

SOLICITATION, OFFER AND AWARD			1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING	PAGE OF PAGES 1 85	
2. CONTRACT NO.		3. SOLICITATION NO. W81XWH-10-R-0029	4. TYPE OF SOLICITATION [] SEALED BID (IFB) [X] NEGOTIATED (RFP)	5. DATE ISSUED 01 Mar 2010	6. REQUISITION/PURCHASE NO. W23RYX91354002		
7. ISSUED BY USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014 TEL: FAX:			CODE W81XWH	8. ADDRESS OFFER TO (If other than Item 7) USA MED RESEARCH ACQ ACTIVITY ATTN: DANA HERNDON 301-619-7140 DANA.HERNDON@US.ARMY.MIL FORT DETRICK MD 21702 TEL: FAX:		CODE W81XWH	

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

SOLICITATION

9. Sealed offers in original and 5 copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if handcarried, in the depository located in 820 Chandler St., Fort Detrick until 12:00 AM local time 31 Mar 2010
(Hour) (Date)

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

10. FOR INFORMATION	A. NAME DANA HERNDON	B. TELEPHONE (Include area code) (NO COLLECT CALLS) 301-619-7140	C. E-MAIL ADDRESS dana.hemdon@us.army.mil
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OFFER (Must be fully completed by)

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

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

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

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

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION		
22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304(e)() <input type="checkbox"/> 41 U.S.C. 253(e)()		23. SUBMIT INVOICES TO ADDRESS SHOWN IN (4 copies unless otherwise specified)		ITEM
24. ADMINISTERED BY (If other than Item 7) CODE		25. PAYMENT WILL BE MADE BY CODE		
26. NAME OF CONTRACTING OFFICER (Type or print) TEL: EMAIL:		27. UNITED STATES OF AMERICA (Signature of Contracting Officer)		28. AWARD DATE

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

Section A - Solicitation/Contract Form

ADDITIONAL INFORMATION

PROJECT TITLE: Development, Preparation, cGMP Manufacture and Testing of Antiplatelet Chewing Gum Containing Antimicrobial Peptides for Phase I Clinical Trial

This is a Research and Development requirement.

The solicitation shall result in a Cost-Plus-Fixed-Fee contract.

The period of performance has been estimated. The actual period of performance will be dependent on meeting the requirements of the four milestones described in Section C of this solicitation.

Award shall be made on a Best Value basis.

HISTORICAL INFORMATION:

This solicitation was previously issued as W81XWH-09-T-0397. That solicitation was canceled and is being reissued as Request for Proposal No. W81XWH-10-R-0029.

SOLICITATION QUESTIONS:

Questions concerning this Request for Proposal are due no later than 3:00 p.m., Eastern Standard Time, on Monday, 15 March 2010. Questions shall be submitted to dana.herndon@us.army.mil by this closing date and time. No questions shall be addressed after this cutoff period. Telephone inquiries will NOT be entertained. Offerors shall submit one set of questions only; multiple emails shall not be accepted. An Amendment to the solicitation will be submitted addressing the answers.

Questions which were asked and answered on Request for Quotations No. W81XWH-09-T-0397 follow:

Question #1: Statement of Work Section 5.1.17.4 (page 7) indicates “KSL-W concentration will not vary within each formulation...” whereas Section 5.1.17.4.1 provides five different formulations with a differing amount of KSL-W for each. On surface, clauses seem contradictory. Please clarify.

Answer: The test gums will contain increasing amounts of peptide and CPC, i.e., five different test doses. The different test doses will begin with a formulation, with each formulation containing an increasing dose of peptide and CPC.

Question #2: Quality Assurance Surveillance Plan (QASP) Section 1.1 (page 13) indicates that the contractor – Fertin Pharma A/S, Denmark – has already been determined. Has Fertin of Denmark already been chosen as the preferred contractor? Has Fertin of Denmark already done some work on this project for the US Army? If so, would we be privy to the information received from Fertin on this project by the US Army?

Answer: This is a full and open competitive solicitation. All offers will be considered in accordance with the evaluation factors provided in FAR Clause 52.212-2 Evaluation—Commercial Items (JAN 1999) of the solicitation.* The QASP has been corrected to remove the names of any potential offerors. Fertin has helped the Army do some preliminary formulation work based on an agreement between Fertin and the Army. At present, the data obtained is not available to the public. However, as allowed within the limits of the agreement with Fertin, the Army intends to use this information in the future development and production of test gum.

*NOTE: The evaluation factors for RFP No. W81XWH-10-R-0029 are found in Section M.

Question # 3: While we have used CPC before in chewing gum, we are unaware of any work regarding peptides. Will the U.S. Army be responsible for filing the appropriate forms with the FDA for the NDA or ANDA this project would seemingly require?

Answer: The Army will be responsible for filing the IND.

Question #4: Could we receive a Safety Data Sheet on the peptide being considered?

Answer: The peptide represents a new entity and there is no MSDS established for the peptide. However, the preclinical animal safety studies have been completed and viewing of the data could be arranged via NDA.

Question # 5: Our plan would include production at our facility, but all testing (including stability testing) [would be] done at 3rd party FDA approved facilities. Would such a proposal be considered responsive to this solicitation?

Answer: It is the preference of the Army that manufacturing of the GMP test gum and formulation and stability testing be conducted at the same GMP facility.

The following information is provided to those interested in responding to this requirement:

At present, we have not established the manufacturing specification for the antiplaque chewing gum; however, we expect to have the test GMP gum manufactured at varying concentrations of the actives as described in the Statement of Work. The chewing gum can be manufactured either by cold-pressed or standard processes. Because of the nature of one of the actives, cold-pressed process may be the process of choice. The actives used in this antiplaque chewing gum include an antimicrobial peptide and a surface active agent and the excipients include sweetener and mild abrasive. The antimicrobial peptide has a broad spectrum of antimicrobial activity against both oral and non-oral bacteria. The peptide is sensitive to high temperatures (60 degrees C) and high humidity (90% RH). For more information, see one of our publications authorized by Faraj et al. AAPS PharmSci Tech. 2007. Article 26.

FREEDOM OF INFORMATION ACT (FOIA) INQUIRIES RELATED TO THE CURRENT CONTRACT SHOULD BE DIRECTED TO:

Mrs. Nancy Gaynor
U.S. Army Medical Research Acquisition Activity
ATTN: MCMR-AAP-A
Fort Detrick, MD 21702-5014

E-mail: nancy.gaynor@us.army.mil
Telephone: 301-619-2389

Section B - Supplies or Services and Prices

LINE ITEM DESCRIPTION

The Contract Line Item Number Description for the period of performance of the resultant contract is as follows:
 Furnish the necessary personnel, facilities, equipment, and supplies to conduct research project entitled
 "Development, Preparation, cGMP Manufacture and Testing of Antiplaque Chewing Gum Containing
 Antimicrobial Peptides for Phase I Clinical Trial" for the U.S. Army Dental Research Detachment, Great Lakes, IL
 60088-5259, in accordance with the Statement of Work (SOW) and all applicable federal requirements, including
 but not limited to 21 CFR 312, 21 CFR 812, and 21 CFR 11.

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	"Development, Preparation, cGMP CPFF Manufacture and Testing of Antiplaque Chewing Gum Containing Antimicrobial Peptides for Phase I Clinical Trial" - Manufacture of a Phase I Lot of Antiplaque Chewing Gum (APCG) with associated internal Quality Assurance (QA) and Quality Control (QC) reviews in accordance with current Good Manufacturing Practices (CGMP), and according to U.S. Code of Federal Regulations (CFR) Parts 210 and 211, for use in nonclinical animal and human clinical studies. Work shall be performed as defined and summarized in the Quality System Plan, provided herein, which identifies the roles and responsibilities of the U.S. Army and Manufacturer. FOB: Destination PURCHASE REQUEST NUMBER: W23RYX91354002		Lot		
				ESTIMATED COST	
				FIXED FEE	
				TOTAL EST COST + FEE	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002			Each		

Contractor Manpower Reporting
FFP

Input of the Accounting for Contract Services information in the website operated and maintained by the Assistant Secretary of the Army (Manpower & Reserve Affairs). See the "Contractor Manpower Reporting" clause for specific reporting information. Reporting period will be the period of performance not to exceed 12 months ending 30 September of each government fiscal year and must be reported by 31 October of each calendar year.

For reporting purposes, the Unit Identification Code (UIC) for the U.S. Army Dental Research Detachment is W03K5.

Note 1: CMR Reporting Certification: Contractor shall provide evidence of compliance with the CMR requirement no later than 30 November of each year. Failure to provide proof of compliance may result in a negative rating on your annual past performance report.

NOTE 2: Price associated with the one-time set-up may be included in this CLIN only.

FOB: Destination

MILSTRIP: W23RYX91354002

PURCHASE REQUEST NUMBER: W23RYX91354002

NET AMT

Section C - Descriptions and Specifications

STATEMENT OF WORK

STATEMENT OF WORK (SOW)
DEVELOPMENT, PREPARATION, cGMP MANUFACTURE and TESTING of ANTIPLAQUE CHEWING GUM
CONTAINING ANTIMICROBIAL PEPTIDES FOR PHASE I CLINICAL TRIAL

1.0 BACKGROUND

Dental emergencies continue to threaten the readiness of deployed military forces. The majority of the dental emergencies are plaque-induced oral infection. The U.S. Army Dental and Trauma Research Detachment (USADTRD), a detachment of Walter Reed Army Institute of Research (WRAIR), has developed several candidate antimicrobial peptides that could be used for controlling plaque-associated oral infection, including dental caries. The USADTRD is particularly interested in developing antimicrobial systems that could be incorporated into the military field ration, specifically into chewing gum. Their use of this novel antiplaque chewing gum could significantly reduce the incidence of dental emergencies among deployed forces by controlling plaque formation, allowing sustained operations in extreme environments while maintaining mission capabilities. In pursuit of this objective, the USADTRD is interested in the development and manufacturing of small scale current Good Manufacturing Practice (cGMP) antiplaque chewing gum containing USADTRD's antimicrobial peptide (KSL-W) and cetylpyridinium chloride (CPC), which exhibit broad-range bactericidal activities, to be used in the oral cavity for improving the oral health of the deployed soldiers. In conjunction with this effort, the USADTRD is interested in determining the stability of this prototype cGMP antiplaque chewing gum and the release kinetics of the bacteria-fighting agent from the gum formulations.

2.0 SPECIFIC OBJECTIVES

- 2.1 To manufacture according to current Good Manufacturing Practices (cGMP), and according to U.S. Code of Federal Regulations (CFR) Parts 210 and 211 a Phase I Lot of Antiplaque Chewing Gum (APCG) with associated internal Quality Assurance (QA) and Quality Control (QC) reviews, for use in nonclinical animal and human clinical studies.
- 2.2 The work shall be performed as defined and summarized in the Quality System Plan which identifies the roles and responsibilities of the US Army and Manufacturer (see attachment 1).

3.0 SCOPE OF WORK

The Manufacturer shall perform the following:

- 3.1 This manufacturing effort will involve the following major components: receipt and testing of raw materials; pilot scale production of product on two platforms (conventional and 1-layer compressed); selection of appropriate platform; pilot production lots; final cGMP lot production of APCG for phase I trial at specified concentrations of KSL-W and CPC; associated in-process and finish/lot release testing.
- 3.2 The work flow for cGMP production of the APCG will be as follows:
 - 3.2.1 **Milestone # M1:** Choice of chewing gum manufacturing platform.
 - 3.2.2 **Milestone # M2:** Selection of chewing gum formulation for Phase I trial.
 - 3.2.3 **Milestone # M3:** Preparation for cGMP production of APCG.
 - 3.2.4 **Milestone # M4:** Production of cGMP APCG.

Milestone Descriptions:

Milestone # M1: Choice of chewing gum manufacturing platform.

Prior to chewing gum manufacturing, initial developmental studies will be conducted to support selection of a chewing gum manufacturing platform. The work will focus on: (1) evaluation of the stability information of the active pharmaceuticals (API) KSL-W and CPC (to be provided by each respective manufacturer/supplier); (2)

the stability of KSL-W during the processing of conventional chewing gum; (3) providing gum extracts to the USADTRD for determination of antimicrobial activity of these extracts in APCG manufactured on both platforms; (4) the release profile of the API's; (5) the softening issues known to be associated with CPC; and (6) the handling of KSL-W related to manufacturing of APCG on two platforms. The selection of the chewing gum platform will be a cooperative decision between representatives of the US Army and Manufacturer.

Activities will include: initial activities for handling and working with KSL-W; collection of information for challenges with respect to CPC softening; initial activities on cleaning verification (analytical methods and Swab method); initial formulation and preparation of APCG on two platforms; trials with different types of gum bases and optimization of *in vitro* analysis; initial analytical development (extraction of KSL-W and CPC); content assays for KSL-W and CPC in gum formulation; *in vitro* release; preparation of extracts for antimicrobial activity analysis (to be conducted at USADTRD); evaluation and update of the Product Target Product Profile (TPP); stability tests on APCG.

