MAMTP Project Review

To: Dr. Alan Rudolph – Division Director
cc. Dr. David Hodge – Program Manager
cc. Dr. Anne Hultgren -- R&D Branch Chief

From Dr. Segaran Pillai – Chief Medical and Science Advisor

Summary of MAMPT Project Review

Project:	**Multi-Application, Multiplex Technology Platform** (MAMTP)
Company:	NVS Technologies, Inc.
Report:	Summary outline of MAMTP Project Changes and Impacts
Project Kick Off:	June 2010
Project Reviewed Date:	May 30th, 2013
Report date:	June 4th, 2013

Content

1. Purpose of this report

The purpose of this report is to capture the progress and impact associated with the modifications based on preferences shared by DHS S&T and other Federal

IPT Stakeholders since project inception through May 2013. The intent of this report is to document the reasons behind each change, the month and year of its occurrence, and the associated cost and timeline shifts.

2. Overall project goals

The original requirements for the MAMPT were derived through a collaborative effort with multiple federal partners (CDC LRN, DoD AFSG, DHS USSS, DHSA OHA, DHS CRSO, DHS CBP, DHS FRG, CDC GDD, FDA CFSAN, USDA, EPA etc.). These requirements called for the development of an easy to use, low cost, robust, high performance multiplex molecular detection system. The system specifications described in the BAA were necessarily ambitious, as they laid out a combination of key critical performance requirements that cannot be met by any existing technology: a system cost of no more than $25K, with a capability to perform up to 100-multiplexing semi-quantitative assay detection, and easy sample-to-answer workflow.

The MAMTP project contract was awarded to NVS on May 2010, where the following general technology requirements were reviewed with and confirmed by DHS S&T during the project IPT kick-off meeting on May 17, 2010:

- The system must be able to perform at least 100 tests or detect 100 targets in a single analysis simultaneously from a single sample

- The system must provide rapid results within 90 minutes from sample input to answer
- The system must be able to handle human clinical samples and Veterinary samples (blood, CSF, stool, respiratory secretions, urine, etc.) and non-clinical samples (environmental, food, white powders, etc.) Note: Due to funding constrains, it was decided that NVS will focus on environmental sample when the contract was executed.
- The sample preparation component can be a separate unit to accommodate different sample matrices to support optimal sample processing and extraction efficiency
- The processed sample must be contained across the analysis process and the system must integrate processes for minimal sample contamination through the use of a closed, self-contained consumable to prevent amplicon contamination and provide easy disposal of biohazard material
- The system must integrate the entire work flow with an intuitively easy-to-use and difficult to misuse systems concept from sample input/processing to answer, including automated sample preparation, analysis and reporting
- The system must have integrated IT capability to track patient, animal, and appropriate sample related information and demographics, including the ability to interface bi-directionally with a laboratory information system.
- The system must be able to generate test reports electronically in a standardized method

with patient or sample information and the ability to transmit results electronically.
- The system must be robust and easily re-locatable without requiring realignment or calibration after moving.
- The system must be able to detect RNA and DNA organisms simultaneously from the same sample.
- The system must have nucleic acid detection sensitivity and specificity that is, at least, equivalent to real-time TaqMan PCR.
- The system must be a competitively priced (less than $25,000) with an inexpensive consumable less than $100/sample).
- Ideally the system/platform will utilize FDA cleared technology for analytical measurement to facilitate in-vitro diagnostic applications.
- Explore the ability to have USDA and Center for Veterinary Biologics licensure.

The following capabilities of the test system are desirable but not mandatory:

- The system can be used to test for both nucleic acid (DNA and RNA) and protein (Antigens/Toxins) detection (excludes prions).
- Consumable reagents will be stable for 12 months at ambient temperature.
- The system will be operable by a single technician.
- The system will have a footprint of < 9 ft^2.

3. MAMTP Project Associated Changes, Modifications and Benefits

Over the course of 36 months, the following project changes were made to accommodate the government (DHS S&T and IPT members) preference and recommendations as the project evolved:

February 2011

Description of Change:	***Benefit / Reason of Change Request:***
a. Change sample type from environmental samples only to include human clinical samples; preference is for product development to be geared towards FDA approval to support clinical diagnostic applications as well.	a. FDA approved platform enables the use of human samples for used by the CDC's Laboratory Response Network (LRN) to detect biothreat agents in people to support clinical diagnosis. Additionally, an FDA approved platform is expected by other government agencies as well as private sector use to perform testing of nonhuman samples (e.g. USDA, FDA, Private Physician Office, Hospitals etc.). FDA approval would also increase product adoption in the commercial sector, which would increase production

	volume, allowing the government to take advantage of economies of scale. In addition to the above, this will also allow for Point of Care use, and contribute to the Enhancement of National BioSurveillance Strategy and Building a Resilient Nation
What NVS had to do: Hire an experienced manufacturing and quality manager to develop the infrastructure, processes and procedures necessary to develop products under Quality Systems Regulation (QSR), which is a requirement for FDA-clearance, and engage all R&D personnel to follow QSR during product development (which required extensive training of most staff and extensive documentation and repeated testing and evaluation of each component to ensure system reproducibility).	
Project Impact: Staffing: NVS had to hire QA/Ops people to help plan out and implement QSR and FDA compliance. Material: QSR management software Infrastructure: Develop and implement a materials database. Timeline Impact: None **Budget Impact: $1.5M** – As per NVS, developing and implementing QSR compliancy requires approx. 10% overhead in general to allow for R&D staff to follow the processes and procedures of design control (e.g. development and documentation of	

specifications written in accordance with QSR guidelines, the keeping of a design history file, setting up and keeping a document control system, documenting all critical decisions and the reasons why they were made, documenting design reviews, etc.).
Achievements / Status: NVS developed high-level plans around April 2011, and formally entered design control at the beginning of December 2012. Design control, quality systems development, and training were required throughout the project life. To date NVS has implemented a document control system, a material management system, and a design control system, and continues to take all necessary steps towards a GMP compliant manufacturing facility.

January 2012

Description of Change	***Benefit / Reason***
a. The need for Point of Care use of the technology to support day to day use in addition to federal partners use, called for a robust and easy to use sample prep process to complement the technology. NVS had a sample prep solution that appeared to be better, cheaper and easier to use than currently available off the shelf solutions.	a. Reduces cost per sample by developing a more cost effective sample prep method. Also, increases market acceptance by reducing product complexity and workflow simplification. b. Using an upper respiratory viral panel allows NVS to travel a clear, well-trodden path through the FDA clearance because of the availability of

b. Transition from environmental samples/BT detection only, to comprehensive infectious diseases applications was requested. First panel to be an upper respiratory panel.	predicative devices for comparison, which will reduce the clinical trial period, shorten FDA review and approval time and thereby save significant cost.
What NVS had to do: NVS had to hire dedicated sample prep chemists and change development plans for sample prep chemistry, design additional assays and rework panel design.	
Project Impact Staffing: NVS had to hire sample prep chemists to complement the existing chemistry team. Material: NVS had to acquire sample prep materials (reagents and a commercial instrument to use as a benchmarking standard during development). Develop and order all new primers and probes for the new upper respiratory panel. Infrastructure: Needed to implement lab changes and capability to accommodate sample prep development activities. Timeline Impact: None **Budget Impact: $0.5M**	
Achievements / Status: NVS successfully developed a bead-based sample prep methodology capable of processing clinical nasal and oral pharyngeal swab samples with equal or better efficiency than commercially available sample prep kits. NVS successfully designed a cost-effective upper respiratory panel with high sensitivity, and specificity, with a wide dynamic range.	

