the "Mammography Continuing Education (MEU) Policy For Mammography Quality Standards Act (MQSA) Certified Inspectors" (Attachment 5).

According to the MEU policy, inspectors shall submit documentation (i.e., certificate copies) of their attendance and completion of continuing education courses to ORA's Division of Human Resources Development (DHRD) for state inspectors and ORA's Office of Partnerships (formerly DFSR) for FDA inspectors. This documentation shall be used to validate the MEUs earned for the purpose of maintaining certification.

2. Minimum Inspection Requirements - Inspectors shall perform a minimum of 24 (twenty-four) inspections within a 24-month period to remain proficient in conducting MQSA inspections and to maintain an "active" certification status as set forth in the "Continuing Experience Policy for Mammography Quality Standards Act (MQSA) Certified Inspectors (9/13/00)" (Attachment 6).

3. Annual Audit - MQSA Inspectors shall receive a satisfactory Audit from a certified MQSA auditor during each federal fiscal year (01 October - 30 September) or satisfactorily complete re-remediation requirements if audit results warrant them. The audit shall consist of observation of the physical measurements completed on the mammography systems; film processor and darkroom; examination of the inspector's evaluation of QA, personnel and medical records, medical physicist report(s) and medical audit system and entering the inspection data in the Mammography Program and Reporting Information System (MPRIS). Of equal importance will be the auditor observing the inspector's personal interaction with facility personnel and the inspector's ability to present serious and significant observations during the discussion with facility management. Serious and significant observations (if applicable) are those that would impact upon the facility's ability to accurately diagnose breast cancer. Additional audits (or mentoring) may be performed if serious deficiencies are observed in any area of the inspection process. Independent audits may be performed only in rare situations. These will be reserved for situations where serious problems that cannot be observed during a joint audit are suspected and will be conducted only after the auditor obtains concurrence from the RRHR, Office of Partnerships, and DMQS.

4. Review of MQSA Inspection Records - The auditor shall review a sample of the MQSA Inspection Records submitted by each certified inspector during each Federal fiscal year. These records will be reviewed as additional indicators of performance problems. If such a review indicates performance problems, additional audits or remedial training may be scheduled to correct the observed deficiencies.

5. Statement of Conduct - Each inspector shall acknowledge and follow the "Statement of Conduct for MQSA Inspectors" (Attachment 7).

6. Review Requirements - MQSA Inspectors shall keep up to date on MQSA policy changes and other important issues related to MQSA inspection procedures by logging on to the MPRIS system on a regular basis, but not less than once a month, to review all inspector e-mail, software upgrades, and other pertinent documents.

NOTE (1): Training on the use of the computers, software, and programs will be provided through training courses, teleconferences, workshops, the RRHR, DMQS staff and FDA MQSA auditors.

NOTE (2): The contractor shall notify DMQS when an inspector leaves the MQSA inspection program to coordinate the return of FDA issued inspection test equipment, FDA issued IT equipment, and FDA issued inspector identification card. The State, through its Progress Report, notify DMQS of any changes to an inspector's status. The State may also give advance notice of the change in the inspector's status to the RRHR.

Inspection Questions/Problems - Any questions or problems resulting from the use of the inspection procedures or testing equipment furnished by FDA shall be reported to the FDA RRHR and DMQS. DMQS may be reached by telephone and/or laptop via the following:

- DMQS Help Desk phone line (08:30am-4:30pm EDT): 800-838-7715
- DMQS Help Desk e-mail: MQSAhotline@HCMSLLC.com

Training Performance Standard: The contractor shall submit documentation (i.e., certificate copies) of their inspector's attendance and completion of continuing education to the DHRD. This documentation shall be used to validate the MEUs earned for the purpose of maintaining certification.

Training Performance Measurement: A random sample of the MQSA Inspection Records submitted on a federal fiscal year basis by each certified inspector shall be reviewed. If such a review indicates performance problems, additional audits or remedial training may be scheduled to correct the observed deficiencies.

Action: Serious and significant deficiencies in any area of the inspector process (inspection requirements, MEUs, etc.) that would impact upon the facilities ability to accurately diagnose breast cancer could result in that inspector being mentored or receiving remedial training. Consequently, the contractor shall not invoice for these inspections until the deficiencies are resolved.