Milestone # M2: Selection of chewing gum formulation for Phase I trial.

This phase will be a continuation of the initial developmental activities in Milestone # M1, and an initiation of activities related to the selected chewing gum platform for content uniformity (CU) and stability. The optimization and formulation of APCG produced on the selected chewing gum platform will be initiated. The primary objective of the effort will be to optimize the CU, stability and release of the API's in the selected chewing gum platform; the secondary objective will be optimization of chewing gum taste and texture.

Continuing activities from Milestone #M1 include: cleaning verification (qualification of analytical methods and Swab method); final analytical development of: content assays for KSL-W and degradation; content assay for CPC and degradation; *in vitro* release; novel raw material analytical method development; and final requirements needed for handling and working the KSL-W peptide. New activities include: (1) optimization and formulation with respect to CU, stability and release; (2) stability tests on APCG at 25°C/60%RH; (3) accelerated stability tests on APCG at 30°C/65%RH and 40°C/75%RH; and (4) evaluation of KSL-W/CPC dose formulations and update of TPP.

Milestone # M3: Preparation for cGMP production of APCG.

The focus of this phase will be the finalization of earlier developmental activities in preparation of the cGMP production of chewing gum in Milestone M#4. Activities will include: pre-validation of analytical methods including KSL-W and degradation: CPC and degradation, *in vitro* release, and novel raw material analytical method developments. This phase will also include: finalization of cleaning verification; preparation of draft batch production records and other associated CMC documentation; finalization of SOPs and training of personnel; establish specifications for raw materials and finished products; release of raw materials; evaluation and update of TPP.

Milestone # M4: Production of cGMP APCG.

This phase will involve the activities for the production of cGMP APCG and testing required for its release. These activities will include: the preparation of raw materials; production; packaging; analysis (in-process and lot release testing); stability testing according to ICH guidelines; finalization of batch production record; TPP and associated CMC documentation for regulatory submission; and COA.

*The final chewing gum product will undergo stability studies as per ICH guidance for 12 months. These studies will use stability chambers that are validated annually. This study will encompass real-time stability at the intended storage temperature of 20 - 25°C and accelerated stability (see Table 7.19). The delivery of final APCG product as needed for the clinical trial will be coordinated by the US Army and the Manufacturer for initiation of the clinical trial. The remaining final APCG product will be stored at the appropriate temperature.

4.0 PERIOD OF PERFORMANCE

The period of performance of the work described herein shall be as follows in accordance with the Milestone Payment Schedule, and the Target Completion Dates and Required Completion Dates to be determined:

Phase	Date/Period
Phase 1	
Milestone 1	
Phase 2	
Milestone 2	
Phase 3	
Milestone 3	
Phase 4	
Milestone 4	

Note: Expenses for the API of KSL-W are not included.

5.0 DELIVERABLES

Manufacturer shall provide the following Deliverables in accordance with projected schedule specified herein. The level of cGMP compliance for the Deliverables will vary according to the goals of each Milestone. During Milestone M#1 and M#2 developmental processes will be documented in protocols and reports. During Milestone M#3 the quality of control will increase to pre-cGMP level in preparation of final product production. Milestone M#4 will be fully cGMP compliant. Deliverables as described below are to be prepared and submitted to the point of contact specified:

5.1 Manufacturing Deliverables are as follows:

For all Milestones:

- 5.1.1 Copies of any production process specific and/or testing SOPs, including qualification, validation and verification plans, and associated documentation; copies of interim, draft and final report testing results.
- 5.1.2 All data required for regulatory submissions as applicable, including but not limited to: batch production records for cGMP production, justification of specifications, specifications, analytical methods, method validation reports and status reports.
- 5.1.3 Manufacturer will participate in appropriate Quality Assurance (QA) audits, provide responses to audit findings to US Army, and provide support during US Army Quality/Person-in-the-Plant (PIP) oversight visits. A mutually agreed upon schedule for any PIP visits will be coordinated between the US Army and Manufacturer.
- 5.1.4 Written and/or electronic versions of all batch production records for all APCG production specific process steps are to be delivered within 30 calendar days of US Army approval of each respective batch production report.
- 5.1.5 Provide Monthly Report (see 5.1.6) and participate in monthly teleconferences (see 5.1.6).
- 5.1.6 **Project Management Requirements.** Schedule, and technical/performance and updates for this SOW will be submitted in monthly reports. Reports shall detail work accomplished with respect to work planned for the report month. Monthly reports shall be submitted in accordance with the following. During the performance of the contract, the Manufacturer shall provide US Army with a monthly technical/performance report due the beginning of each calendar month, but not later than the 10th day. This report will focus, at a minimum, on the following project management responsibilities. Monthly teleconferences between Manufacturer and US Army representatives will be held at a regularly scheduled time to discuss updates/issues related to technical development, schedule and expenditures.

5.1.6.1 Schedule Management

- 5.1.6.1.1 The schedule incorporated into the contract shall become the baseline schedule against which all work performance will be measured.
- 5.1.6.1.2 This schedule shall be prepared by the Manufacturer using Microsoft Project 98 or 2000 (or a comparable scheduling tool and agreed upon version) to allow tasks to be properly linked between previous and future tasks.
- 5.1.6.1.3 The Manufacturer shall update this schedule monthly by determining the percent complete of each scheduled task item. Percent complete is defined as the cumulative amount of work actually performed through the end of the reporting month expressed as a percentage of the total amount of work to be performed.
- 5.1.6.1.4 As part of the monthly schedule update, the Manufacturer shall also reforecast all outstanding task activities; the reforecast will be based on a three month schedule.

5.1.6.2 Variance Analysis

- 5.1.6.2.1 Any significant positive or negative deviation to the schedule or scope of a task shall be explained and documented by the Manufacturer in its monthly technical/performance report.
- 5.1.6.2.2 Any anticipated future significant positive or negative deviation to the schedule or scope of a task shall be explained and documented by Manufacturer in its monthly technical/performance report.

Milestone # M1: Choice of chewing gum manufacturing platform.

- 5.1.7 Release profile for developmental purposes for KSL-W and CPC for APCG produced on both conventional and compressed chewing gum platforms.
- 5.1.8 Level of anti microbial activity of KSL-W and CPC in *in vitro* buffer for APCG produced on both conventional and compressed chewing gum platforms (as per 5.1.9).
- 5.1.9 Resistance to the following bacterial strains as determined by antimicrobial testing of extracts from both gum platforms provided to the USADTRD:
 - 5.1.9.1 Resistance to the following cariogenic organisms:
 - 5.1.9.1.1 *Streptococcus mutans*
 - 5.1.9.1.2 *Streptococcus sobrinus*
 - 5.1.9.1.3 *Lactobacillus acidophilus*
 - 5.1.9.2 Resistance to the following early colonizer for plaque formation:
 - 5.1.9.2.1 *Actinomyces naeslundii*
 - 5.1.9.2.2 *Streptococcus gordonii*
 - 5.1.9.3 Resistance in normal flora:
 - 5.1.9.3.1 *Streptococcus oralis/mitis* (oralis group)
 - 5.1.9.4 Resistance to *in vitro* plaque (formed by isolated human salivary bacteria)
- 5.1.10 Initial information on the stability of APCG.
- 5.1.11 Procedures for handling KSL-W peptide.
- 5.1.12 Procedures for overcoming known CPC softening characteristics.
- 5.1.13 Developmental activities to evaluate the production of APCG on the conventional and compressed chewing gum platforms.

- 5.1.14 Initial data regarding CU for APCG manufactured on the conventional chewing gum platform, and the compressed chewing gum platform if required.
- 5.1.15 Selection of platform for the manufacture of APCG.
- 5.1.16 Evaluation and update of TPP.

Milestone # M2: Selection of Chewing Gum Formulation for Phase I Trial.

- 5.1.17 Formulation of APCG to meet the following criteria:
 - 5.1.17.1 Release Profile of KSL-W and CPC: 70% after 20 minutes.
 - 5.1.17.2 Stability of APCG at 25°C/60%RH for a minimum of 9 months shelf-life.
 - 5.1.17.2.1 Note: After meeting the criteria of 9 months stability, this stability study will continue into M#3 and M#4 (as necessary) with a goal of achieving 12 month shelf-life stability.
 - 5.1.17.3 Activity of the API's in the chewing buffer after *in vitro* release.
 - 5.1.17.4 Formulations of Placebo and APCG will be at the following formulations. KSL-W concentration will not vary within each formulation; the CPC concentration may vary as limited by APCG consistency.
 - 5.1.17.4.1 Placebo and five (5) different formulations: 2 mg KSL-W/0.25 mg CPC, 10 mg KSL-W/1.25 mg CPC, 20 mg KSL-W/2.5 mg CPC, 50 mg KSL-W/6.25 mg CPC, 100 mg KSL-W/12.5mg CPC.
 - 5.1.17.5 Sufficient optimization of the taste and texture of the APCG to make the product palatable for the phase I trial. This optimization will be based on Manufacturer's expertise with other product formulations using CPC.
- 5.1.18 Copies of *in vitro* release and accelerated stability study test results.
- 5.1.19 Copies of all ongoing stability test results for formulated APCG product.
- 5.1.20 Data regarding CU for APCG manufactured on the selected chewing gum platform.
- 5.1.21 Evaluation and update of TPP.

Milestone # M3: Preparation for cGMP production of APCG.

- 5.1.22 Copies of draft batch production record and associated records will be provided for review and accepted by US Army.
- 5.1.23 Copies of all analytical methods (whether verified, qualified or validated) including KSL-W assay and degradation, CPC assay and degradation, *in vitro* release, and raw material methods.
- 5.1.24 Copy of final cleaning verification method.
- 5.1.25 Evaluation and update of TPP.

Milestone # M4: Production of cGMP APCG.

- 5.1.26 Preparation of raw materials for cGMP production of APCG.
- 5.1.27 Lot release, in-process, and stability testing will be conducted in accordance with cGMP regulations (Title 21 CFR Part 211) as appropriate.
- 5.1.28 Production, packaging, analysis (lot release testing, in-process testing), stability testing of final cGMP APCG will be performed according to ICH guidelines through the 12 month point (see 7.19).
- 5.1.29 Copies of all batch production records, lot release, in-process, and stability testing documents and final reports will be provided for review and accepted by US Army. To include the results, description, protocols and data for studies performed, the interpretation of findings and conclusions, and any final report amendments. Protocol amendments, memoranda to the file, copies of audits/inspections, and all laboratory notebooks related to this SOW, study and equipment logs, log of comments, and signature log(s) will be provided to the US Army as requested during an audit or PIP visit.

- 5.1.30 Generate COA and final TPP; finalization of batch production record and related CMC documentation for regulatory submission.
- 5.1.31 At a minimum, Manufacturer will produce and provide quantities of APCG as indicated in the table below (unit = piece):

Formulation	# Pieces of APCG for Phase I Trial	# Pieces of APCG for Stability Testing	# Pieces of APCG for Retain
Placebo	4,941	240	225
2mg KSL-W/0.25 mg CPC	600	240	225
10 mg KSL-W/1.25 mg CPC	3,482	240	225
20 mg KSL-W/2.5 mg CPC	1,050	240	225
50 mg KSL-W/6.25 mg CPC	1,050	240	225
100 mg KSL-W/12.5mg CPC	1,750	240	225
TOTAL	12,873	1,440	1,350

- 5.1.32 As a known routine packaging format, it is anticipated that the final APCG product will be supplied in blisters. Each blister card will contain several blister cavities with one (1) piece of APCG in each cavity. APCC of the same formulation/strength will be included in the same blister card, i.e. a blister card will either contain 2 mg KSL-W/0.25 mg CPC, 10 mg KSL-W/1.25 mg CPC, 20 mg KSL-W/2.5 mg CPC, 50 mg KSL-W/6.25 mg CPC or 100 mg KSL-W/12.5mg CPC. Re-packaging of the individual dosages as needed for the Phase I trial is the responsibility of the US Army / Clinical Trial Site.

6.0 US ARMY RESPONSIBILITIES

- 6.1 The Army will verify the Manufacturer is a cGMP compliant facility at the onset of this effort. Throughout this effort, Quality involvement through audits, inspections and person in the plant visits will reconfirm this compliance.
- 6.2 The US Army will provide the following starting materials for all Milestones (# M1 - #M4):
- 6.2.1 cGMP peptide KSL-W as required to perform the development and manufacturing activities as described in the Milestones and Period of Performance in this Statement of Work. The Army will provide the amount of KSL-W needed in the project period for the manufacturing development and production. Manufacturer will review and approve the specifications on KSL-W.
- 6.3 US Army's Regulatory Affairs and Quality representatives, and the Product Scientist (and others as designated by the US Army) will be responsible to review and approve the draft and final batch production record, validation of assays, stability plans/protocols and all Manufacturer Deliverables prior to US Army acceptance. Upon receipt of the documents, the Army and representatives will have 15 working days to review and provide comments to Manufacturer.
- 6.4 US Army will provide a PIP during any critical process of manufacturing, to include non-GMP processes and GMP manufacturing and testing. US Army's representative PIP will be that of a technical observer/consultant and be available to discuss observations with the Manufacturer's study director/manufacturing supervisor while onsite. US Army will provide copies of written report of PIP visits to the Manufacturer within 30 calendar days of the visit.
- 6.5 The Army (USADTRD) will perform assays for the level of activity of KSL-W and CPC in *in vitro* buffer for APCG produced on both conventional and compressed chewing gum platforms (as per 5.1.9).