January 2012

Description of Change	***Benefit / Reason***
a. DHS PM Mr. Chris Russell reduced allotted project budget by 33% for the active period for redirection to support other projects.	a. As per NVS, COTR Mr Chris Russell's indicated to them that this was due to some unexplained "temporary government budget issues"
What NVS had to do: As per NVS, this slowed down operations and stopped their recruiting process, and in some cases, stopped material orders to balance out the sudden budget shortfall. Delayed their scheduled facility move, and further postponed needed hires.	
Project Impact Staffing: Postponed hires Material: Delayed procurement of required project material and limited laboratory work. Infrastructure: None Timeline Impact: 2-4 months schedule delays due temporary slow-down. **Budget Impact: Budget was reduced by 33% from $5.2M down to $3.5M**	
Achievements / Status: Budget issues were temporarily resolved as I managed to find some dollars for the project to continue after temporary delay.	

May 2012

Description of Change	***Benefit / Reason***
a. DHS S&T and IPT members shared our preference for a two cycling parameter to reduce platform cost, increase life cycle and ability to leverage knowledge base of existing TaqMan assays.	a. Leveraging vast existing knowledge base of TaqMan assays and bioinformatics investments b. Decreased platform and reagent cost. c. Increased assay robustness (decreased complexity) d. Simplified assay design e. Reduced background fluorescence
What NVS had to do: Change the approach from "flap-assay" to a "dark-assay" approach which included proving feasibility of new assay format, re-design assay panels to be compatible with new format, re-configure chip spotting, re-design image analysis algorithms for spot finding and analysis, and re-engineer consumable to accommodate all changes.	
Project Impact Staffing: None Material: Procurement of new reagents and chemicals for dark-assay design, spotting conditions and surface chemistry. Infrastructure: None Timeline Impact: 3 months. **Budget Impact: $0.6M**	

Achievements / Status:
Successfully transitioned from "flap assay" format to the new and improved "dark assay" format around November / December 2012.

July 2012

Description of Change	***Benefit / Reason***
 a. Change system from a two-module, two-consumables-based system (see image) to a fully integrated single module, single consumable system to support Point of Care use and CLIA waiver.	a. Decreased cost of system b. Simplified workflow c. Less chance of cross-contamination and increase sample integrity. d. Reduction of instrument footprint. e. Supports Point of Care Use f. CLIA Waiveable g. Single consumable – cost savings
What NVS had to do:	
Merge sample prep instrument and detection instrument into one system. This required redesigning the instrument's electronic boards, inner chassis, and consumable loading. Elimination of external computer, re-designing operating software, user interaction and usability. Merge bead-based sample prep consumable with detection cartridge. Re-design in-consumable fluidics, and instrument controls.	

Project Impact Staffing: None. Material: Re-design and re-build system sub-assembly test fixtures. New reagents and chemicals for sample prep chemists, new circuit boards Infrastructure: None Timeline Impact: 3 months to accommodate re-design period. **Budget Impact: $1.4M**
Achievements / Status: A new all-in-one instrument design and consumable design was successfully demonstrated at M6 stake-holder meeting (October 2012). New system concept has been defined; critical sub-assemblies have been built and verified.

October 2012

Description of Change	***Benefit / Reason***
 a. IPT members shared their views and preference for a further reduced cost of instrumentation and consumables. The cost targets were: • Consumable sales price needs to be $25 instead of $100/-.-	a. Accelerated product adoption due to lower cost to procure and operate and increased possibility of eventual CLIA waiver. b. Support Primary Care Physician to use and bill CMS c. Supports affordability, adoption and sustainability to support National Bio Surveillance strategy and enhance U.S. Health Care Practice

• Instrument sales cost needs to be $10,000 instead of $25,000-	d. Provide return of investment for the Tax payers

What NVS had to do:
Move away from bead-based sample prep ("cubo concept"), develop new methodology to perform simpler and less-expensive sample prep ("matchbox concept"). Re-optimize sample prep protocol and re-do proof of feasibility for reagent lyophilisation based on new sample prep formulations. All reagent SOPs had to be redone and inventory purged for introduction and testing of new sample prep reagents and chemistries. The consumables and instrument had to be completely redesigned to accommodate new sample prep process, fluidic handling, valving and controls.

Project Impact
Staffing: As per NVS, they had to hire a usability consulting firm and engineering consulting firm for quick turn-around redesign and reviews in order to avoid having to add full-time, permanent staff to perform these tasks.
Material: More clinical samples, all new test fixtures, new SLA parts, new electronic boards, new early-consumable molds for testing.
Infrastructure: Second BSL2 hood and more freezer capacity to accommodate increased number of clinical samples and reagents.
Timeline Impact: 6 Months
Budget Impact: $4.7M

Achievements / Status:
An all new fully integrated single instrument, single consumable design was presented on 30th May 2013. Consumable cost is anticipated to be reduced from $100 to $25 (75% cost reduction) and instrument

cost is anticipated to be reduced from $25,000 down to $10,000 (60% cost reduction). Entire system has been designed from the ground up to support CLIA waiver for Point of Care use to support rapid and accurate treatment of patients, reduce the cost for laboratory diagnostics tests, support federal partners (CDC-LRN, DHS USSS, DHS CBP, FDA CFSAN, USDA, CDC GDD, DHS FRG, DHS CRSO, DHS OHA, EPA etc.) in their Public Health, Surveillance and BioSecurity mission, and to support the generation of data for National Biosurveillance and Situational Awareness. 