NOTE: THE FDA RESERVES THE RIGHT TO INACTIVATE CONTRACTOR PERSONNEL IN PERFORMANCE OF THIS CONTRACT AT ANY TIME.

Equipment and Calibration: FDA shall furnish applicable equipment including reference film and laptop computers for use in this contract in accordance with the respective policies for the issuance of inspection test equipment and laptop computers. If the Contractor wishes to use their

own equipment (such as densitometers or sensitometers), the Contractor shall obtain approval by DMQS. In addition, the Contractor shall maintain their equipment within calibration and compatibility with program standards.

Effective January 1, 2013, FDA no longer provide annual calibration of the FDA provided sensitometers and densitometers used in support of the MQSA inspections.

II. Dissemination of Information

The State inspector shall notify the facility of the preliminary inspection results during the discussion with facility management in accordance with FDA Compliance Program 7385.014. A copy of the MQSA Facility Inspection Report shall be:

- left at the facility at the completion of the inspection, or
- sent to the facility no later than five (5) working days from the date of the inspection.

III. Quality Assurance Measurements

A. Contractor performance will be evaluated by FDA throughout the duration of the contract. This will be accomplished by various methods including review of inspection records and joint State-Federal inspections (Joint Audit Inspections). Independent audits may be performed only in rare situations. These will be reserved for situations where serious problems that cannot be observed during a joint audit are suspected and will be conducted only after the auditor obtains concurrence from the RRHR, ORA Office of Partnerships and DMQS. Results of all FDA quality assurance reviews that pertain to the Contractor will be furnished to the Contractor.

B. The FDA will also monitor inspector performance. The FDA will provide the Contractor with relevant information on the monitoring of inspector performance for the purpose of identification of any area where improvement of such performance is required. Please see attached "Complaint Resolution Process" (Attachment 8).

C. A sample of inspection records will be reviewed by FDA to verify that the required data and information is complete and accurate. During each twelve (12) month period, the FDA regional or district office will request the Contractor to send a minimum of two inspection reports with the inspection films for each certified inspector. The reports will be selected at random by FDA and all records and films will be returned to the Contractor at the completion of the audit. If FDA finds an inspection record to be unacceptable, the Contractor will be advised and given an opportunity to correct the report or submit a new inspection record.

SECTION D – PACKING AND MARKING

This section is not applicable to this contract.

SECTION E – INSPECTION AND ACCEPTANCE

E-1 – 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, Rockville, Maryland 20857.

52.246-4 Inspection of Services – Fixed Price

- (a) *Definition.* “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 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 re-performance, the Government may—
- (1) Require the Contractor to take necessary action to ensure that future performance conforms to contract requirements; and
 - (2) Reduce the contract price to reflect the reduced value of the services performed.
- (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—
- (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
 - (2) Terminate the contract for default.

SECTION F – DELIVERIES OF PERFORMANCE

F-1 – Period of Performance

The contract will be from the effective date of award for 12 months plus three option years.

F-2 – Reports/ Deliverables

The contractor shall submit the following reports:

A. Inspection Reports

The Contractor shall complete the computer generated inspection record. Inspection records shall be submitted to the FDA's central computer system via telecommunication using the FDA supplied portable computer (or Contractor supplied computer equipment, with approval by FDA).

NOTE: (1) Complete Inspection Reports and supporting documentation must be submitted no later than thirty (30) working days after an inspection.

NOTE: (2) The contractor shall maintain, in either electronic or paper form, a copy of the MOSA Facility Inspection Report and the Inspection Detail Report for the duration of the current contract. Both of these reports can be created using the FDA supplied portable computer (or Contractor supplied computer equipment, with approval by FDA) using the FISS software. If maintained in electronic form, these reports must be kept in a location other than on the computer used to conduct the inspection.

B. Progress Reports

The Contractor shall submit to the Government technical reports describing progress of the program electronically via MPRISweb (Mammography Program Reporting & Information System) <https://mpris.fda.gov/MPRISWeb/user/login.jsp>

The report must be used to 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
 - Inspector name and ID
 - Date uploaded to DMQS

- Level(s) of observations
2. Cumulative Inspections Performed - A cumulative total of the number of inspections performed since the beginning of the contract period of performance.
 3. Facility Status changes – A list of the facilities with status or address changes, including:
 - Facility name
 - Address
 - Identification number
 - Date inspected
 - Inspector
 - Change
 4. State Adverse Actions – The contractor shall report any action taken at the state level against mammography facilities. If there was no adverse action taken, the contractor shall check “no”.