7.0 MANUFACTURER RESPONSIBILITIES

- 7.1 cGMP manufacturing stages identified above will be preceded by appropriate room and equipment cleaning, qualification/validation of critical utility systems and US Army approval of relevant draft and final BPRs, protocols, stability plans/protocols and/or Technical Specifications.
- 7.2 cGMP manufacturing stages identified above will be followed by appropriate internal QC review of procedures, documentation, and data. Participate in appropriate US Army Quality audits, provide responses to audit findings to US Army, and provide support during US Army QA or PIP visits.
- 7.3 Provide written and/or electronic versions of all cGMP-compliant (Milestone M#4) protocols/test methods, deviations, amendments, any out-of-specification or failure investigations, QC/standard curve test results, certificates of analysis, validation of assays, stability plans/protocols and/or final reports; to be delivered within 30 calendar days of US Army approval or completion of each respective activity or event. Each protocol and associated records will be reviewed and approved by the Manufacturer's Quality and production groups before they are provided to US Army.
- 7.4 Manufacturer will prepare a Technology Transfer Package for the transfer of the manufacturing and testing procedures within 90 calendar days of notification by US Army.
- 7.5 During the cGMP manufacturing stage of M#4, notify US Army within 24 – 48 hours of any unplanned deviations, out-of-specification results, process failures, or environmental excursions and will provide investigation reports and product impact assessments for US Army evaluation and approval. Written notification will be provided within 72 hours of the occurrence.
- 7.6 Provide final reports, reviewed and approved by US Army that include the results, description, protocols and data of the studies performed, batch production records, assay validations, stability plans/protocols protocol amendments, the interpretation of findings and conclusions, and any final report amendments. Memoranda to the file, meeting minutes, copies of audits/inspections, and all laboratory notebooks related to this SOW, study and equipment logs, log of comments, and signature log(s) will be provided as requested by US Army during an audit or PIP visit. As required, Manufacturer's effort is expected to include informal discussions, monthly technical meetings, telephone calls, e-mail, and fax correspondence with US Army personnel.
- 7.7 Manufacturer shall provide access to all data, draft reports, assay validations, protocols and technical specifications for development, quality assurance and quality control methods/procedures. Allow for audit of the facility/records for compliance with relevant environmental/safety/regulatory standards.
- 7.8 Manufacturer shall allow US Army to have a PIP during any critical process of manufacturing; to include non-GMP (i.e., developmental, pilot or production runs) and the cGMP manufacturing.
 - 7.8.1 Manufacturer will allow US Army to have a PIP present in testing laboratories that are performing testing using either the quality standard of GLP or GMP, for the US Army's materials and during any of the following, including but not limited to: assay development; assay qualification, verification or validation; qualification of testing personnel and the performance of assays on US Army's materials.
 - 7.8.2 Manufacturer will allow US Army's PIP to be physically present in the manufacturing/testing suite during the above operations and allowed to view or review records in real-time. In those instances where the PIP is not able to view/review records in real-time, those records will be made available to the PIP at the end of each day's operation.
 - 7.8.3 In order to qualify as a PIP at a Manufacturer's facility, the US Army PIP will submit to the Manufacturer any training or immunization records (e.g., gowning and safety training) or other prerequisite that is required for entry into Manufacturer facilities.
 - 7.8.4 Manufacturer shall provide gowning training and qualification for US Army Person-in-Plant prior to or in conjunction with the manufacture and testing of APCG chewing gum.
- 7.9 Manufacturer shall provide to US Army true and exact copies of completed batch records, including deviation reports, which have been approved by Manufacturer's Quality and production staff, for manufactured material within 30 calendar days of completion of manufacture in Milestone M#4.
- 7.10 Store all test raw materials and samples at the appropriate storage conditions for a period to be determined by US Army. Manufacturer will maintain adequate sample accounting records including, but not limited to: storage unit qualification and calibration/maintenance records, storage unit inventory records, temperature monitoring records, and associated SOPs/SSPs.

- 7.11 Schedules, data (where possible), reports, protocols, and other documentation will be provided to US Army electronically, preferably in Microsoft compatible formats.
- 7.12 Manufacturer will provide product management for their developmental and manufacturing efforts as described in section 5.1.6.
- 7.13 Manufacturer will ensure compliance with local biosafety requirements, including any inspections as required, provide documents and respond to significant findings to the proper authorities.
- 7.14 If the Manufacturer has a facility Drug Master File (DMF) with the FDA, the Manufacturer will allow US Army to review any relevant DMF during preparation of the CMC section. If the Manufacturer does not have a DMF, the Manufacturer will allow US Army access to facility information as applicable for preparation of the CMC section.
- 7.15 If requested during an audit or PIP visit, provide documentation demonstrating the validation, testing, maintenance and or calibration related to electronic systems used to create, modify, maintain, archive, retrieve, and/or transmit records or data related to the testing/manufacture of US Army products.
- 7.16 All test methods will meet either the current United States Pharmacopeia (USP) or 21 CFR Part 211 requirements. Assay development and APCG product characterization will include but is not limited to: Identity, Strength, Purity.
- 7.17 Tests for Product Characterization, Specifications and Testing Plan for APCG chewing gum will be part of the Target Product Profile (TPP) and developed for:
- 7.17.1 In-Process Testing
 - 7.17.2 Lot release/Release Testing
 - 7.17.3 Stability Testing Plan and Testing Intervals

7.18 Final APCG Stability Testing Conditions and Testing Intervals:

Stability Conditions	Testing Interval (months)						
	0	1	2	3	6	9	12
25°C ± 2°C/60%RH ± 5%RH	X			X	X	X	X
30°C ± 2/65%RH ± 5%RH	X			X	X	X	X
40°C ± 2°C/75%RH ± 5%RH	X	X	X	X	X		

- 7.19 The final APCG product will be stored in validated and monitored temperature controlled devices at Manufacturer's facility, at approximately 16°C – 24°C (final storage conditions to be determined) and shipped at the request of the Sponsor to either a central repository or clinical site location. Product will be stored at Manufacturer for a maximum of two years past final APCG product release by Manufacturer's Quality. As the two year deadline approaches, the Sponsor will be contacted to determine further storage options.

8.0 ASSUMPTIONS

- 8.1 Raw materials are tracked and accepted with at least the specific material manufacturer's Certificate of Analysis. All materials and products will be stored under appropriate and controlled conditions.
- 8.2 Manufacturer Facility shall be of suitable size and construction to facilitate testing and cGMP manufacturing, so there is separation to prevent functions from having an adverse effect on the test or process. The labs and critical systems will be maintained/qualified appropriate to the level of testing/process being performed.
- 8.3 All developmental and pre-cGMP efforts will be conducted using Manufacturers quality system; all cGMP manufacturing efforts will be conducted under current Good Manufacturing Practices (cGMP) as specified in the U.S. Code of Federal Regulations (CFR) 210 and 211.

1. The manufacturer will produce according to current Good Manufacturing Practices (cGMP) U.S Code of Federal Regulations (CFR) Parts 210 and 211 Phase I lots of Antiplaque Chewing Gum (APCG) with acceptable internal Quality Control (QC) processes to ensure the quality of the APCG and associated Quality Assurance (QA) reviews for nonclinical animal and human clinical studies.
2. Sponsor (US Army) has primary responsibility for the conduct and oversight of all quality activities executed to support the development, preparation, cGMP manufacturing, and testing of antiplaque chewing gum containing antimicrobial peptides for a phase I clinical Trial.
3. The Manufacturer will allow US Army to have a Person in the Plant (PIP) present during any critical process of manufacturing to include laboratory operations (testing and stability), non-GMP activities (pilot or production runs) and the cGMP manufacturing.
4. Based on initial Quality Systems (due diligent) Audit results by the IPT Quality Representative (the WRAIR Office of Quality Activities), additional oversight of critical processes will be determined.

Project Task	IPT /PM USADTRD/USAMRMC	Manufacturer	IPT Quality Representative(s) and/or Quality Management Office (QMO)	Date(s) Conducted	Report Date
Development/preparation					
Due Diligent Audit	C	I	R, OA		
Requirements, Technical Product Profile (TPP)	A		I		
Technical Transfer package for product	R	C	OD		
Requirements, Contract Milestone M1	R				
Stability of KSL-W peptide (API) and CPC	C	R			
Antimicrobial activity of extract analyses	R	R			
CPC softening issue	C	R			
Gum platform selection	A	R			
Evaluation and update of TPP (specifications)	A	R	OD		
Deliverable No. 1 Report, Performance Metric	A	R	OD	Oct. 2009	
Requirements, Contract Milestone M2	R				
Selection of formulation for Phase I trial	A	R	i		
Content uniformity (CU), stability, and release Analyses	C	R	I		
Optimize CU, stability, and release criteria	C	R	I		
Validation of analytical methods	I	R	I		
Cleaning Validation	I	R	i		
Final requirements for KSL-W peptide	A	R	I		
Accelerated Stability test on APCG	I	R	I		
Evaluation and update of TPP (specifications)	A	R	OD		
Deliverable No. 2 Report, Performance Metric	A	R	OD		

Project Task	IPT /PM USADTRD/USAMRMC	Manufacturer	IPT Quality Representative(s) and/or Quality Management Office (QMO)	Date(s) Conducted	Report Date
Preparation for cGMP Manufacturing	C	I	R, OA		
Requirements, Contract Milestone M3	R				
Draft Master Batch Records	A	R, A	OD		
Establish acceptance and release specifications	A	R, A	R, OA		
Finalize cleaning validation	C	R	I		
Finalize analytical methodology	C	R	I		
Finalize SOP and training requirements	C	R	I		
Draft Batch Production Records	A,OD	A,R	I		
Draft CMC documentation	OD	R	I		
Evaluation and update of TPP (specifications)	A	R	OD		
Deliverable No. 3 Report, Performance Metric	A	R	OD		
APCG cGMP Production					
Requirements, contract Milestone M4	R				
Receipt and preparation of API, raw materials, and packaging materials (in process testing)	I	R			
Stability testing (ICH guidelines)	C, A	R	I		
Product Specifications, evaluation of final TPP	A	R	OD		
Final batch production records	A	R, A	R, OA		
Certificate of Analyses	OD	R, A	OD		
CMC Documentation	OD	R	I		
Deliverable No. 4 Production Report, Performance Metric	A	R	R, OA		

*Analysis to be performed at/by USADTRD

R = Responsible

A = Accountable (Approve)

C = Consulted

I = Informed

OD = Oversight of Document

OA = Oversight Audit

9.0 QUALITY ASSURANCE SURVEILLANCE PLAN (QASP)

1.1 Purpose

This Quality Assurance Surveillance Plan (QASP) defines the performance standards and performance measures of deliverables indicated in the Contract. The QASP also describes the procedures that the US Army Dental and Trauma Research Detachment (USADTRD) and the Combat Casualty Care (CCC; Research Area Directory II) of the US Army Medical Research and Materiel Command (USAMRMC) will use to monitor the contractor's contract performance. It is important to note USADTRD's primary concern is with the products and services provided by the contractor and not with the procedures used to produce them. Therefore, the QASP focuses on examining the products and services provided by the contractor and not the processes used to produce them. It is intended that the QASP be a tool to guide the Contracting Officer (CO), Mr. Aaron Wade, US Army Medical Research Acquisition Activity, and the Contracting Officer's Representative (COR), Dr. Kai P. Leung, USADTRD in assessing contractor performance. In some cases, specific metrics are used to measure contractor performance, in other cases subjective judgment and evaluation by the USADTRD/USAMRMC personnel will be the determining criteria. This plan describes the methodology utilized to make both quantitative and qualitative evaluation of contractor performance under this Contract.

1.2 QASP Relation to the Solicitation

This QASP is not part of the contract but is included in the solicitation for information purposes. USADTRD/USAMRMC will retain the right to change the surveillance methods and Quality Assurance (QA) procedures, or to increase or decrease the degree of surveillance efforts at any time necessary to assure contract compliance. USADTRD/USAMRMC may provide the contractor with an informational copy of the QASP to enable the contractor to enhance its Quality Control Program (QCP).

1.3 QASP Relation to the QCP

The QCP is a required element of the contractor's technical proposal in response to the solicitation. While the QCP represents the way in which the contractor will ensure its quality and timeliness of services, as defined in the PWS, the QASP represents the way in which USADTRD/USAMRMC will evaluate the contractor's performance. The contractor's QCP and the QASP should be complementary programs that ensure successful contract performance.