April 2013

Description of Change	***Benefit / Reason***
a. DHS S&T issued a stop work order effective May 24, 2013 until further notice.	a. Government budget issues.
What NVS had to do: All MAMTP has been put on hold effective May 24, 2013.	
Project Impact Staffing: **TBD** Material: **TBD** Infrastructure: **TBD** Timeline Impact: **TBD**	

4. Project Change History Snap-Shot

Green boxes:	Milestone capability and achievement demonstrations
Yellow cells:	DHS change requests
Red cells:	Project impacts

	NVS Milestone Reviews and Performance Demonstrations						
	Kick-Off with DHS Definition	M2 - Review	M3 - Review	M4 - Review	M5 - Review	M6 - Review	DHS Meeting
Project Scope	**June 2010**	**October 2010**	**June 2011**	**November 2011**	**May 2012**	**October 2012**	**May 2013**
Consumable Cost	Lower than commercial	–	–	Lower than commercial design	$15.- for detection consumable	$37	$25
Instrument cost	Lower than commercial	–	–	–	$25,000.- for full system	$13,000	$10,000
System Design Approach	S/P separate from Detection	–	–	–	S/P separate from Detection	Sample-to-Answer all-in-one	Sample-to-Answer all-in-one
Detection Unit	NVS Developed	–	BB1 u-scope based	BB2 Detection unit	BB3 Detection Unit	BB5 Detection system	S-A system Design
Detection Technology	n/a	–	low-cost optics approach	low-cost optics approach	low-cost optics & electronics	low-cost optics & electronics	low-cost optics & electronics
Sample Prep Unit	Separate Off-the-shelf	–	–	–	BB S/P unit	BB S/P unit	Integrated sample prep
Sample Prep Technology	Off-the-shelf	–	–	–	Bead-based approach	Bead-based approach	Lyse & heat approach
Panel	Biothreat	Assay Design Quality	URP Assay Design Quality	URP Assay Design Quality	URP Assay Design Quality	URP Assay Design Quality	URP Assay Design Quality
Sample Matrix	Environmental	–	–	–	–	--	Nasal swab samples
Market	Government	–	–	–	Government & Clinical	Government & Clinical	Government & Clinical
FDA Approval	n/a	–	–	–	–	--	Under design control
Project Budget	Per contract	–	–	–	–	--	–

Timeline in Months

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37

	Direction Received from DHS						
Project Scope	1 **December 2010**	2 **February 2011**	3 **January 2012**	4 **May 2012**	5 **July 2012**	6 **October 2012**	7 **April 2013**
Consumable Cost	--	–	–	–	–	Lower cost to $25.-	–
Instrument cost	--	–	–	–	–	Lower cost to $10,000.-	–
System Design Approach	--	–	–	Reduce assay complexity	Convert to an all-in-one-system	--	–
Detection Unit	--	–	–	–	–	--	–
Detection Technology	--	–	–	–	–	--	–
Sample Prep Unit	--	Better than off-the-shelf	–	–	–	--	–
Sample Prep Technology	--	Better than off-the-shelf	–	–	–	--	–
Panel	--	Upper Resp Panel (URP)	–	–	–	--	–
Sample Matrix	--	Nasal Swab	–	–	–	--	–
Market	Government & Clinical	–	–	–	–	--	–
FDA Approval	Must be FDA approved	–	–	–	–	--	–
Project Budget	--	–	Reduced budget by 50%	–	–	--	All expenses on hold

Staffing Impact	Hired Quality / Mfg	Hired S/P chemists					DHS: No hire for proto line
Material Impact		S/P related matl	Slowed down procurement			All new enginering material	DHS: All materials on hold
Infrastructure Impact	Plan out QSR compliance	Lab space for S/P				More space for BSL for samples	DHS: All improvements on hold
Development Time Impact			Delayed by ~ 1-2 mths	About 6 months	Delayed by ~ 3 mths	Delayed by ~ 6 mths	Impact from 'On-Hold' yet TBD
Budget Impact	~10% additional overhead						Budget for material on hold

Final Conclusion of Review:

NVS has done a tremendous job in fulfilling our requirements. In addition they have gone out of their way to accommodate DHS S&T and IPT member's preferences and suggestions. The accomplishments to date are remarkable and the Lab tour provided by NVS was illuminating. They have a come a long way and I was able to observe all the components of the system and their functional reality. The changes made through the course of the project were critical and resulted in multiple benefits (for example, ease of use, inexpensive and integrated consumables that does sample processing and analysis, affordable and reduced platform cost, broad coverage of agents and user application, and highly flexible and easy to use system that will be CLIA waiveable technology). This will significantly contribute to affordability, sustainability and adoptability by Federal, State, Local, and Private sectors to support the National BioSurveillance Activities while providing a Return on Investments for the Tax Payers when they visit their physicians for infectious disease related reasons allowing for rapid diagnosis and lower cost for laboratory diagnostics test.

It is my recommendation that we continue to invest in this project and to ensure a successful outcome for the Nation.

AMENDMENT OF SOLICITATION/ MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES 1 | 5
2. AMENDMENT/ MODIFICATION NO. P00013	3. EFFECTIVE DATE See Block 16C
4. REQUISITION/ PURCHASE REQ. NO. See Schedule	5. PROJECT NO. *(if applicable)*
6. ISSUED BY CODE U.S. Dept. of Homeland Security Office of Procurement Operations S&T Acquisition Division 245 Murray Lane, SW Building 410 Washington DC 20528	DHS/OPO/S&T/CHEMB
7. ADMINISTERED BY *(if other than Item 6)* CODE	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

NVS TECHNOLOGIES INC
3603 HAVEN AVE SUITE A
MENLO PARK CA 940251010

CODE	FACILITY CODE
0254402600000	

(x)	9A. AMENDMENT OF SOLICITATION NO.
	9B. DATED *(SE ITEM 11)*
x	10A. MODIFICATION OF CONTRACT/ORDER NO. HSHQDC–10–C–00053
	10B. DATED *(SE ITEM 13)*

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 right to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 6 and 15, returning ___ copies of the amendment; (b) By acknowledging receipt of the amendment on each copy of the offer submitted; or (o) 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 makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION *(if required)* Net Increase: $3,200,000.00 3100000-000-35-52-01-03-000-08-02-0000-00-00-00-00-GE-OE-25-50-20411	
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(b)
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	FAR 43.103(a) 3
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor ☐is not. ☒is required to sign this document and return 1 copies to the issuing office.

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

DUNS Number: 025440260+0000

SEE MODIFICATION PAGE 3.

AAP Number: NONE DO/DPAS Rating: NONE

Discount Terms:

Net 30

FOB: Destination

Period of Performance: 04/21/2010 to 07/31/2014

Change Item 3001 to read as follows (amount shown is the obligated amount):

Continued . . .

Except as provided herein, all terms and conditions of the document referenced in Item 6A and 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*

Cheryl Cathey, Chief Operating Officer

15B. CONTRACTOR/OFFEROR 15C. 6/28/13

Cheryl Cathey
(Signature of person authorized to sign)

16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*

Shelby Buford, Jr.

16B. UNITED STATES OF AMERICA 16C. 6/28/13

Shelby Buford, Jr.
(Signature of Contracting Officer)

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

CONTINUATION SHEET	REFERENCE NO. OF AMENDMENT BEING CONTINUED HSHQDC-10-C-00053/P00013	PAGE OF 2	5

NAME OF OFFEROR OR CONTRACTOR
NVS TECHNOLOGIES INC

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)
3001	Option Period 3 Est Unit. Cost: $2,700,848 Fixed Fee: $168,116 Total Not to Exceed: $2,868.963 Total Line Item Value$14,477,263.00 Requisition No: RSRD-13-00034, RSRD-13-00063, RSRD-13-00069, RSRD-13-00082, RSRD-13-00094	

UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
		3,200,000.00

NSN 7540-01-152-8067 OPTION FORM 336 (4-86)
Sponsored by GSA
FAR (48 CFR) 53.110

HSHQDC-10-C-00053
P00013

A. The purpose of this modification is to extend the period of performance, revise the due dates of all the remaining deliverables, incorporate optional tasks 20- 23 in the Statement of Work and add funding to CLIN 3001.