The contractor shall report both adverse actions and patient notification information in the monthly progress report. The contractor shall report only those state cases that are comparable to those that could be the subject of adverse actions under MQSA.

The following information for each cited mammography facility shall be captured on the Adverse Actions Report form:

- a. Name and address of the mammography facility.
 - b. MQSA facility identification number if known.
 - c. Current status of the facility.
 - d. Summary of the problems that initiated the State action, including dates of inspections, violations cited, and other pertinent information.
 - e. Description of the State action (include copies of orders or letters to the facility that were used to inform them of the action).
5. Work to be Performed - A brief discussion of the work to be performed during the next month(s).
 6. Changes to Inspector Information - Changes in Inspector status, phone numbers, mail addresses, email addresses, and/or names.
 7. Current problems – Provide a brief synopsis of problems that are being encountered (or were encountered), proposed corrective action, as well as a point of contact and telephone number.

In addition to the electronic submission, progress reports shall also be prepared and submitted along with the signed invoices via email (preferably), facsimile or mail within fifteen (15) working days after each month to your FDA Contract Officer (your point of contact is listed in the first page of MQSA contract). Progress reports should be sent by only one method (i.e. if a report is sent via email, there is no need to also send it by fax or hard copy).

FDA Contracts Office

Food and Drug Administration
State Contracts and Compliance, HFA-500
Attn: Contracting Officer
5630 Fishers Lane, Room 2113
Rockville, Maryland 20857

Fax: (301)827-7106
e-mail: Yared.Girmai@fda.hhs.gov
POC: Yared Girmai
Phone: 301-827-7117

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

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:

Contracting Officer Representative (COR):
Mei-Ying Li
301-796-5903
Meiying.Li@fda.hhs.gov

Co-Contracting Officer Representative: Regional Radiological Health Representative (RRHR):

Northeast Region: George Allen Jr. at: george.allen@fda.hhs.gov

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

The COR and Co-COR 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 Contracting Officer Representative and Co-Contracting Officer Representative 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 Contracting Officer Representative or Co-Contracting Officer Representative 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: Augustinus Ong

Title: Administrator, Radiological Health Section

Email Address: Augustinus.Ong@dhhs.state.nh.us

Telephone: (603) 271-4588

G-3 - Invoice Submission

Fixed Price - Quarterly

The Contractor shall submit vouchers or invoices in accordance with the FAR 52.232-25 "Prompt Payment (OCT 2008)," and FAR 52.232-33 "Payments by Electronic Funds Transfer – Central Contractor Registration (Oct. 2003).

A. In accordance with the above clauses, your invoices should include the following:

- Name and address of the Contractor
- Invoice date and Invoice Number
- Contract or Purchase Order Number which authorizes supplies/services
- Shipping and Payment terms
- Name and address of Contractor Official to whom payment is sent
- Bank Name of the financial institution receiving payment,
- Routing transit number of the financial institution receiving payment,
- Name and phone number of the person to notify in the event of a defective invoice
- Tax Identification Number
- DUNS

All payments will be made by Electronic Funds Transfer (EFT) and the Contractor shall be responsible for providing any changes to the Central Contractor Registration (CCR) database.

B. Travel for contract purposes – All travel negotiated and agreed to under this contract for training, contract meetings with FDA field office(s), etc. will be accomplished under state travel authorities and be reimbursed to the contractor through the contract voucher/invoice.

Invoices with reimbursable travel costs must include a list of expenditures or receipts for associated costs, such as incurred per diem, airfare, ground transportation costs, etc.

Note: Salary costs are not reimbursable expenditures while receiving Continuing Education.

C. An original and one (1) copy of invoices shall be submitted to the attention of the designated Contracting Officer at the following address:

- DHHS/FDA/OAGS
- State Contracts and Compliance
- 5630 Fishers Lane, HFA-500
- Rockville, Maryland 20857

D. In addition, one informational copy of all vouchers shall be submitted to the Co-Contracting Officer Technical Representative in the Regional/ District Office designated in Section G.

G-4 - Government Furnished Property – Authorization - Transfer

A. The Contractor is authorized the retention and use of the equipment listed below. The accountability of this equipment is hereby transferred to this contract from Contract No. N/A.