1.4 Revisions to the QASP

The QASP is a tool for use in Government administration of the Statement of Work (SOW) and remains subject to revision at any time by the Government throughout the contract performance period. Revisions to this surveillance plan are the responsibility of the Contracting Officer's Representative (COR). Changes may be made unilaterally and need not be announced to the contractor; the Government may provide informational copies to the contractor at its option.

The contractor will assume responsibility for all tasks and deliverables in the SOW under this award. All operational procedures and quality control measures will be tested and implemented. As the performance period progresses, the levels of surveillance may be altered for service areas in cases where performance is either consistently excellent or consistently unsatisfactory. If observations reveal consistently good performance, then the amount of surveillance may be reduced. If observations reveal consistent deficiencies, increased surveillance may be implemented.

1.5 Performance Standard

A performance standard is a level of performance the contractor must meet for each performance measure for each deliverable defined in the Contract. USADTRD/USAMRMC is contracting to have all work performed as specified. Any inaccuracies or omissions in services or products are referred to as "defects" on the part of the contractor. The contractor shall be held responsible for all identified defects, and USADTRD/USAMRMC may require the work to be re-performed. Performance standards take into account that in some instances an allowable level of deficiencies (deviations) is possible while overall performance continues to meet USADTRD/USAMRMC desired level of service. Often deficiencies result from misunderstandings or inadequate communication between contractor, COR and customers. In general, these detected deviations can be quickly corrected and resolved by contractor through communication with COR and customer.

1.5.1 Allowable Deviation

The allowable deviation is the level or number of performance deficiencies the contractor is permitted to reach under this contract. Allowable deviations take into account the difference between an occasional defect and a gross number of defects. Allowable deviations can be expressed as a percentage of or as an absolute number

(e.g., three per month). There will be instances, such as in the case of FDA acceptance, where 100 percent compliance is required, and no deviation is acceptable.

1.5.2 Substantially Complete

Many service contracts deal with service outputs that are evaluated using subjective values (e.g., excellent, satisfactory, unsatisfactory). The criteria for acceptable performance and for defects must be defined for these service outputs. The concept of "substantially complete" should be the basis for inspections based on subjective scales.

Work is considered "substantially complete" where there has been no significant departure from the terms of the Contract and no omission of essential work. In addition, the contractor has performed the work required to the best of its ability and the only variance consists of minor omissions or deficiencies.

1.6 Non-performance

Non-performance occurs when the contractor's performance does not meet or exceed the prescribed performance standard for a given requirement. Requirements may contain multiple performance elements, and therefore, deficiencies may occur in one or more aspects of performance (e.g., timeliness, accuracy, completeness, comprehensiveness, etc.) or subject areas of effort.

When inspection and review indicates that the contractor's service output is not in compliance with the Contract requirements, the COR must determine whether the contractor or the Government caused the deficiency. If the cause of the defect rests with the Government, corrective action must be taken through Government channels. If the cause of the defect is due to action or inaction by the contractor, the contractor is responsible for correction of the problem at no additional expense to the Government.

1.6.1 Documentation

Thorough documentation of unperformed or poorly performed work is essential for tracking contractor performance throughout the period of performance. The COR will document deficient work by compiling facts describing the inspection methods and results. The COR will develop documentation to substantiate nonconformance with the Contract. The COR will decide whether to elevate the problem to the cognizant Contracting Officer (CO) for corrective action.

1.6.2 Remedial Actions

Service contracts allow for penalties in the event that the contractor fails to perform the required services. Penalties are defined as those actions taken under the direction of the CO against the contractor within the general provisions of the Contract for nonconformance.

In accordance with *FAR 52.246-4: Inspection of Services-Fixed-Price*, the Government may require the contractor to re-perform any services that do not conform to contract requirements. If the defects cannot be corrected by re-performance, the CO may either require the contractor to take the necessary action to ensure that future performance conforms to the requirements, or the CO may reduce the Contract price to reflect the reduced value of the services performed. At an extreme decision point, penalties may include a decision not to exercise contract options. The CO will determine the penalty for nonconformance based upon his or her judgment and the severity of the nonconformance.

SECTION 2: ROLES AND RESPONSIBILITIES

The purpose of QA is to ensure that the customers are satisfied with the products and services received from the contractor and to ensure that the contractor is meeting its obligation to USADTRD/USAMRMC. The roles and responsibilities of the stakeholders involved in QA are described below.

2.1 Contractor Responsibility

The contractor is responsible for delivering products or services in accordance with the Contract. The contractor is responsible for implementing a Quality Control Plan (QCP), which is included as part of its technical proposal. The QCP describes the contractor's methods for ensuring all products and services provided under this Contract meet established deliverables and performance standards. The contractor is responsible for producing, maintaining, and providing for audit, quality control records and reports and all records associated with the investigation. The contractor shall appoint a single quality control point-of-contact to act as a central recipient of communication from the Government. Any additional reports required by the Government on the total contract-level will be on an 'ad-hoc' basis.

2.2 Government Responsibility

This section of the QASP briefly defines the duties and responsibilities of key Government personnel involved in contract administration and quality assurance. The key personnel who will be responsible for QA are the Contracting Officer (CO), the Contracting Officer's Representative (COR), USADTRD/USAMRMC contractor and FDA.

2.2.1 Contracting Officer

The CO has the authority to administer USADTRD/USAMRMC Contract. The CO may delegate many of the day-to-day contract administration duties to the COR. However, certain contractual actions such as negotiation and issuance of contract modifications, resolution of contractor claims and disputes, issuance of cure notices, issuance of show-cause letters, termination of the Contract, and Contract close-out functions are retained by the CO. Administrative actions such as invoice approval and issuance of contractor Deficiency Reports (CDR) may be, and normally shall be, delegated by the CO to the COR. For tasks and/or subtasks (e.g., deliverables) which include incentive arrangements (award fee, shared savings, award term, etc.), the COR shall provide recommendations to the CO for action. All communication regarding questions or issues related to QA and inspection will be directed to the CO or the COR. The CO shall approve any revision to the QASP processes or standards.

2.2.2 Designated Government Representative

The COR shall be appointed for each task/subtask as required, and shall serve as the first line manager of all tasks and/or subtasks issued under this Contract. The COR represents the CO in the Contracting Officer's Representative functions and therefore is the contractor's initial point-of-contact with the Government. In turn, the COR may delegate some of his/her responsibilities by appointment of Task Monitors by task/subtask to execute some administrative duties in order to ensure that the QA function is properly executed. If modifications to the Contract, or at the task/subtask level, are necessary, the COR will assist the cognizant CO in preparing and negotiating the modifications. If there are problems with contractor performance, the COR will inform the contractor of the problems and recommend to the CO that adverse contractual actions are appropriate (e.g., CDR, issuance of a cure notice or task/subtask closure) if the contractor fails to correct the problem. Also, the COR must refer differences of contract interpretation to the CO.

The COR will perform the actual contract surveillance and report to CO. Some of the key QA contract administration duties of COR include, but are not limited to, the following:

- Complete surveillance as required by this QASP and the specific task/subtask, and make recommendations to the CO.
- Make recommendations to the CO for the acceptance or rejection of completed work and for administrative actions based on unsatisfactory work or non-performed work;
- Identify necessary changes to the task/subtask, prepare DTRD cost and/or staffing requirements estimates, conduct QA/contractor meetings, approve submittals of effort and/or reports, and maintain work files;
- Promptly furnish the CO with any requests for changes, deviations, or waivers to the task/subtask, with justifications/rationale;

2.2.3 Customers

Customers (users) are the USADTRD/USAMRMC and USADTRD/USAMRMC associated users supported by the contractor. This includes the Federal employees who will be the recipients of contractor support under this Contract. Customers are responsible for assisting the COR in conducting QA by providing information on contractor performance through a Customer Feedback Program.

2.2.3 Food and Drug Administration

Ultimately, deliverables from task/subtask will support submission of a data package for medical product to the FDA. Acceptance of FDA of deliverables will provide final validate of performance quality.

SECTION 3: PERFORMING QUALITY ASSURANCE

3.1 Quality Assurance Methods

The methods used in the QA process are the Government's tools to monitor the contractor's products and services. The means of determining whether the contractor has met all contract requirements will be by three approaches: COR review and approval, customer review and feedback, and FDA review and acceptance. Reviews either confirm the contractor's successful achievement of all performance requirements or highlight areas where defects exist and improvements are necessary.

In cases of poor performance, USADTRD/USAMRMC may increase the level of review and focus on known problem areas. In either case, the reasons for the change in review will be documented. In all cases, the applicable requirements shall be included in each task/subtask at issuance.

3.1.1 COR review and approval

COR review and approval provides a systematic way of looking at service outputs and forming conclusions about the contractor's level of performance in accordance with a planned schedule of deliverables.

Application

Contractor will submit completed deliverables (e.g. protocols, plans and reports) to COR for review and approval.

Performance Standards

Performance standards will include accuracy, completeness, comprehensiveness, timeliness of deliverables.

3.1.2 Customer Feedback

Validated customer review and feedback is a quality assurance method based on customer and contractor interaction. Customers continually receive the outputs of contractor performance and are in a position to evaluate the contractor on a recurring basis. Because customers have a clear stake in the quality of contractor services, they are valuable resource for QA.

Application

Contractor will submit completed deliverables (e.g. protocols, plans and reports) through COR to customer for review and feedback. Customers are made aware of contract requirements and monitor the services provided by the contractor, both positive and negative. Where there is a case of poor performance or non-performance, customers notify the COR. The COR then investigates the report and, if found to be valid, document their findings. The numbers of complaints and resulting inspections depend upon customer awareness and response. If the complaint is valid and caused by poor performance or non-performance by the contractor, the contractor must take appropriate corrective action. A valid complaint is one in which the COR confirms that poor performance or non-performance violates contract requirements.

Customer Feedback Process

Upon award of the task/subtask, the COR will send letters to all contractor's points-of-contact. These letters will inform them of the need for their active participation in the overall Quality Assurance Program. The COR will also provide a Customer Feedback Record for the customer to use to either document performance problems or identify when superior services are received. Copies of all such documents shall be provided to COR. If CO involvement is required, the COR shall request it.

Customer Feedback Records submitted to the COR will be validated. It is primarily the responsibility of the contractor to investigate each complaint to determine the problem. While COR can also investigate customer complaints, the responsibility for initial review shall remain with the contractor. At the Government's discretion, the COR will investigate problems from customer groups and complaints involving major problems with services being provided.

The contractor shall take action when a Customer Feedback Record is received. If a valid complaint exists, the contractor shall re-perform the product or service. The contractor may use the complaint as an indicator that the QCP needs improvement. Corrective actions shall be implemented prevent the recurrence of similar problems in the future or detect and fix such problems before a product or service is delivered to a customer. If the customer complaint is found to be invalid, the COR shall educate the customer regarding contract/task/subtask scope of work as it pertains to the customer's expectations.

3.1.3 FDA review and acceptance

Deliverables must be suitable and acceptable to the FDA. The FDA review and acceptance provides a final validation of deliverables submitted to the FDA and provides way of looking at service outputs and forming conclusions about the contractor's level of performance concerning quality of deliverables.

Application

Contractor will submit completed deliverables slated for FDA packages (e.g., final reports) to COR and customer, who in turn will submit deliverables, as part of FDA data package submission to the FDA for review and approval. Where FDA indicates non-suitability or failure to accept task/subtask deliverable, customers will notify the COR. The COR then investigates the issue and, if found to be valid and related to contractor

performance, COR documents findings. If the issue is valid and caused by poor performance or non-performance by the contractor, the contractor must take appropriate corrective action. A valid complaint is one in which the COR confirms that poor performance or non-performance violates contract requirements.

Performance Standards

Performance standards will include acceptance of task/subtask deliverables by FDA.

3.2 Analysis and Results

Once the reviews or customer feedback records have been completed, an analysis of the contractor's performance will be conducted. The purpose of the analysis is to ensure that USADTRD/USAMRMC is receiving high-quality products and services from the contractor. COR will review the results, rate contractor compliance with the performance standards, and characterize the contractor's overall performance. Analysis of all types of contract monitoring will result in one of the following outcomes: excellent performance, satisfactory performance, or unsatisfactory performance.

3.2.1 Excellent Performance

Excellent performance is the result of the contractor significantly exceeding the performance requirement being inspected. USADTRD may reduce its level of surveillance when the COR determines there are very few or no deficiencies and the contractor performance has significantly exceeded requirements. The COR may notify the contractor that their performance has been excellent.

3.2.2 Satisfactory Performance

When the contractor's performance is satisfactory, performance meets the specified standard and the number of defects does not exceed the allowable deviation. Although the contractor's performance may be deemed satisfactory, the COR may determine that an increased level of surveillance be used for individual products or services that show defect rates approaching the minimum performance standards. The contractor will be notified by the COR when performance is marginal, or approaching an unacceptable level in any area.