1) The period of performance is extended from 04/21/2010 through 02/28/2014 to 04/21/2010 through 07/31/2014.

2) The task list and deliverables is entirely deleted and replaced with the following:

Task 10: Finalize reagent formulations (June-September 2013)
Task 11: Procure parts and test sub-components for instrument prototypes (June-August 2013)
Task 12: Pre-submission meting with the FDA to discuss regulatory approach (June-August 2013)
Task 13: Order molds for plastic consumable parts (June-August 2013)

Deliverables for September 2013	**Description**
Report on reagent formulation down-select with go/no go phase gate for full reagent testing of respiratory panel	• Using samples from the CDC, test the assays in solution phase; only retain those that show at least 10-100 copy sensitivity or are equivalent and comparable to real-time TaqMan PCR on an ABI 7500 Platform (gold-standard assay);

	show no measurable cross reactivity with near neighbors, and no measurable interference with other assays during solution phase assay multiplex. • Verify the capture probes spot down on the surface with the required positioning and shape. • Verify that the hybridization probes do not cross react on the array.
Report on results from initial discussions with FDA and detailed test plan for Task 14	• Present findings to DHS.
Prototype design review	• Review system requirements. • Review performance and testing data. • Verify system performance against specifications. • Achieve DHS approval prior to executing prototype build.

Task 14: Test finalized reagents (September-November 2013)

Task 15: Test first articles from consumable molds (October-November 2013)

Deliverable for November 2013	**Description**
Report on results of final reagent testing with go/no go phase gate to set up pilot manufacturing	Verify pilot scale manufacturing: • Make three batches of at least 50 consumables per batch,
	• Test consumable performance with spiked in samples, • Analyze date • Determine if performance is equivalent to performance of batches produced by R&D.

Task 16: Complete manufacturing documentation (November-December 2013)
Task 17: Set up pilot manufacturing for prototypes (January-February 2013)
Task 18: Build units and consumables for government testing (March-April 2014)
Task 19: Test prototype systems in-house (May-July 2014)

Deliverable for July 2014	Description
Report on and demonstrate the performance of the prototype system	• Verify assay sensitivity using spiked samples. • Determine the limits of detection for targets in panel. • Verify no cross reactivity using near neighbor samples. • Verify no assay cross-reactivity within the multiplex reaction. • Document prototype instrument reproducibility among similar target samples.

3) Tasks 20- 23 are Optional Tasks

Task 20: Develop test plan to support pilot testing (August 2014)

Cost: $181,967

Deliverable	Description
Test plan, subject to DHS approval	• Present test plan to DHS.

Task 21: Perform pilot testing in selected laboratories, e.g., CDC (September-October 2014)

$0- Performed by the Government

Task 22: Support testing and optimization during testing as required (September-October 2014)

Cost: $308,490

Deliverable	Description
Summary report on pilot testing	• Present testing results per test plan.

Task 23: Perform appropriate data analysis (November 2015)
Cost: $120,683

Deliverable	Description
Final program report analyzing data from pilot testing of prototypes	• Present final testing results. • Deliver written report of findings.

4) $3,200,000 is added to CLIN 3001.

5) The total obligated value for Option 3 has increased from $4,489,491 by $3,200,000 to $7,689,491.00.

7) The optional tasks are not funded yet. However, when the optional tasks are. funded, the total amount will be $571,160. Moreover, the Government reserves the right to execute the optional tasks as needed through a bilateral modification and extend the period of performance through November 30, 2015.

8) The total obligated has increased from $20,226,988.41 by $3,200,000 to $23,426,988.41

9) Total contract ceiling amount has changed from $21,098,624.00 by $9,116,136.00 to $30,214,760.

B) Except as modified herein, all other terms and conditions of the contract remain unchanged.

Statement of Work
For
Highly Multiplexed, Fully Integrated Quantitative Nucleic Acid Detection System

Conducted by
NVS Technologies, Inc.
for
Directorate of Science and Technology
U.S. Department of Homeland Security
Chemical and Biological Defense Division

I. ***Background***

It is vital to the biosecurity of the Nation that public health and agricultural productivity be safeguarded by quickly and reliably identifying potential pathogens at the point of outbreak or point of entry into the country. In addition, we need to guard against the ever present threat that bioterrorism agents pose to public health and force readiness, as they are typically very dangerous pathogens that can spread easily through a population. In fact, our nation spends billions of dollars a year on biosecurity and bioterrorism preparedness – the request for the 2009 CDC bioterrorism budget alone was over $1.4 billion. The key to controlling the impact of dangerous emerging infectious diseases as well as potential bioterrorism attacks is to identify and contain the outbreak as soon as possible. The currently available decentralized evaluation technology lacks specificity and sensitivity, and the few quantitative systems available have very limited multiplexing capabilities. The ability to identify and quantitate the

pathogen responsible for an infection in near real time is essential to avoid the spread of disease through rapid intervention. This capability would enable post exposure containment through initiation of quarantine measures for exposed individuals and decisions to support deterrence of further spread of disease to troops and civilian populations.

To address this critical need, NVS Technologies, Inc. (NVS) plans to develop and provide a rapidly deployable, quantitative, easy-to-use, highly multiplexed nucleic acid detection system with high specificity and sensitivity for both U.S. government and commercial sector use. This system will be ideal for distributed identification of existing and emerging infectious disease pathogens and bioterrorism/biowarfare agents. Additionally, there are many underserved or developing clinical settings that require a highly multiplexed, quantitative nucleic acid detection system with the key benefits of ease of use, low cost, ease of installation and relocation, and little to no maintenance requirements. These market opportunities include small and medium sized hospital labs and clinics, retail clinics, first responder facilities, and other distributed testing sites. For these settings, applications include the rapid and distributed detection and identification of common respiratory infections, determination of viral load, detection of antibiotic resistant pathogens, and food, animal and environmental testing.

II. ***Scope of Work***

Phase 3: Design Transfer and Verification

During this phase, the manufacturing procedures and the bill of materials will be completed to provide the documentation required for production. Pilot materials will be produced by manufacturing under R&D supervision. Documentation of the system configuration of all prototypes will be generated. Also during this phase, NVS will:

- integrate all the components and build prototype systems,
- optimize all the critical and necessary functions and reagents,
- conduct the appropriate testing and validation for the performance of each of the components,
- develop the assays,
- evaluate the full assay panel for primer-dimer and other interactions issues common in a multiplex chemistry,
- determine the robustness of the assay to identify target agents, taking into account strain diversity (inclusivity panels),
- ensure that the assays do not cross react with other agents or micro flora to yield a false positive result (exclusivity panels),
- compare the performance of the assay run on the integrated sample prep/analysis consumable to a "gold standard" run using a Qiagen Kit

extraction and ABI 7500 Dx platform to determine if they function at a comparable level,

- ensure that the IT component of the system functions to fulfill CLIA and HIPPA rules and regulations,
- make necessary adjustments to ensure the prototype meets all of the DHS performance requirements (below).