Items

1. Field Inspection Kits
2. Laptop
3. Printer

C. The inspection record format will be furnished to the Contractor with the portable computer system. With the approval of the Division of Mammography Quality Standards (DMQS), the Contractor may use their own computers and software for the recording of inspection data, provided that the inspection data is the same as that produced by FDA supplied equipment and software. The Contractor shall obtain approval from DMQS before loading any state owned software on the FDA computer.

D. Field Inspection Test Equipment (field inspection equipment and MQSA Inspector ID card) return - Upon the departure or reassignment of an inspector, ALL FDA provided non-IT inspection test equipment shall be returned to DMQS within 30 days of the departure or reassignment of an inspector to the following address:

U. S. Food and Drug Administration
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health (OIR)
Division of Mammography Quality Standards (DMQS)
10903 New Hampshire Avenue
WO62 - 3101
Silver Spring, MD 20993-0002

Telephone Number: (301) 796-5710

Attention: Calibration Laboratory

E. IT Equipment (laptop, printer and carrying case) Return -- Upon the departure or reassignment of an inspector, ALL FDA provided IT equipment shall be returned to DMQS within 30 days of the departure or reassignment of an inspector to the following address:

U. S. Food and Drug Administration
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health (OIR)
Division of Mammography Quality Standards (DMQS)

MPRIS Computer Support
 Food and Drug Administration
 10903 New Hampshire Avenue
 WO66 - 4525
 Silver Spring, MD 20993-0002
 Telephone Number: (301) 796-6633

F. Additional Equipment - Unless stated otherwise, no other equipment or supplies are provided under this contract.

G. Equipment/Laptop Security - Each user of the Mammography Program Reporting and Information System (MPRIS), whether a State inspector or a State supervisor, must read and accept annually the MPRIS Rules of Behavior (RoB) (Attachment 10), which are available to each user after logon to the MPRISweb software application.

The MPRIS RoB, which is required by security regulations for both FDA and the Department of Health and Human Services (HHS), details system responsibilities, policies for system use, and the rules for the use of all MPRIS applications. FDA maintains a record of every user's acceptance of the RoB.

Section 4 in the MPRIS RoB explains in detail the rules for the use of the FDA-furnished MQSA laptops. In particular, please note:

- Section 4.2, *Connection to the Internet*, states, "Users can access the Internet only in order to visit sites such as the FDA public web site and MPRISweb."
- Section 4.5, *Use of Government Equipment*, states, "The use of MQSA-furnished government equipment is restricted to official FDA business only."

Additionally, State personnel must not install software on FDA-issued MQSA laptops by State personnel without first obtaining the written permission of the MPRIS Program Manager, Division of Mammography Quality Standards (DMQS), FDA.

These rules and policies prohibit the configuration and use of FDA-issued MQSA inspector laptops, and the installation of software on them, for any non-MQSA usage, such as connecting to the Internet.

H. In addition to the applicable Government Property Clause in Part II, Section I, the contractor shall comply with the provisions of HHS Property Management Review Guide, which is incorporated by reference. This handbook is available on the HHS website:
http://www.knownet2.com/logistics/hhs_property_management_review_guide.htm

The Contractor shall inventory all accountable Government property and submit a list of that property to the Contracting Officer annually on the anniversary of contract award and within 90 days after completion or termination of the contract. The inventory list, reflecting each item of accountable property as a separate line item, shall contain the following data elements:

1. Barcode/tag number
2. Item name/description
3. Manufacturer's name
4. Manufacturer's model number
5. Manufacturer's serial number
6. Unit cost
7. Date received/inventoried
8. Contract number
9. Remarks (optional)

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.gov/>.

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

a. 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.

b. 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.

c. 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.

d. Contractor:

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

e. Personal privacy information:

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

f. Pre-decisional information:

Pre-decisional 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. Pre-decisional 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 pre-decisional may include confidential commercial or trade secret information.

g. 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).

h. 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 4). 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 and Contracting Officer. Any new contractor and subcontractor employees assigned to this contract shall sign the form, and the contractor shall submit 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 or District Technical Advisor) 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.

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.

This clause applies to the contractor, any subcontractors, and any consultants. Non-public information will be released to only those persons authorized under this contract.