3.2.3 Unsatisfactory Performance

When the performance standard for any service has not been met, the contractor's performance is unsatisfactory, and is, therefore, unacceptable. The following responses are available to the COR regarding that task/subtask:

- The CO and/or COR meet with the contractor to discuss discrepancies, trends, and intended corrective measures;
- The level of surveillance is increased until the contractor demonstrates acceptable performance over a period of time;
- The CO issues a Contract Deficiency Report for each service that the contractor has not met its performance standard;
- Should deficiencies be significant and affect multiple tasks/subtasks, CO action such as a 'Cure' notice may be appropriate.

Performance Requirements Summary

The following performance requirements will be used to measure the performance of the Service Provider (contractor). USADTRD/USAMRMC Designated Government Representatives (COR) will monitor contractor performance as stipulated in the Contract under the performance based task assignments.

The following table outlines contractor responsibilities for performance metrics, performance standards, and surveillance methods.

Deliverable*	Performance Metric	Performance Standard or Deviation	Surveillance Method
1	Demonstrate level of activity of KSL-W and Cetylpyridinium Chloride(CPC) in <i>in vitro</i> buffer for antiplaque chewing gum (APCG) produced on both conventional and compressed chewing gum platforms.	Submission of accurate, comprehensive report according to deliverable timeline.	COR review and Customer Feedback
1	Susceptibility to the following bacterial strains as determined by antimicrobial testing of extracts from both gum platforms provided to the USADTRD: Susceptibility to the following cariogenic organisms: <i>Streptococcus mutans</i> , <i>Streptococcus sobrinus</i> , <i>Lactobacillus acidophilus</i> . Susceptibility to the following early colonizer for plaque formation: <i>Actinomyces naeslundii</i> , <i>Streptococcus gordonii</i> . Susceptibility in normal flora: <i>Streptococcus oralis/mitis</i> (oralis group). Susceptibility to <i>in vitro</i> plaque (formed by isolated human salivary bacteria).	Submission of accurate, comprehensive report according to deliverable timeline.	COR review and Customer Feedback
1	Initial information of the stability of APCG; Developmental activities to evaluate the production of APCG on the conventional and compressed chewing gum platforms.	Submission of accurate, comprehensive report according to deliverable timeline.	COR review and Customer Feedback
1	Initial data regarding the content uniformity (CU) for APCG manufactured on the conventional and compressed chewing gum platforms; Selection of platform for the manufacture of APCG with above-described kinetic profiles.	Submission of accurate, comprehensive report according to deliverable timeline.	COR review and Customer Feedback
2	Release profile for KSL-W and CPC (70% release in 20 min) for APCG produced on both conventional and compressed chewing gum platforms.	Submission of accurate, comprehensive report according to deliverable timeline.	COR review and Customer Feedback
2	Stability testing for a minimum of 12 months shelf-life at 25°C ± 2°C/60% RH ± 5%RH; Accelerated stability testing of the prototype antiplaque gum.	Submission of accurate, comprehensive report according to deliverable timeline.	COR review and Customer Feedback

Deliverable*	Performance Metric	Performance Standard or Deviation	Surveillance Method
2	Placebo and five different formulations: 2 mg KSL-W/0.25 mg CPC, 10 mg KSL-W/1.25 mg CPC, 20 mg KSL-W/2.5 mg CPC, 50 mg KSL-W/6.25 mg CPC, 100 mg KSL-W/12.5mg CPC.	Submission of accurate, comprehensive report according to deliverable timeline.	COR review and Customer Feedback
2	Optimization of the taste (sensory) and texture of the APCG to make the product palatable for the phase I trial.	Submission of accurate, comprehensive report according to deliverable timeline.	COR review and Customer Feedback
2	Receipt of: <i>in vitro</i> release and accelerated stability study test results; on-going stability test results for formulated APCG; data regarding the CU for APCG on the selected platform.	Submission of accurate, comprehensive report according to deliverable timeline.	COR review, Customer Feedback and FDA acceptance
3	Receipt of draft batch production and associated records; records of validation of analytical methods for the API including their degradation assays; record of <i>in vitro</i> release of API from cGMP APCG.	Submission of accurate, comprehensive report according to deliverable timeline.	COR review, Customer Feedback and FDA acceptance
4	Production, packaging, analysis (lot release testing, in-process testing, and stability testing) conducted in accordance with cGMP regulations (Title 21 CFR Part 211) as appropriate.	Submission of accurate, comprehensive report according to deliverable timeline.	COR review, Customer Feedback and FDA acceptance

- * 1. Choice of chewing gum manufacturing platform
2. Selection of Chewing Gum Formulation for Phase I Trial
3. Preparation for cGMP production of APCG
4. Production of cGMP APCG

C.10. REGULATORY REQUIREMENTS

Federal Food, Drug and Cosmetic Act: The contractor shall comply with and be responsible for compliance by its subcontractors, with the requirements of the Federal Food, Drug, and Cosmetic Act, as amended, and regulations promulgated thereunder. In addition, the Contractor shall comply with, and be responsible for compliance by its subcontractors/suppliers, the requirements of all other applicable Federal, State, and local statutes, ordinances and regulations. This work may require QA/QC audits by regulatory organizations.

A reference to this document is provided as a guideline and does not imply that this is the only regulation that is applicable. The offeror/contractor is required to be familiar with the entire contents of the referenced documents.

C.11. CONTRACTING OFFICER'S REPRESENTATIVE AUTHORITY

Contracting Officer's Representative (COR) shall be designated by the Contracting Officer to perform technical liaison between the contractor's management and the Contracting Officer in routine technical matters, i.e., prioritization of requirements. Under no circumstances is the COR authorized to effect any changes in the work required under this contract whatsoever, nor to enter into any agreement that has the effect of changing the terms and conditions of this contract, or that causes the contractor to incur any unforeseeable costs. In addition, the COR will not supervise, direct or control contractor employees. Notwithstanding this provision, to the extent that contractor accepts any direction that constitutes a change to this contract without the prior written authorization of the Contracting Officer, costs incurred in connection therewith are incurred at the sole risk of the contractor, and if invoiced under this contract, will be disallowed.

C.12. CONTRACTING OFFICER'S AUTHORITY

The Contracting Officer is the only person authorized to direct changes in any of the requirements under this contract and notwithstanding any provisions contained elsewhere in this contract, the said authority remains solely in the Contracting Officer. In the event that the contractor effects any such changes at the direction of any person other than the Contracting Officer, the change will be considered to have been made without authority and is solely the risk of the contractor.

C.13. FREEDOM OF INFORMATION ACT (FOIA) AND PRIVACY ACT (PA)

Any FOIA or PA request received by the Contractor shall be forwarded, no later than the next workday after receipt, to the COR. The COR will deliver the request to the appropriate unit for processing action. The Contractor shall protect the privacy of all information reported by or about contract employees and shall protect against unauthorized disclosure. The Contractor shall ensure personal privacy data is protected to prevent unauthorized disclosure and ensure proper disposal of records subject to the Act.

C.14. THIRD PARTIES

Nothing contained in this Contract or its modifications shall be construed to grant, vest or create any rights in any person not a party to this Contract. This clause is not intended to limit or impair the rights which any person may have under applicable Federal Statutes.

C.15. REPORTING WASTE, FRAUD, ABUSE AND THEFT

The Contractor shall notify the KO and the COR of any instances of suspected waste, fraud, abuse, loss, or theft of Contractor or Government-furnished property by employees or subcontractors.

CLAUSES INCORPORATED BY FULL TEXT

**CONTRACTOR MANPOWER REPORTING (CMR) - (ACCOUNTING FOR CONTRACT SERVICES)
(OCT 2007) (USAMRAA)**

The Office of the Assistant Secretary of the Army (Manpower & Reserve Affairs) operates and maintains a secure Army data collection site where the contractor will report ALL contractor manpower (including sub-contractor

manpower) required for performance of this contract. The contractor is required to completely fill in all the information in the format using the following web address: <https://cmra.army.mil>. The required information includes: (1) Contract Number; (2) Delivery Order Number (If applicable); (3) Task Order Number (If applicable); (4) Requiring Activity Unit Identification Code (UIC); (5) Command; (6) Contractor Contact Information; (7) Federal Service Code (FSC); (8) Direct Labor Hours; (9) Direct Labor Dollars; and, (10) Location. In the event the Contracting Officer's Representative (COR)/Contracting Officer's Technical Representative (COTR) has not entered their data requirements first, the contractor must also enter the COR/COTR required data with the exception of fund cite, obligations, and disbursement data. The CMRA help desk number is 703-377-6199 for any technical questions. As part of its quote or offer, the contractor will also provide the estimated total cost (if any) incurred to comply with this reporting requirement. The reporting period will be the period of performance not to exceed 12 months ending 30 September of each government fiscal year and must be reported by 31 October of each calendar year.

ORGANIZATIONAL AND CONSULTANT CONFLICTS OF INTEREST (MAR 1999) (USAMRAA)

- a. It is recognized by the parties hereto that the effort performed by the contractor under this contract is of a nature that it creates a potential organizational conflict of interest as is contemplated under the FAR Subpart 9.5.
- b. In the performance of this contract, the contractor may have access to data which is procurement sensitive or is proprietary to other companies, Government consultants or advisors, or the Government. The contractor agrees that he will not utilize such procurement sensitive or proprietary data in performance of future competitive contracts, for studies in the same field, procured either through sealed bids or competitive negotiations. The contractor further agrees not to act as a subcontractor or consultant to any other prime contractor or subcontractor seeking to utilize such data.
- c. The contractor will include the provisions of paragraphs a and b in every first tier subcontract for performance of any portion of this requirement.
- d. This clause shall have effect from _____ to _____.

SAFEGUARDING PROPRIETARY INFORMATION (MAY 1999) (USAMRAA)

- a. "Proprietary information" shall mean all information, whether disclosed orally, in writings, by drawings, or otherwise relating to the work to be performed under this contract, whether proprietary to the Government or one of its collaborating partners. Proprietary information includes, but is not limited to, information regarding properties, formulae, structures, manufacturing processes, and test results. Information ceases to be proprietary when it is generally available to the public or is available from sources other than the Department of the Army. All information submitted to the contractor under this contract shall be presumed to be proprietary to the Department of the Army or one of its collaborating partners until the Department of the Army announces to the contrary.
- b. The contractor shall safeguard proprietary information both during and after the term of this contract, and shall neither appropriate, nor disclose, nor make unauthorized use of the proprietary information received under this contract. The requirements of this paragraph include, but are not limited to, the following:
 - (1) Maintenance of a high degree of physical security over proprietary information at all times;
 - (2) Discussion of proprietary information only among contractor's employees whose duties and responsibilities require knowledge of that information; and,
 - (3) Elimination of proprietary information in open publications by the contractor and its personnel.

c. The contractor shall require all personnel who receive proprietary information to execute the statement in paragraph d below when this contract becomes effective or when first employed (if employed after the contract becomes effective). All statements executed pursuant to this paragraph shall be forwarded to the U.S. Army Medical Research Acquisition Activity when this contract terminates, when the employment ends, or upon request of the Contracting Officer.

d. The following statement shall be executed pursuant to paragraph c above:

I hereby acknowledge that I have been informed that my duties may require that I have access to proprietary information. I understand this proprietary information which I will receive includes, but is not limited to, properties, formulae, structures, protocols, manufacturing processes, and test results.

I agree that I will neither appropriate nor disclose nor make unauthorized use of proprietary information both during and after my employment. I further agree that I will neither include nor draw upon proprietary information received under this contract in open publication. This agreement is executed with the intention that collaborating partners of the United States Government who have submitted information to the Government under non-disclosure obligations shall be third party beneficiary hereunder, and shall have the right to enforce the obligations undertaken herein.

Name:

Date:

e. The contractor shall insert the substance of paragraphs a through d above in each subcontract hereunder. Compliance with the provisions of this clause shall be the responsibility of the contractor.

PRINCIPAL INVESTIGATOR (DEC 2006) (USAMRAA)

The Principal Investigator for this contract is TO BE COMPLETED AT TIME OF AWARD. This individual shall be continuously responsible for the conduct of the research project. The contractor shall obtain the Contracting Officer's approval to change the Principal Investigator or to continue the research work during a continuous period in excess of three months without the participation of an approved Principal Investigator. This contract is based on the Principal Investigator devoting TO BE COMPLETED AT TIME OF AWARD of effort to the project over the term of the contract. The contractor shall advise the Contracting Officer if the Principal Investigator will, or plans to, revise the level of effort estimated in the contractor's proposal. A curriculum vitae shall be provided for professional associates added to the research project or substituted during the course of work.

GOOD LABORATORY PRACTICES (DEC 2006) (USAMRAA)

The conduct of studies on investigational new drugs or devices shall comply with the GOOD LABORATORY PRACTICE (GLP) FOR NONCLINICAL LABORATORY STUDIES regulations 21 CFR 58. The contractor shall notify the Administrative Contracting Officer by telephone immediately upon announcement by a representative of the Food and Drug Administration (FDA) of an inspection of studies performed under this contract. In addition to the FDA representative, the Contracting Officer's Representative (COR) shall have access to the contractor's records and specimens. With reference to paragraph 58.195(h) of the GLP regulations, the contractor shall notify the COR in writing in addition to the FDA, should the contractor go out of business and/or transfer the records during the periods prescribed in paragraph 58.195. On expiration or termination of the contract, the contractor shall notify the COR of any remaining unused test articles.