NVS will build three prototype instruments for government use and evaluation and deliver them to DHS in April of 2014. NVS will also provide 360 respiratory panel sample prep/analysis cartridges to the government for evaluation in April of 2014.

Performance Specifications:

The Performance Specifications, sometimes referred to as Target Product Profile (TPP), reflect the advice and opinions of the MAMPT IPT which consists of subject matter experts from Federal end user groups and senior science advisors at CDC, HHS, USDA, FDA, and DHS. NVS will develop (and has developed) the MAMPT to meet the requirements and targets described *post*.

Detection Capability: The system is intended to determine the presence of a biothreat agent from either clinical or environmental samples. The same hardware shall be used for either sample type, but the sample preparation steps and reagents within the consumable can vary depending on sample type. For clinical

detection panels, the system must multiplex commonly encountered diseases with relevant threat agents (depending on sample matrix) in the panels.

- The system must be able to **detect both RNA and DNA** organisms simultaneously from the same sample.
- **Assay Limit of Detection (LoD):** The system must have nucleic acid detection sensitivity and specificity that is at least equivalent and comparable to real-time TaqMan PCR on an ABI 7500 Platform.[1] The LoD provides a measure of the analytical sensitivity of an assay for a particular target and is defined as the lowest concentration of target distinguishable from negative specimens that is consistently detected in 95% of the specimen replicates. Proper determination of the LoD is critical since many of the analytical

[1] According to guidance received from the FDA, there is not a specific value, number, or concentration of a target organism required as a predicate to obtaining clinical use approval of a particular assay for infectious agents. Instead, the FDA looks at the assay in its entirety, and makes a judgment according to the ability of the end-to-end assay and platform to detect and identify targets, *i.e.*, is the detection of the particular agent producing clinical data which can be compared favorably to a 'gold standard', or other commonly acceptable reference method. In this case, the FDA has recommended that comparison to ABI 7500 TaqMan PCR is the most relevant commonly accepted reference method. The FDA does not evaluate design specifications, and is primarily interested in the clinical performance of the final diagnostic device (in which the design is finalized and locked down for manufacturing). Moreover, each diagnostic assay that is cleared or approved is evaluated independently in terms of performance and is not based on an arbitrary value from a design specification or a TPP.

validation studies, as well as the levels included in the reproducibility analysis, are based on this target concentration. Equivalent and comparable LoD for the respiratory panel is between the values of approximately 10 to 100 copies of a target analyte (about 2-20 fg DNA for viruses and 20-200 fg DNA for bacteria, depending on genome size) ***or*** as required for clearance by the FDA using the standards applicable for similar multiplexed nucleic acid diagnostic systems or platforms. Determination of the LoD for each target included in the assay menu and each specimen type is necessary. This can be accomplished by limiting dilutions of calibrated target material into a negative (non-infected) clinical matrix. The target material should be made from isolated culture material and can be calibrated using acceptable molecular approaches and expressed as colony forming unit/plaque forming unit (CFU/PFU) or genome equivalents/mL. A preliminary evaluation of LoD can be done individually then substantiated with multiple replicates using pools of multiple targets. One approach would be to prepare serial dilutions using appropriate pooled negative specimen matrix as diluent that include three to five replicates for each dilution to establish the preliminary range. A caveat here is that CFU (colony forming units) represents a term referring to the experimental determination of the approximate *infectious* amount of organism present in a sample; copy number is related to both infectious and non-infectious amount of nucleic acid targets. There can be many copy numbers present in a sample, but they may not represent

viable organisms. The report from the LoD study must clearly describe the technique used to quantify the amount of target analyte.

- **System Limit of Detection:** With all the sample preparation steps and cartridge included, the system shall demonstrate detection of samples with less than 10^6 CFUs directly from a swab sample. The detection capabilities of the system shall be equivalent and comparable to levels achievable using the same prepared samples on the ABI 7500 platform.
- The system/platform will either utilize FDA cleared technology for analytical measurement to facilitate in-vitro diagnostic applications or will pursue FDA clearance once a prototype system is integrated. For those applications that meet the definition of an *in-vitro* diagnostic (IVD), the manufacturer must address their plans for FDA approval for the IVD. ("ND products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body." [21 CFR 809.3])
- **Multiplexing Capacity:** The system must be able to detect 100 unique targets in a single analysis from a single sample. A target is recognized by a single primer and probe set; in some cases multiple primer and probe sets may be necessary to achieve reliable and robust

identification of an organism or virus. The required capability of the system is to perform 100 individual assays utilizing different primer and probe sets. Some agents will require more than one individual target assay to reach the required specificity levels, so the maximum level of agent multiplexing will vary depending on the agents within the panel. The approach to establish inclusivity should use both intact cultured organisms that undergo all pre-analytical steps, as well as pre-extracted and defined nucleic acids to significantly augment traditional laboratory testing. The pre-extracted nucleic acid target material should be made from isolated culture material and calibrated using acceptable molecular approaches and expressed as CFU/PFU and genome equivalents/mL. The evaluation should use panels designed to include different strains, laboratory isolates, serotypes, and other closely related subspecies relevant to the specimen type. It is important to note that the panel design for inclusivity should incorporate a diverse and clinically relevant specimen set. To ensure the highest quality comprehensive data is generated, the use of Government supplied materials and samples from the Public Health Actionable Assays (PHAA) program will be utilized for the studies conducted above.

- **Time to Detection:** The system must provide results within 90 minutes from sample input to answer.
- **Sample Types:** The system must be able to handle human clinical samples and non-clinical samples (environmental, food, white powders,

etc.). The sample preparation component can be supplemented with a pre-processing step to accommodate different sample matrices to support optimal sample processing and extraction efficiency.

- **Sample Containment:** The processed sample must be contained across the analysis process and the system must integrate processes for minimal sample contamination through the use of a closed, self-contained consumable to prevent amplicon contamination and provide easy disposal of biohazard material.

System Interface Requirements: The system is intended to be CLIA-waived for use in many laboratory settings, and is intended to be easy to use with minimal training requirements. For use in clinical settings, the system must comply with IT requirements for human sample diagnostics.

- The system must integrate the entire work flow with an intuitively easy-to-use and difficult to misuse systems concept from sample input/processing to answer, including automated sample preparation, analysis and reporting.
- The system must have capability to integrate appropriate IT support to track patient, animal, and appropriate sample related information and demographics, including the ability to interface bi-directionally with a laboratory information system.
- The system must be able to generate test reports electronically in a standardized method

with patient or sample information and the ability to transmit results electronically.

- The system must be robust and easily re-locatable without requiring realignment or calibration after moving.

System Cost: The system must be a competitively priced with an inexpensive consumable.

- The system should be less than $10,000 for the platform and $25 for consumables, based on appropriate quantity for procurement and use.
- The system should have minimal maintenance requirements.