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

1. Documents to be transmitted internally shall be transmitted on a person-to-person basis between approved employees only.
2. 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.
3. 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.
4. A receipt log shall be maintained for all external transmittals.
5. The contractor shall follow up all transmittals in order to obtain signed receipt within five (5) business days of transmittal. Failure of recipient to furnish such receipt shall be reported to the FDA Physical Security Office within ten (10) business days of transmittal.

If 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 may 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.

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).

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/>

<http://www.hhs.gov/policies/hhsar/>

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

Reg	Clause	Date	Clause Title
FAR	52.202-1	Jan-2012	Definitions
FAR	52.203-3	Apr-1984	Gratuities
FAR	52.203-5	Apr-1984	Covenant Against Contingent Fees
FAR	52.203-6	Sep-2006	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	Oct-2010	Anti-Kickback Procedures
FAR	52.203-8	Jan-1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	Jan-1997	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-12	Oct-2010	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Apr-2010	Contractor Code of Business Ethics and Conduct
FAR	52.204-4	May-2011	Printed or Copied Double-Sided on Recycled Paper
FAR	52.204-7	Dec-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
FAR	52.215-2	Oct-2010	Audit and Records - Negotiation
FAR	52.215-8	Oct-1997	Order of Precedence - Uniform Contract Format
FAR	52.215-15	Oct-2010	Pension Adjustments and Asset Reversions
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	52.216-5	Oct-1997	Price Redetermination - Prospective
FAR	52.216-7	Jun-2011	Allowable Cost and Payment
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 Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.222-36	Oct-2010	Affirmative Action for Workers with Disabilities
FAR	52.222-37	Sep-2010	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.222-50	Feb-2009	Combating Trafficking in Persons
FAR	52.222-54	Jul-2012	Employment Eligibility Verification
FAR	52.223-6	May-2001	Drug-Free Workplace
FAR	52.227-1	Dec-2007	Authorization and Consent
FAR	52.227-2	Dec-2007	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.229-4	Feb-2013	Federal, State and Local Taxes (State and Local Adjustments)
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

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	52.233-2	Sep-2006	Service of Protest
FAR	52.233-3	Aug-1996	Protest After Award
FAR	52.233-4	Oct-2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr-1984	Notice of Intent to Disallow Costs
FAR	52.243-1	Aug-1987	Changes - Fixed-Price, Alternate I (Apr 1984)
FAR	52.245-1	Apr-2012	Government Property – Alternate I (Jun 2007)
FAR	52.246-25	Feb-1997	Limitation of Liability - Services
FAR	52.249-4	Apr-1984	Termination for Convenience of the Government (Services) (Short Form)
FAR	52.253-1	Jan-1991	Computer Generated Forms

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

HHSAR	352.201-70	Jan-2006	Paperwork Reduction Act
HHSAR	352.202-1	Jan-2006	Definitions
HHSAR	352.203-70	Jan-2006	Anti-Lobbying
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	352.239-72	Jan-2010	Security Requirements for Federal Information Technology Resources
HHSAR	352.239-73	Jan-2010	Electronic and Information Technology Accessibility
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 thirty (30) days.

52.217-9 Option to Extend the Term of the Contract (MAR 2002)

a) The Government may extend the term of this contract by written notice to the Contractor within 15 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days 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.

SECTION J – LIST OF ATTACHMENTS

The following attachments are incorporated into this contract:

Attachment 1 - Computer Equipment Specifications for MQSA Inspections

Attachment 2 - MQSA Inspector Initial Training-Qualification Process and Nomination For

Attachment 3 - MQSA Inspector Training Chart

Attachment 4 – DMQS’s State Contract Policy for Training MQSA Inspectors and Assigning Inspection Equipment (Updated: 1/2013)

Attachment 5 -Mammography Continuing Education (MEU) Policy for Mammography Quality Standards Act (MQSA) Certified Inspectors (Updated: 1/2013)

Attachment 6 – Continuing Experience Policy for Mammography Quality Standards Act (MQSA) Certified Inspectors (Updated: 1/2013)

Attachment 7 - Statement of Conduct for MQSA Inspectors (Updated: 1/2013)

Attachment 8 – Complaint Resolution Process (Updated: 1/2013)

Attachment 9 – MQSA Progress Reporting

Attachment 10 – MRPIS Rules of Behavior

Attachment 11 – Disclosure of Lobbying Activities

Attachment 12 – Contractor Certificate and Government Grant of Commission

Attachment 13 – Contractor’s Commitment To Protect Non-Public Information (NPI) Agreement