**INVESTIGATING AND REPORTING POSSIBLE SCIENTIFIC MISCONDUCT (MAR 1999)
(USAMRAA)**

a. "Misconduct" or "Misconduct in Science" is defined as fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

b. Contractors shall foster a research environment that prevents misconduct in all research and that deals forthrightly with possible misconduct associated with research for which U.S. Army Medical Research and Materiel Command funds have been provided or requested.

c. The contractor agrees to:

- (1) Establish and keep current an administrative process to review, investigate, and report allegations of misconduct in science in connection with research conducted by the contractor;
- (2) Comply with its own administrative process;
- (3) Inform its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures;
- (4) Take immediate and appropriate action as soon as misconduct on the part of employees or persons within the organization's control is suspected or alleged; and
- (5) Report to the Administrative Contracting Officer (ACO) a decision to initiate an investigation into possible scientific misconduct.

d. The contractor is responsible for notifying the ACO of appropriate action taken if at any stage of an inquiry or investigation any of the following conditions exist:

- (1) An immediate health hazard is involved;
- (2) There is an immediate need to protect Federal funds or equipment;
- (3) A probability exists that the alleged incident will be reported publicly; or
- (4) There is a reasonable indication of possible criminal violation.

PROHIBITION OF HUMAN RESEARCH (JAN 2007) (USAMRAA)**** PROHIBITION – READ FURTHER FOR DETAILS ****

Research under this award involving the use of human subjects, to include the use of human anatomical substances and/or human data, may not begin until the US Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol. Written approval to begin research or subcontract for the use of human subjects under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the Contractor. A copy of the approval will be provided to the US Army Medical Research Acquisition Activity for the official file. Non-compliance with any provisions of this clause may result in withholding of funds and or the termination of the award.

PROHIBITION OF USE OF LABORATORY ANIMALS (JAN 2007)(USAMRAA)

PROHIBITION – READ FURTHER FOR DETAILS

Notwithstanding any other provisions contained in the award or incorporated by reference herein, the Contractor is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the US Army Medical Research and Materiel Command's Office of Research Protections, Animal Care and Use Office (ACURO). The Contractor will receive written approval to begin research under the applicable protocol proposed for this award from the US Army Medical Research and Materiel Command, Acquisition Activity for the official file. Non-compliance with any provision of this clause may result in the termination of the award.

52.035-4036 PROHIBITION OF USE OF HUMAN CADAVERS (JAN 2005) (USAMRAA)**** PROHIBITION – READ FURTHER FOR DETAILS****

Research under this award using human cadavers may not begin until the US Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol. Written approval to begin research or subcontract for the use of human cadavers under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the Contractor. A copy of this approval will be provided to the US Army Medical Research Acquisition Activity for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award.

KEY PERSONNEL (MAR 1999) (USAMRAA)

a. The Contractor's* Key Personnel are as follows:

*Contractor add here:

- b. The above Key Personnel shall be utilized as necessary to fulfill the requirements of this contract.
- c. The offerer must provide thorough and detailed documentation of the experience, abilities, and background for Key Personnel under this contract in the form of resumes or equivalent statements of qualifications. Such documentation should include but not be limited to: name, curriculum vitae, type and description of experience.
- d. The contractor agrees that during the contract performance period substitution for Key Personnel shall not be permitted unless such substitution is necessitated by sudden illness, death, or termination of employment. In any of these events, the contractor shall promptly notify the Contracting Officer and provide the information required by paragraph (e) below.
- e. All requests for substitutions must provide a detailed explanation of the circumstances necessitating the proposed substitution(s), a complete resume for the proposed substitute(s), and any other information requested by the Contracting Officer needed to approve or disapprove the proposed substitution(s). All proposed substitutes shall have qualifications that are equal to or higher than the qualifications of the person to be replaced. The Contracting

Officer or his authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

f. If any of the listed Key Personnel are subcontractor personnel, the contractor shall include the substance of this clause in any subcontract which he awards under this contract.

Section E - Inspection and Acceptance

CLAUSES INCORPORATED BY REFERENCE

52.246-8	Inspection Of Research And Development Cost Reimbursement	MAY 2001
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Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0001	POP 17-MAY-2010 TO 16-JUN-2011	N/A	USA DENTAL RESEARCH DET DR. KAI LEUNG BLDG 1 H ROOM G 13 310 B B ST NAVAL TRAINING CEN GREAT LAKES IL 60088-5259 847-688-7373 X230 FOB: Destination	W74SQZ
0002	POP 17-MAY-2010 TO 16-JUN-2011	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W74SQZ

CLAUSES INCORPORATED BY REFERENCE

52.242-15	Stop-Work Order	AUG 1989
52.242-15 Alt I	Stop-Work Order (Aug 1989) - Alternate I	APR 1984
52.247-34	F.O.B. Destination	NOV 1991

CLAUSES INCORPORATED BY FULL TEXT

REPORTING REQUIREMENTS (OCT 2009) (USAMRAA)**XX QUARTERLY REPORTS**

a. Quarterly reports are the most immediate and direct contact between the Principal Investigator (PI) and the Contracting Officer's Representative (COR). The reports provide the means for keeping this Command advised of developments and problems as the contract effort proceeds. The quarterly reports also provide a measure against which decisions on release of funding and on requests for supplements are made.

b. In accordance with Section C., a Quarterly Report shall be submitted for each three-month period beginning with the effective date of the contract. This requirement includes all three-month periods of the contract.

c. Copies of each report shall be submitted in the quantities indicated to the addresses shown below within fifteen (15) days after the end of each quarter. Internal Government distribution will be made by those offices.

(1) One (1) copy of the report to:

Dr. Kai Leung

Chief, Microbiology Branch
U.S. Army Dental and Trauma Research Detachment
Walter Reed Army Institute of Research
Building 1 H, Room G-13
310 B B St., Naval Training Center
Great Lakes, IL 60088-5259
Telephone: 847-688-7373 X230
Facsimile: 847-688-7380
Email: kai.leung@us.army.mil

(2) One (1) copy of the report to:

Director
U.S. Army Medical Research Acquisition Activity
ATTN: MCMR-AAA-W (Mrs. Dana Herndon)
820 Chandler Street
Fort Detrick, MD 21702-5014
Telephone: 301-619-7140
Facsimile: 301-619-3002
Email: dana.herndon@us.army.mil

d. The Quarterly Report sample (See following Quarterly Report Format) shall serve as the format. Each item of the report format shall be completed.

QUARTERLY REPORT FORMAT

1. Contract No. _____ 2. Report Date _____

3. Reporting period from _____ to _____

4. PI _____ 5. Telephone No. _____

6. Institution _____

7. Project Title _____

8. Current staff, with percent effort of each on project.

_____ % _____ %

_____ % _____ %

9. Contract expenditures to date (as applicable):

This Qtr/Cumulative	This Qtr/Cumulative
Personnel _____ / _____	Travel _____ / _____
Fringe Benefits _____ / _____	Equipment _____ / _____

Supplies _____ / _____ Other _____ / _____

This Qtr/Cumulative

Subtotal _____ / _____

Indirect Costs _____ / _____

Fee _____ / _____

Total _____ / _____

10. Comments on administrative and logistical matters.

11. Use additional page(s), as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work for this contract.

12. Use additional page(s) to present a brief statement of plans or milestones for the next quarter.

XX FORMAT REQUIREMENTS FOR ANNUAL/FINAL REPORTS

a. Annual reports must provide a complete summary of the research accomplishments to date with respect to the approved Statement of Work. Journal articles can be substituted for detailed descriptions of specific aspects of the research, but the original articles must be attached to the report as an appendix and appropriately referenced in the text. The importance of the report to decisions relating to continued support of the research cannot be over-emphasized. An annual report shall be submitted within 30 calendar days of the anniversary date of the award for the preceding 12-month period. If the award period of performance is extended by the Contracting Officer then an annual report must still be submitted within 30 calendar days of the anniversary date of the award. A final report will be due upon completion of the extended performance date that describes the entire research effort.

b. A final report summarizing the entire research effort, citing data in the annual reports and appended publications shall be submitted at the end of the award performance period. The final report will provide a complete reporting of the research findings. Journal publications can be substituted for detailed descriptions of specific aspects of the research, but an original copy of each publication must be attached as an appendix and appropriately referenced in the text. All final reports must include a bibliography of all publications and meeting abstracts and a list of personnel (not salaries) receiving pay from the research effort.

Although there is no page limitation for the reports, each report shall be of sufficient length to provide a thorough description of the accomplishments with respect to the approved Statement of Work. Submission of the report in electronic format (PDF or Word file only) shall be submitted to <https://ers.amedd.army.mil>.

All reports shall have the following elements, in this order:

FRONT COVER: A Sample front cover is provided at <https://mrmc.amedd.army.mil/rpindex.asp>. The Accession Document (AD) Number should remain blank.

STANDARD FORM 298: A Sample SF 298 is provided at <https://mrmc.amedd.army.mil/rpindex.asp>. The abstract in Block 13 must state the purpose, scope, major findings and be an up-to-date report of the progress in terms of results and significance. Subject terms are keywords that may have previously assigned to the proposal abstract or are keywords that may be significant to the research. The number of pages shall include all pages that have printed data (including the front cover, SF 298, table of contents, and all appendices). Please count pages carefully to ensure legibility and that there are no missing pages as this delays processing of reports. Page numbers should be typed: please do not hand number pages.

TABLE OF CONTENTS: Sample table of contents provided at <https://mrmc.amedd.army.mil/rpindex.asp>.

INTRODUCTION: Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

BODY: This section of the report shall describe the research accomplishments associated with each task outlined in the approved Statement of Work. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the report. Provide data explaining the relationship of the most recent findings with that of previously reported findings. Appended publications and/or presentations may be substituted for detailed descriptions of methodology but must be referenced in the body of the report. If applicable, for each task outlined in the Statement of Work, reference appended publications and/or presentations for details of result findings and tables and/or figures. The report shall include negative as well as positive findings. Include problems in accomplishing any of the tasks. Statistical tests of significance shall be applied to all data whenever possible. Figures and graphs referenced in the text may be embedded in the text or appended. Figures and graphs can also be referenced in the text and appended to a publication. Recommended changes or future work to better address the research topic may also be included, although changes to the original Statement of Work must be approved by the Army Contracting Officer's Representative. This approval must be obtained prior to initiating any change to the original Statement of Work.

KEY RESEARCH ACCOMPLISHMENTS: Bulleted list of key research accomplishments emanating from this research.

REPORTABLE OUTCOMES: Provide a list of reportable outcomes that have resulted from this research to include:

manuscripts, abstracts, presentations; patents and licenses applied for and/or issued; degrees obtained that are supported by this award; development of cell lines, tissue or serum repositories; infomatics such as databases and animal models, etc.; funding applied for based on work supported by this award; employment or research opportunities applied for and/or received based on experience/training supported by this award.

CONCLUSION: Summarize the results to include the importance and/or implications of the completed research and when necessary, recommend changes on future work to better address the problem. A "so what section" which evaluates the knowledge as a scientific or medical product shall also be included in the conclusion of the report.

REFERENCES: List all references pertinent to the report using a standard journal format (i.e. format used in Science, Military Medicine, etc.).

APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

Pages shall be consecutively numbered throughout the report. DO NOT RENUMBER PAGES IN THE APPENDICES.

Mark all pages of the report which contain proprietary or unpublished data that should be protected by the U.S. Government. REPORTS NOT PROPERLY MARKED FOR LIMITATION WILL BE DISTRIBUTED AS APPROVED FOR PUBLIC RELEASE. It is the responsibility of the Principal Investigator to advise the U.S. Army Medical Research and Materiel Command when restricted limitation assigned to a document can be downgraded to Approved for Public Release. DO NOT USE THE WORD "CONFIDENTIAL" WHEN MARKING DOCUMENTS.

Section G - Contract Administration Data

CONTRACT ADMINISTRATION DATA**CONTRACT INSIGHT/OVERSIGHT AND TECHNICAL DIRECTION OF CONTRACTING OFFICER'S REPRESENTATIVE**

The KO is the only individual authorized to amend in any way the terms of the contract. The KO shall appoint a COR to provide all required technical advice and surveillance under the contract. The KO shall exercise oversight of the COR. Costs incurred as the result of changes made to the terms and conditions without the KO's written approval, may not be considered an allowable cost.

REPRESENTATIONS AND CERTIFICATIONS

The representations, certifications and other statements submitted by the Contractor shall be incorporated herein by reference at the time of contract award.