Proposed Initial Panel for Phase 3 Testing

Bacteria	**Viruses**
Acinetobacter baumanii	Adenovirus B, C, E
Bordetella bronchiseptica	Corona virus 229E
Bordetella parapertussis	Corona virus HKU1
Bordetella pertussis	Corona virus NL63
Brucella spp (abortus, melitensis, suis)	Corona virus 0C43
Corynebacterium diphtheriae	Enterovirus A, B, C, D
Haemophilus influenza	Human Bocavirus
Klebsiella pneumoniae	Human Metapneumovirus A and B
Mycoplasma hominis	Influenza A
Mycoplasma pneumoniae	Influenza A - H3
Neisseria meningitidis	Influenza A - H5
Serratia marcescens	Influenza A – Hlpdm09
Staphylococcus aureus	Influenza B – Victoria

Streptococcus pyogenes	Influenza B - Yamagata
Streptococcus pneumoniae	Influenza C
Ureaplasma parvum	Parainfluenza – 1
Bacillus anthracis	Parainfluenza – 2
Burkholderia mallei	Parainfluenza – 3
Burkholderia pseudomallei	Parainfluenza – 4
Francisella tularensis	Parechovirus
Yersinia pestis	Rhinovirus A, B, C
	RSV A and B

This panel will initially be tested against upper respiratory nasal or oral pharyngeal swab samples. However, there are very limited clinical specimens available at the current time for a robust evaluation of the above panel. As this is a multiplex assay, there is no access to well characterized clinical samples or specimens for evaluation. Furthermore, clinical samples are hard to come by because most of the clinical samples are collected on a swab, and the clinical labs typically process the entire swab sample. These samples also degrade faster when they are on a swab. As such, archiving swab samples for an extended period will have limited value in the evaluation. For these reasons, the majority of samples tested will be generated using spiked samples composed of a surrogate for respiratory secretion manufactured and distributed by Bioreclamation.

Assay performance evaluation will be conducted as follows:

Controls

Controls should approximate the composition and quality of a clinical specimen in order to adequately

challenge the system. The factors regarding quality control and calibration are:

• The nature and function of the various controls included with the system. These controls shall enable the user to determine if all steps and critical reactions have proceeded properly without contamination or non-specific interference.

• Methods for value assignment (relative or absolute) and validation of control and calibrator material, if applicable.

• The control parameters that could be used to detect failure of the instrumentation to meet required specifications.

Negative Controls *Blank or no template control*

The blank, or no-template control, contains buffer or specimen transport media and all of the assay components except nucleic acid. This control is used to rule out contamination with target nucleic acid or increased background in the amplification reaction. Negative controls should be run at a justifiable frequency. The negative specimen control contains non-target nucleic acid. It reveals non-specific detection and indicates that signals are not obtained in the absence of target sequences. Examples of acceptable negative specimen control materials could include:

• Patient specimen from a non-infected individual that has been tested to exclude any of the pathogens detected by the assay.

- Specimens containing a non-target organism.

- Surrogate negative control (e.g., packaged RNA), use of artificial or contrived matrix materials used to mimic natural secretions or biological materials.

ii. Positive Controls

Positive control for complete assay. The positive control is designed to mimic a patient specimen, contains target nucleic acids, and is used to control the entire assay process, including nucleic acid extraction, amplification, and detection. For the clinical and analytical studies, a minimum of one positive and one negative external control should be run daily during the evaluation. Positive controls can be a subset of the larger assay menu and can be rotated through a pre-defined schedule. In the case of a single use/test consumable with an internal control, periodic external control testing may need to be performed with every new lot. Some examples of acceptable external positive assay controls include:

- Vaccine or prototypic vaccine strains of appropriate virus or bacteria
- Low pathogenic virus or bacteria
- Inactivated virus or bacteria
- Packaged RNA/DNA containing target sequences

Positive control for amplification/detection. The positive control for amplification/detection can contain purified target nucleic acid near the limit of detection for a qualitative assay. It controls for the integrity of the

device and the reaction components when negative results are obtained.

Using the final, locked down design of the platform, in accordance with FDA policy and practice, determination of the LoD for each target included in the assay menu and each specimen type is necessary. This can be accomplished by limiting dilutions of calibrated target material into a negative (non-infected) clinical matrix. The target material should be made from isolated culture material and can be calibrated using acceptable molecular approaches and expressed as colony forming unit/plaque forming unit (CFU/PFU) or copy number – genome equivalents/mL. For example, for a 3,000,000 base pair bacterial genome, 100 copies of a bacterial genome or "genome equivalents" represents approximately 320 femtograms. For a viral sample possessing a 30,000 base pair genome (double-stranded), 100 copies of the viral genome or "genome equivalents" represents approximately 3.2 Femtograms; for single stranded RNA viruses this value would be only 1.6 femtograms. A preliminary evaluation of LoD can be done individually, then substantiated with multiple replicates using pools of multiple targets. One approach would be to prepare serial dilutions using appropriate pooled negative specimen matrix as diluent that include three to five replicates for each dilution to establish the preliminary range.

After the preliminary LoD range is established, the preliminary LoD is confirmed by demonstrating a detection rate of 95% using a minimum of 20 independent specimens. Alternatively, performers may desire to

pool targets for the preliminary estimation and final confirmation of LoD. This approach can be taken with the understanding that developers provide justification for the number of targets included in the evaluation pool. It is important to note that pooling of multiple targets may negatively affect the LoD; thus, the justification provided by developers should indicate what steps were taken to ensure the LoD obtained in the study is accurate. The use of Probit analysis may also be used to establish LoD provided the study is appropriately designed. Additionally, an analysis to confirm the Limit of Blank (LoB) of zero using a minimum of 50 negative individual clinical specimens should also be provided.

- The assays will be tested against a *PHAA inclusivity panel* of organisms to ensure that the assays are detecting the agents (elimination of false negatives).
- Limit of detection (LOD) will be determined by spiking known concentrations of organisms followed by detection to determine what the LOD is for the assays.
- The assays will be tested against a *PHAA exclusivity panel* of organisms (background respiratory micro flora and other respiratory pathogens) to ensure that the assays are highly specific to the target organisms.
- Initial testing of the cassettes and instruments will involve the use of non-blinded panels to allow for the evaluation and refinement (if required) of the assays. Once the assays have been

sufficiently tested by NVS in this manner, blinded samples will then be employed to perform the validations. Following successful testing the platforms will then be transferred to the CDC testing laboratories, where a similar protocol will be followed, *i.e.*, the use of non-blinded followed by blinded panels. This will also be the method used at the CDC laboratories who will be supplying the materials.

Task List and Deliverables[2]

Task 10: Finalize reagent formulations (June-September 2013)
Task 11: Procure parts and test sub-components for instrument prototypes (June-October 2013)
Task 12: Pre-submission meeting with the FDA to discuss regulatory approach (June-August 2013)
Task 13: Order molds for plastic consumable parts (June-August 2013)

[2] These tasks have been delayed by up to two months compared to previously submitted timelines due to the stop work order effective as of May 24, 2013 and the recent modification of the initial panel. DHS shared with NVS on May 30, 2013 that the upper respiratory panel that will encompass both bacteria and viruses. NVS will work to get these assays developed and incorporated. The pilot evaluation of this panel will now have to encompass a larger number of organisms for testing, evaluation and optimization.