INCORPORATION OF CONTRACTOR'S PROPOSAL INTO THE CONTRACT

During the evaluation and source selection process, the proposing Contractors are anticipated to have offered specific features in their proposals considered by the Government to be beneficial approaches to meeting RFP requirements. These features are captured in the Contractor's RFP documents which are incorporated, in whole or in part, into this contract by reference as contract requirements. Any improvement statements made in the Contractor's proposal shall be considered a part of the resultant contract as long as they do not conflict with the contract terms and conditions. The Contractor shall meet these features along with all other contract requirements. The estimated cost for providing these features is included in the contract CLINs for the contract period of performance.

CONTRACTING OFFICER (KO) POINT OF CONTACT

The Contracting Officer for this project is located at the U.S. Army Medical Research Acquisition Activity, ATTN: MCMR-AAA-W, 820 Chandler Street, Fort Detrick, MD 21702-5014. The following applies:

NOTE: Contact information shall be provided at contract award.

CONTRACTING OFFICER'S REPRESENTATIVE (COR) POINT OF CONTACT

The Contracting Officer's Representative for this project is located at the U.S. Army Dental Research Detachment, Walter Reed Army Institute of Research, Building 1 H, Room G-13, 310 B B St. Naval Training Center, Great Lakes, IL 60088-5259. The following applies:

NOTE: Contact information shall be provided at contract award.

CLAUSES INCORPORATED BY FULL TEXT

INCREMENTAL FUNDING (MAR 1999) (USAMRAA)

To Be Completed At Time of Award

a. It is estimated that the total cost to the Government for the full performance of this contract for the period to will be \$. There have been funds allotted for reimbursement of allowable costs, and applicable fee, incurred in the performance of this contract in the amount of only \$. It is estimated that such funded amount shall be sufficient to cover allowable expenses for the period to . The amount of the funds currently allotted may be increased by the Contracting Officer without further concurrence of the contractor. It is estimated that the remaining funds will be made available in accordance with the following schedule:

Amount	On or about
\$	

b. Pending the availability of additional funds, performance by the contractor shall be governed by the contract clause entitled "Limitation of Funds", FAR 52.232-22.

VOUCHERS (DEC 2006) (USAMRAA)

a. The Contractor shall submit an original and one copy of public vouchers (SF 1034), with supporting documentation, not less frequently than monthly to the Contract Specialist and the Contracting Officer's Representative for review and forwarding for payment.

b. All vouchers shall state the total amount claimed and the subtotals claimed, by category. The Government will make payments to the Contractor in amounts determined to be allowable by the Contracting Officer in accordance with the FAR clause at 52.216-7, Allowable Cost and Payment. For instance, travel costs shall include, as a minimum: date and place (city, town, or other similar designation) of the expenses; purpose of the trip; name of person and that person's title or relationship to the contractor, number of trips, public carrier rates, per diem costs, incidental costs, etc.

c. Cumulative totals of expenditures in each category shall also be shown.

d. Each voucher submitted must state the period of performance. Each voucher submitted must request payment for only those man-hours or cost expenditures incurred in that period.

e. The Contracting Officer shall be notified immediately in the event a budget category is expected to deviate from the negotiated budget.

f. The completion voucher shall be submitted by the Contractor to the Contract Specialist.

TRAVEL (JULY 2007) (USAMRAA)

a. Approval of Foreign Travel. The cost of foreign travel is allowable only when the specific written approval of the Contracting Officer is obtained prior to commencing the trip. Approval shall be requested at least 90 calendar days before the scheduled departure date in order that all necessary clearances may be processed. Each individual trip must be approved separately, even though it may have been included in a previously approved budget. Foreign travel under this contract is defined as any travel outside of the United States and its territories and possessions.

b. Costs incurred by contractor personnel on official company business, whether foreign travel and/or domestic/local travel, are allowable, subject to the limitations contained in the Federal Acquisition Regulation (FAR) clause at 52.216-7, Allowable Cost and Payment, incorporated into this contract.

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	JUL 2004
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	APR 1984
52.203-6	Restrictions On Subcontractor Sales To The Government	SEP 2006
52.203-7	Anti-Kickback Procedures	JUL 1995
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	JAN 1997
52.203-10	Price Or Fee Adjustment For Illegal Or Improper Activity	JAN 1997
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	SEP 2007
52.204-4	Printed or Copied Double-Sided on Recycled Paper	AUG 2000
52.211-15	Defense Priority And Allocation Requirements	APR 2008
52.215-2	Audit and Records--Negotiation	MAR 2009
52.215-2 Alt II	Audit and Records--Negotiation (Mar 2009) - Alternate II	APR 1998
52.215-8	Order of Precedence--Uniform Contract Format	OCT 1997
52.215-10	Price Reduction for Defective Cost or Pricing Data	OCT 1997
52.215-11	Price Reduction for Defective Cost or Pricing Data--Modifications	OCT 1997
52.215-12	Subcontractor Cost or Pricing Data	OCT 1997
52.215-14	Integrity of Unit Prices	OCT 1997
52.215-15	Pension Adjustments and Asset Reversions	OCT 2004
52.215-16	Facilities Capital Cost of Money	JUN 2003
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other than Pensions	JUL 2005
52.215-19	Notification of Ownership Changes	OCT 1997
52.215-20	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data	OCT 1997
52.215-21	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data--Modifications	OCT 1997
52.216-8	Fixed Fee	MAR 1997
52.219-8	Utilization of Small Business Concerns	MAY 2004
52.219-9	Small Business Subcontracting Plan	APR 2008
52.219-16	Liquidated Damages-Subcontracting Plan	JAN 1999
52.222-3	Convict Labor	JUN 2003
52.222-21	Prohibition Of Segregated Facilities	FEB 1999
52.222-22	Previous Contracts And Compliance Reports	FEB 1999
52.222-26	Equal Opportunity	MAR 2007
52.222-35	Equal Opportunity For Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans	SEP 2006
52.222-37	Employment Reports On Special Disabled Veterans, Veterans Of The Vietnam Era, and Other Eligible Veterans	SEP 2006
52.222-50	Combating Trafficking in Persons	FEB 2009
52.223-6	Drug-Free Workplace	MAY 2001
52.223-14	Toxic Chemical Release Reporting	AUG 2003
52.225-17	Evaluation of Foreign Currency Offers	FEB 2000
52.226-1	Utilization Of Indian Organizations And Indian-Owned Economic Enterprises	JUN 2000
52.227-1 Alt I	Authorization And Consent (Dec 2007) - Alternate I	APR 1984

52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	DEC 2007
52.227-14	Rights in Data--General	DEC 2007
52.228-7	Insurance--Liability To Third Persons	MAR 1996
52.232-9	Limitation On Withholding Of Payments	APR 1984
52.232-17	Interest	OCT 2008
52.232-23	Assignment Of Claims	JAN 1986
52.232-25	Prompt Payment	OCT 2008
52.232-33	Payment by Electronic Funds Transfer--Central Contractor Registration	OCT 2003
52.233-1	Disputes	JUL 2002
52.233-3 Alt I	Protest After Award (Aug 1996) - Alternate I	JUN 1985
52.242-1	Notice of Intent to Disallow Costs	APR 1984
52.242-3	Penalties for Unallowable Costs	MAY 2001
52.242-4	Certification of Final Indirect Costs	JAN 1997
52.242-13	Bankruptcy	JUL 1995
52.243-2 Alt I	Changes--Cost-Reimbursement (Aug 1987) - Alternate I	APR 1984
52.243-6	Change Order Accounting	APR 1984
52.244-5	Competition In Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	DEC 2009
52.245-1	Government Property	JUN 2007
52.245-9	Use And Charges	JUN 2007
52.246-23	Limitation Of Liability	FEB 1997
52.247-23	Contractor Liability for Loss of and/or Damage to Household Goods	JAN 1991
52.247-63	Preference For U.S. Flag Air Carriers	JUN 2003
52.249-5	Termination For Convenience Of The Government (Educational And Other Nonprofit Institutions)	SEP 1996
52.249-6	Termination (Cost Reimbursement)	MAY 2004
52.249-14	Excusable Delays	APR 1984
52.251-1	Government Supply Sources	APR 1984
52.253-1	Computer Generated Forms	JAN 1991
252.201-7000	Contracting Officer's Representative	DEC 1991
252.203-7001	Prohibition On Persons Convicted of Fraud or Other Defense-Contract-Related Felonies	DEC 2008
252.204-7000	Disclosure Of Information	DEC 1991
252.204-7003	Control Of Government Personnel Work Product	APR 1992
252.205-7000	Provision Of Information To Cooperative Agreement Holders	DEC 1991
252.209-7001	Disclosure of Ownership or Control by the Government of a Terrorist Country	JAN 2009
252.209-7004	Subcontracting With Firms That Are Owned or Controlled By The Government of a Terrorist Country	DEC 2006
252.209-7005	Reserve Officer Training Corps and Military Recruiting on Campus	JAN 2000
252.215-7000	Pricing Adjustments	DEC 1991
252.215-7002	Cost Estimating System Requirements	DEC 2006
252.217-7012	Liability and Insurance	AUG 2003
252.219-7003	Small Business Subcontracting Plan (DOD Contracts)	APR 2007
252.225-7006	Quarterly Reporting of Actual Contract Performance Outside the United States	MAY 2007
252.225-7012	Preference For Certain Domestic Commodities	DEC 2008
252.227-7013	Rights in Technical Data--Noncommercial Items	NOV 1995
252.227-7017	Identification and Assertion of Use, Release, or Disclosure Restrictions	JUN 1995

252.227-7030	Technical Data--Withholding Of Payment	MAR 2000
252.227-7037	Validation of Restrictive Markings on Technical Data	SEP 1999
252.227-7039	Patents--Reporting Of Subject Inventions	APR 1990
252.231-7000	Supplemental Cost Principles	DEC 1991
252.235-7011	Final Scientific or Technical Report	NOV 2004
252.242-7004	Material Management And Accounting System	JUL 2009
252.243-7002	Requests for Equitable Adjustment	MAR 1998
252.247-7023	Transportation of Supplies by Sea	MAY 2002

CLAUSES INCORPORATED BY FULL TEXT

52.204-1 APPROVAL OF CONTRACT (DEC 1989)

This contract is subject to the written approval of _____ and shall not be binding until so approved.

(End of clause)

52.209-6 PROTECTING THE GOVERNMENT'S INTEREST WHEN SUBCONTRACTING WITH CONTRACTORS DEBARRED, SUSPENDED, OR PROPOSED FOR DEBARMENT (SEP 2006)

(a) The Government suspends or debar Contractors to protect the Government's interests. The Contractor shall not enter into any subcontract in excess of the \$30,000 with a Contractor that is debarred, suspended, or proposed for debarment unless there is a compelling reason to do so.

(b) The Contractor shall require each proposed first-tier subcontractor, whose subcontract will exceed \$30,000, to disclose to the Contractor, in writing, whether as of the time of award of the subcontract, the subcontractor, or its principles, is or is not debarred, suspended, or proposed for debarment by the Federal Government.

(c) A corporate officer or a designee of the Contractor shall notify the Contracting Officer, in writing, before entering into a subcontract with a party that is debarred, suspended, or proposed for debarment (see FAR 9.404 for information on the in the Excluded Parties List System). The notice must include the following:

(1) The name of the subcontractor.

(2) The Contractor's knowledge of the reasons for the subcontractor being in the Excluded Parties List System.

(3) The compelling reason(s) for doing business with the subcontractor notwithstanding its inclusion in the Excluded Parties List System.

(4) The systems and procedures the Contractor has established to ensure that it is fully protecting the Government's interests when dealing with such subcontractor in view of the specific basis for the party's debarment, suspension, or proposed debarment.

(End of clause)

52.211-14 NOTICE OF PRIORITY RATING FOR NATIONAL DEFENSE, EMERGENCY PREPAREDNESS, AND ENERGY PROGRAM USE (APR 2008)

Any contract awarded as a result of this solicitation will be DX rated order; DO rated order certified for national defense, emergency preparedness, and energy program use under the Defense Priorities and Allocations System (DPAS) (15 CFR 700), and the Contractor will be required to follow all of the requirements of this regulation. [Contracting Officer check appropriate box.]

(End of provision)

52.216-7 ALLOWABLE COST AND PAYMENT (DEC 2002)

(a) Invoicing.

(1) The Government will make payments to the Contractor when requested as work progresses, but (except for small business concerns) not more often than once every 2 weeks, in amounts determined to be allowable by the Contracting Officer in accordance with Federal Acquisition Regulation (FAR) subpart 31.2 in effect on the date of this contract and the terms of this contract. The Contractor may submit to an authorized representative of the Contracting Officer, in such form and reasonable detail as the representative may require, an invoice or voucher supported by a statement of the claimed allowable cost for performing this contract.

(2) Contract financing payments are not subject to the interest penalty provisions of the Prompt Payment Act. Interim payments made prior to the final payment under the contract are contract financing payments, except interim payments if this contract contains Alternate I to the clause at 52.232-25.

(3) The designated payment office will make interim payments for contract financing on the (Contracting Officer insert day as prescribed by agency head; if not prescribed, insert "30th") day after the designated billing office receives a proper payment request.