Deliverables for September 2013	**Description**
Report on reagent formulation down-select with go/no go phase gate for full reagent testing of respiratory panel	• Using samples from the CDC, test the assays in solution phase; only retain those that show at least 10-100 copy sensitivity or are equivalent and comparable to real-time TaqMan PCR on an ABI 7500 Platform (gold-standard assay); show no measurable cross reactivity with near neighbors, and no measurable interference with other assays during solution phase assay multiplex. • Verify the capture probes spot down on the surface with the required positioning and shape. • Verify that the hybridization probes do not cross react on the array.
Report on results from initial discussions with FDA and detailed test plan for Task 14	• Present findings to DHS.

Prototype design review	• Review system requirements. • Review performance and testing data. • Verify system performance against specifications. • Achieve DHS approval prior to executing prototype build.

Task 14: Test finalized reagents (September-November 2013)
Task 15: Test first articles from consumable molds (October-November 2013)

Deliverable for November 2013	**Description**
Report on results of final reagent testing with go/no go phase gate to set up pilot manufacturing	Verify pilot scale manufacturing: • Make three batches of at least 50 consumables per batch, • Test consumable performance with spiked in samples, • Analyze data • Determine if performance is equivalent to performance of batches produced by R&D.

Task 16: Complete manufacturing documentation (November-December 2013)

Task 17: Set up pilot manufacturing for prototypes (January-February 2013)
Task 18: Build units and consumables for government testing (March-April 2014)
Task 19: Test prototype systems in-house (May-July 2014)

Deliverable for July 2014	**Description**
Report on and demonstrate the performance of the prototype system	• Verify assay sensitivity using spiked samples. • Determine the limits of detection for targets in panel. • Verify no cross reactivity using near neighbor samples. • Verify no assay cross-reactivity within the multiplex reaction. • Document prototype instrument reproducibility among similar target samples.

OPTIONAL TASKS Phase 4: Perform Pilot Testing

The tasks below are not part of the contract and represent the performer's tasks in support of any government testing of the prototype. Prior to any government evaluation, NVS will do the necessary testing in-house with the prototype and will provide the data to DHS. At the current time, DHS is working with NVS to develop and optimize the technology and the respiratory

panel for government evaluation. NVS will conduct in-house testing and will provide the data package to DHS before April 2014.

The government (through the CDC) will need to perform any government testing due to the fact that the CDC is not able to transfer any of the clinical samples to NVS because of legal issues. If this package becomes available sooner, and if the prototypes are available earlier, DHS will conduct an independent testing at the CDC to understand the technology's robustness and performance at:

- Dr. Dean Erdman's lab, which is responsible for all the respiratory viruses and the GDD program except for influenza
- Dr. Steve Lindstrom's lab, which is responsible for all the Influenza testing and surveillance
- Dr. Jonas Winchell's lab, which is responsible for all the bacterial associated respiratory infections.

Potential future work, also outside of the scope of this contract is to, upon any evaluation of the prototype system by the government, have NVS take the feedback from the end users and make the necessary updates and changes/modification before finalizing the platform and assay design for manufacturing. This will be followed by in depth testing, evaluation and data collection that will encompass sensitivity, specificity, limit of detection, repeatability, reproducibility, reagent stability, etc. for FDA submission and clearance.

The CDC is not currently testing for all the possible agents that can cause a respiratory disease because of

the lack of validated tests. As NVS's multiplex chemistry-based system that has a broad pathogen screening capability becomes available for testing, DHS will have a better understanding of the positive predictive value (PPV), negative predictive value (NPV) etc. PPV and NPV can only be calculated if the prevalence of the disease (incidence) is known. Once the pre-test probability (prevalence) is known, then one can calculate the post-test probability to predict positively or negatively about the disease / incidence following the test.

"Note that the positive and negative predictive values can only be estimated using data from a cross-sectional study or other population-based study in which valid prevalence estimates may be obtained. In contrast, the sensitivity and specificity can be estimated from case-control studies."

Task List and Deliverables

Task 20: Develop test plan to support pilot testing August 2014

Deliverable	**Description**
Test plan, subject to DHS approval	• Present test plan to DHS.

Task 21: Perform pilot testing in selected laboratories, e.g., CDC (September-October 2014)
Task 22: Support testing and optimization during testing as required September-October 2014

Deliverable	**Description**
Summary report on pilot testing	• Present testing results per test plan.

Task 23: Perform appropriate data analysis (November 2015

Deliverable	**Description**
Final program report analyzing data from pilot testing of prototypes	• Present final testing results. • Deliver written report of findings.

III. Other Contract Details

1. **Period of Performance.** The period of performance for this SOW is from the contract modification award date to April 30, 2014. DHS may give subsequent extension notices to NVS in writing for further performance in accordance with the terms of this SOW.

   Travel. Regional travel and travel to Washington D.C. will be required throughout the contract period. The DHS Director and the DHS S&T Special Assistant for International Policy must approve all foreign travel in advance.

2. **DHS-Furnished Information.**

   a. DHS will provide certain DHS information, materials, and forms unique to DHS to NVS to support certain tasks under this SOW.

   b. The DHS S&T Technical Representative identified in this SOW will be the point of contact (POC) for identification of any required information to be supplied by DHS.

   c. NVS will prepare any documentation according to the guidelines provided by DHS.

3. **DHS-Furnished Facilities, Supplies, and Services.** If work at DHS-provided facilities is necessary for the services being performed under this SOW, such facilities will be provided at S&T's office in Washington, D.C. Parking facilities are not provided, however several commercial parking facilities are located near S&T's office. Basic facilities such as work space and associated operating requirements (e.g., phones, desks, utilities, desktop computers, and consumable and general purpose office supplies) will be provided to NVS personnel working in S&T's office.

4. **Place of Performance.** NVS will perform the work under this SOW in the Menlo Park, California office and as required in Washington, DC.

5. **DHS-Furnished Property.** DHS property will not be provided to NVS unless otherwise agreed in a task order issued under this SOW. In such instances, DHS will maintain property records.

   Before purchasing any individual item equal to or exceeding $50,000 that is required to support technical tasks performed pursuant to this SOW, NVS shall obtain the DHS S&T Technical Representative's prior written consent. The DHS S&T Technical Representative may lower or raise the aforementioned $50,000 threshold at his/her discretion and on written notice to NVS. If the DHS S&T Technical Representative consents to such purchase, such item shall become the property of DHS. NVS will maintain any such items according to currently existing property accountability procedures. The DHS S&T Technical Representative will determine the final disposition of any such items.

6. **Deliverables.** NVS will provide all deliverables identified in this SOW directly to the DHS S&T Technical Representative with a copy of the transmittal letter to the Contracting Officer.

   Acceptance Criteria. Deliverables shall be subject to testing, review, and acceptance by DHS to verify that each deliverable satisfies DHS's applicable acceptance criteria. "Acceptance Criteria" mean the criteria developed by DHS to determine whether a deliverable is ready for acceptance by DHS and may include, without limitation, requirements that the applicable deliverable: (i) has been completed and delivered/achieved according to this SOW; (ii) meets or exceeds the identified requirements in this SOW, including but not limited to technical specifications and performance standards; and (iii) complies with such other criteria as may be developed and agreed on by DHS and NVS. Deliverables for which DIIS wishes to develop Acceptance Criteria will be identified by DHS, in writing, prior to initiation of any work on such deliverables. DHS and NVS will agree in writing on the Acceptance Criteria associated with such deliverables.

   Correction of Nonconformities. If a deliverable fails to meet the relevant Acceptance Criteria (each such failure or deficiency is referred to as a "Nonconformity"), DHS will provide written notification to NVS of such failure. Upon receiving such notice NVS will inform DHS in writing of the costs associated with correction and proposed **actions** to correct. Corrective actions will not be undertaken until additional funding has been received as well as clear written guidance as to what actions are authorized. The corrected Nonconformity will be redelivered to DHS, which will then confirm in writing

whether the re-delivered deliverable conforms to and satisfies the applicable Acceptance Criteria. The process described in this Section may be repeated as necessary until all Nonconformities are corrected and the deliverable conforms to and satisfies its Acceptance Criteria or until either party reasonably determines that continued efforts would be unsuccessful. DHS will cover all expenses associated with these corrective activities.

Program Status Report. NVS will deliver a monthly program status report to the DHS S&T Technical Representative and DHS S&T Resource Manager containing metrics pertaining to financial, schedule, and scope information, risk information, and performance assessment information of all work performed hereunder.

7. **Security Requirements.**

   a. All work performed under this SOW is unclassified unless otherwise specified by DHS.

   b. If classified work is required under this SOW, DHS will provide specific guidance to NVS as to which work will be conducted in a classified manner and at which classification level.

IV. Points of Contact

Points of Contact (POCs) are as follows:

- Technical POC(s) – Dar Bahatt
  NVS Technologies, Inc.
  1505 Adams Drive Suite D,
  Menlo Park, CA 94025-5223
  dar@nvs-teclmologies.com
  650-477-0919

- Financial POC(s) – Cheryl Cathey
  NVS Technologies, Inc.
  1505 Adams Drive, Suite D.
  Menlo Park, CA 94025-5223
  650-906-2728
  cheryl@nvs-technologies.com

NVS may change the individual designated as a POC upon notice to DHS S&T of such change.

The DHS POCs are as follows:

- DHS S&T Technical Representative – David Hodge
  Program Manager
  Department of Homeland Security
  Science & Technology Directorate
  Chem/Bio R&D Section
  Washington, DC 20528
  202-254-5813
  David.hodge@dhs.gov

- DHS S&T Financial Representative –
  Christopher Nolan
  Department of Homeland Security
  Homeland Security Science and
  Technology Directorate
  Office of the Chief Financial Officer
  Washington, DC 20528
  202-254-2264
  Christopher.Nolan@dhs.gov

DHS S&T may change the individual designated as a POC upon notice to NVS of such change.

CIVILIAN BOARD OF CONTRACT APPEALS

IN THE MATTER OF:	)	
NVS TECHNOLOGIES, INC.,	)	
Appellant,	)	
v.	)	CBCA Nos.: 4775, 5360
U.S. DEPARTMENT OF HOMELAND SECURITY,	)	
Respondent.	)	

Courtroom No. 3
Civilian Board of Contract Appeals
1800 M Street, N.W.
Washington, D.C.
Thursday,
September 13, 2018

The parties met, pursuant to the notice, at 9:08 a.m.

BEFORE: HONORABLE ALLAN H. GOODMAN
Board Judge

APPEARANCES:
For the Appellant:
JAMES DELSORDO, Esquire
Argus Legal, PLLC
9255 Center Street, Suite 307
Manassas, Virginia 20110
(703) 368-8772

For the Respondent:
MARION T. CORDOVA, Esquire
U.S. Department of Homeland Security
245 Murray Lane, S.W.
Washington, D.C. 20520
(202) 254-5787

* * *

[317] Q Has your office prepared some replacement device?

A Let me just correct that. I did hear that there was a requirement to have a device to be delivered by February of 2014 for test.

THE WITNESS: Have we -- did we seek a replacement?

MR. DELSORDO: Or have you been able to obtain a replacement?

THE WITNESS: I don't think there's -- there was never any additional work on the MAMPT project. Essentially, the MAMPT project was terminated.

There was exploration -- as I believe you're aware -- to determine whether there were other cheaper alternatives to address the requirement, number one. And number two, to determine whether we had a good understanding of the requirements that needed to be addressed. Number three, whether the requirement was really ours to be addressed at DHSS&T, or should it be addressed at some other government agency.

MR. DELSORDO: That's all the questions I have.

JUDGE GOODMAN: Okay.

MR. CORDOVA: Just one. May I approach the witness?

[318] JUDGE GOODMAN: Yes.

REDIRECT EXAMINATION

BY MR. CORDOVA:

Q Do either of these documents look familiar to you?

A Yes. These were the documents that were -- this -- I believe this -- I don't know that I saw this version. But that looks like it went from Shelby, and this is the document that came back to me.

JUDGE GOODMAN: What is it?

MR. CORDOVA: And this is the document that was -- the discs were sent to NVS to get them to correct the nonconforming markings. And they would not accept delivery of them.

JUDGE GOODMAN: Okay. Is that what it is? I mean you're saying that's what it is.

How do you know that's what it is?

THE WITNESS: Because I saw it. That's the way it came back to me.

JUDGE GOODMAN: Okay. So --

THE WITNESS: What relevance is it?

JUDGE GOODMAN: No, I'm just saying that you -- when did that happen?

THE WITNESS: Well there's a date -- is there a date on it?

[319] MR. CORDOVA: There is a date on it, yes.

THE WITNESS: Is it in the fall or early winter of 2000 -- it's late 2013, 2014, right?

MR. CORDOVA: No, I think this is -- it was later. This is 2015.

THE WITNESS: '15.

JUDGE GOODMAN: So, you're saying -- what are on the discs?

THE WITNESS: Oh, the discs were basically all the information that I believe that we had from NVS. So Dave Hodge had been asked by Don Woodbury to provide to him, to Don, the full body of information that had been provided by NVS, which would include monthly reports, as well as other reports.

Those five volumes of printed material, I had them in electronic version principally to ensure that they got on that disc, and while I had them I did a spot check that I referred to earlier.

JUDGE GOODMAN: Okay. So, you sent them -- you -- who sent them back to NVS?

THE WITNESS: I provided them to -- I believe Shelby is --

MR. CORDOVA: I believe the contracting officer.

MR. DELSORDO: Your Honor --