In the event that the Government requires an audit or other review of a specific payment request to ensure compliance with the terms and conditions of the contract, the designated payment office is not compelled to make payment by the specified due date.

(b) Reimbursing costs. (1) For the purpose of reimbursing allowable costs (except as provided in subparagraph (b)(2) of the clause, with respect to pension, deferred profit sharing, and employee stock ownership plan contributions), the term "costs" includes only--

(i) Those recorded costs that, at the time of the request for reimbursement, the Contractor has paid by cash, check, or other form of actual payment for items or services purchased directly for the contract;

(ii) When the Contractor is not delinquent in paying costs of contract performance in the ordinary course of business, costs incurred, but not necessarily paid, for--

(A) Supplies and services purchased directly for the contract and associated financing payments to subcontractors, provided payments determined due will be made--

(1) In accordance with the terms and conditions of a subcontract or invoice; and

(2) Ordinarily within 30 days of the submission of the Contractor's payment request to the Government;

(B) Materials issued from the Contractor's inventory and placed in the production process for use on the contract;

(C) Direct labor;

(D) Direct travel;

(E) Other direct in-house costs; and

(F) Properly allocable and allowable indirect costs, as shown in the records maintained by the Contractor for purposes of obtaining reimbursement under Government contracts; and

(iii) The amount of financing payments that have been paid by cash, check, or other forms of payment to subcontractors.

(2) Accrued costs of Contractor contributions under employee pension plans shall be excluded until actually paid unless--

(i) The Contractor's practice is to make contributions to the retirement fund quarterly or more frequently; and

(ii) The contribution does not remain unpaid 30 days after the end of the applicable quarter or shorter payment period (any contribution remaining unpaid shall be excluded from the Contractor's indirect costs for payment purposes).

(3) Notwithstanding the audit and adjustment of invoices or vouchers under paragraph (g) of this clause, allowable indirect costs under this contract shall be obtained by applying indirect cost rates established in accordance with paragraph (d) of this clause.

(4) Any statements in specifications or other documents incorporated in this contract by reference designating performance of services or furnishing of materials at the Contractor's expense or at no cost to the Government shall be disregarded for purposes of cost-reimbursement under this clause.

(c) Small business concerns. A small business concern may receive more frequent payments than every 2 weeks.

(d) Final indirect cost rates. (1) Final annual indirect cost rates and the appropriate bases shall be established in accordance with Subpart 42.7 of the Federal Acquisition Regulation (FAR) in effect for the period covered by the indirect cost rate proposal.

(2)(i) The Contractor shall submit an adequate final indirect cost rate proposal to the Contracting Officer (or cognizant Federal agency official) and auditor within the 6-month period following the expiration of each of its fiscal years. Reasonable extensions, for exceptional circumstances only, may be requested in writing by the Contractor and granted in writing by the Contracting Officer. The Contractor shall support its proposal with adequate supporting data.

(ii) The proposed rates shall be based on the Contractor's actual cost experience for that period. The appropriate Government representative and the Contractor shall establish the final indirect cost rates as promptly as practical after receipt of the Contractor's proposal.

(3) The Contractor and the appropriate Government representative shall execute a written understanding setting forth the final indirect cost rates. The understanding shall specify (i) the agreed-upon final annual indirect cost rates, (ii) the bases to which the rates apply, (iii) the periods for which the rates apply, (iv) any specific indirect cost items treated as direct costs in the settlement, and (v) the affected contract and/or subcontract, identifying any with advance agreements or special terms and the applicable rates. The understanding shall not change any monetary ceiling, contract obligation, or specific cost allowance or disallowance provided for in this contract. The understanding is incorporated into this contract upon execution.

(4) Failure by the parties to agree on a final annual indirect cost rate shall be a dispute within the meaning of the Disputes clause.

(5) Within 120 days (or longer period if approved in writing by the Contracting Officer) after settlement of the final annual indirect cost rates for all years of a physically complete contract, the Contractor shall submit a completion invoice or voucher to reflect the settled amounts and rates.

(6)(i) If the Contractor fails to submit a completion invoice or voucher within the time specified in paragraph (d)(5) of this clause, the Contracting Officer may--

(A) Determine the amounts due to the Contractor under the contract; and

(B) Record this determination in a unilateral modification to the contract.

(ii) This determination constitutes the final decision of the Contracting Officer in accordance with the Disputes clause.

(e) Billing rates. Until final annual indirect cost rates are established for any period, the Government shall reimburse the Contractor at billing rates established by the Contracting Officer or by an authorized representative (the cognizant auditor), subject to adjustment when the final rates are established. These billing rates--

(1) Shall be the anticipated final rates; and

(2) May be prospectively or retroactively revised by mutual agreement, at either party's request, to prevent substantial overpayment or underpayment.

(f) Quick-closeout procedures. Quick-closeout procedures are applicable when the conditions in FAR 42.708(a) are satisfied.

(g) Audit. At any time or times before final payment, the Contracting Officer may have the Contractor's invoices or vouchers and statements of cost audited. Any payment may be (1) Reduced by amounts found by the Contracting Officer not to constitute allowable costs or (2) Adjusted for prior overpayments or underpayments.

(h) Final payment. (1) Upon approval of a completion invoice or voucher submitted by the Contractor in accordance with paragraph (d)(4) of this clause, and upon the Contractor's compliance with all terms of this contract, the Government shall promptly pay any balance of allowable costs and that part of the fee (if any) not previously paid.

(2) The Contractor shall pay to the Government any refunds, rebates, credits, or other amounts (including interest, if any) accruing to or received by the Contractor or any assignee under this contract, to the extent that those amounts are properly allocable to costs for which the Contractor has been reimbursed by the Government. Reasonable expenses incurred by the Contractor for securing refunds, rebates, credits, or other amounts shall be allowable costs if approved by the Contracting Officer. Before final payment under this contract, the Contractor and each assignee whose assignment is in effect at the time of final payment shall execute and deliver--

(i) An assignment to the Government, in form and substance satisfactory to the Contracting Officer, of refunds, rebates, credits, or other amounts (including interest, if any) properly allocable to costs for which the Contractor has been reimbursed by the Government under this contract; and

(ii) A release discharging the Government, its officers, agents, and employees from all liabilities, obligations, and claims arising out of or under this contract, except--

(A) Specified claims stated in exact amounts, or in estimated amounts when the exact amounts are not known;

(B) Claims (including reasonable incidental expenses) based upon liabilities of the Contractor to third parties arising out of the performance of this contract; provided, that the claims are not known to the Contractor on the date of the execution of the release, and that the Contractor gives notice of the claims in writing to the Contracting Officer within 6 years following the release date or notice of final payment date, whichever is earlier; and

(C) Claims for reimbursement of costs, including reasonable incidental expenses, incurred by the Contractor under the patent clauses of this contract, excluding, however, any expenses arising from the Contractor's indemnification of the Government against patent liability.

(End of clause)

52.222-2 PAYMENT FOR OVERTIME PREMIUMS (JUL 1990)

(a) The use of overtime is authorized under this contract if the overtime premium cost does not exceed _____ or the overtime premium is paid for work --

(1) Necessary to cope with emergencies such as those resulting from accidents, natural disasters, breakdowns of production equipment, or occasional production bottlenecks of a sporadic nature;

(2) By indirect-labor employees such as those performing duties in connection with administration, protection, transportation, maintenance, standby plant protection, operation of utilities, or accounting;

(3) To perform tests, industrial processes, laboratory procedures, loading or unloading of transportation conveyances, and operations in flight or afloat that are continuous in nature and cannot reasonably be interrupted or completed otherwise; or

(4) That will result in lower overall costs to the Government.

(b) Any request for estimated overtime premiums that exceeds the amount specified above shall include all estimated overtime for contract completion and shall--

(1) Identify the work unit; e.g., department or section in which the requested overtime will be used, together with present workload, staffing, and other data of the affected unit sufficient to permit the Contracting Officer to evaluate the necessity for the overtime;

(2) Demonstrate the effect that denial of the request will have on the contract delivery or performance schedule;

(3) Identify the extent to which approval of overtime would affect the performance or payments in connection with other Government contracts, together with identification of each affected contract; and

(4) Provide reasons why the required work cannot be performed by using multishift operations or by employing additional personnel.

* Insert either "zero" or the dollar amount agreed to during negotiations. The inserted figure does not apply to the exceptions in paragraph (a)(1) through (a)(4) of the clause.

(End of clause)

52.227-11 PATENT RIGHTS--OWNERSHIP BY THE CONTRACTOR (DEC 2007)

(a) As used in this clause--

Invention means any invention or discovery that is or may be patentable or otherwise protectable under title 35 of the U.S. Code, or any variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.)

Made means--

(1) When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of the invention; or

(2) When used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

Nonprofit organization means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)), or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

Practical application means to manufacture, in the case of a composition of product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

Subject invention means any invention of the Contractor made in the performance of work under this contract.

(b) Contractor's rights. (1) Ownership. The Contractor may retain ownership of each subject invention throughout the world in accordance with the provisions of this clause.

(2) License. (i) The Contractor shall retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, unless the Contractor fails to disclose the invention within the times specified in paragraph (c) of this clause. The Contractor's license extends to any domestic subsidiaries and affiliates within the corporate structure of which the Contractor is a part, and includes the right to grant sublicenses to the extent the Contractor was legally obligated to do so at contract award. The license is transferable only with the written approval of the agency, except when transferred to the successor of that part of the Contractor's business to which the invention pertains.

(ii) The Contractor's license may be revoked or modified by the agency to the extent necessary to achieve expeditious practical application of the subject invention in a particular country in accordance with the procedures in FAR 27.302(i)(2) and 27.304-1(f).

(c) Contractor's obligations. (1) The Contractor shall disclose in writing each subject invention to the Contracting Officer within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this contract under which the subject invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the subject invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the subject invention, or whether a manuscript describing the subject invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the Contractor shall promptly notify the Contracting Officer of the acceptance of any manuscript describing the subject invention for publication and any on sale or public use.

(2) The Contractor shall elect in writing whether or not to retain ownership of any subject invention by notifying the Contracting Officer within 2 years of disclosure to the agency. However, in any case where publication, on sale, or

public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.

(3) The Contractor shall file either a provisional or a nonprovisional patent application or a Plant Variety Protection Application on an elected subject invention within 1 year after election. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the Contractor shall file the application prior to the end of that statutory period. If the Contractor files a provisional application, it shall file a nonprovisional application within 10 months of the filing of the provisional application. The Contractor shall file patent applications in additional countries or international patent offices within either 10 months of the first filed patent application (whether provisional or nonprovisional) or 6 months from the date permission is granted by the Commissioner of Patents to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) The Contractor may request extensions of time for disclosure, election, or filing under paragraphs (c)(1), (c)(2), and (c)(3) of this clause.

(d) Government's rights--(1) Ownership. The Contractor shall assign to the agency, on written request, title to any subject invention--

(i) If the Contractor fails to disclose or elect ownership to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain ownership; provided, that the agency may request title only within 60 days after learning of the Contractor's failure to disclose or elect within the specified times.

(ii) In those countries in which the Contractor fails to file patent applications within the times specified in paragraph (c) of this clause; provided, however, that if the Contractor has filed a patent application in a country after the times specified in paragraph (c) of this clause, but prior to its receipt of the written request of the agency, the Contractor shall continue to retain ownership in that country.

(iii) In any country in which the Contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

(2) License. If the Contractor retains ownership of any subject invention, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the subject invention throughout the world.

(e) Contractor action to protect the Government's interest. (1) The Contractor shall execute or have executed and promptly deliver to the agency all instruments necessary to--

(i) Establish or confirm the rights the Government has throughout the world in those subject inventions in which the Contractor elects to retain ownership; and

(ii) Assign title to the agency when requested under paragraph (d) of this clause and to enable the Government to obtain patent protection and plant variety protection for that subject invention in any country.

(2) The Contractor shall require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in the Contractor's format, each subject invention in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. The disclosure format should require, as a minimum, the information required by paragraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, as to the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The Contractor shall notify the Contracting Officer of any decisions not to file a nonprovisional patent application, continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than 30 days before the expiration of the response or filing period required by the relevant patent office.

(4) The Contractor shall include, within the specification of any United States nonprovisional patent or plant variety protection application and any patent or plant variety protection certificate issuing thereon covering a subject invention, the following statement, "This invention was made with Government support under (identify the contract) awarded by (identify the agency). The Government has certain rights in the invention."

(f) Reporting on utilization of subject inventions. The Contractor shall submit, on request, periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining utilization of the subject invention that are being made by the Contractor or its licensees or assignees. The reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and other data and information as the agency may reasonably specify. The Contractor also shall provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph (h) of this clause. The Contractor also shall mark any utilization report as confidential/proprietary to help prevent inadvertent release outside the Government. As required by 35 U.S.C. 202(c)(5), the agency will not disclose that information to persons outside the Government without the Contractor's permission.

(g) Preference for United States industry. Notwithstanding any other provision of this clause, neither the Contractor nor any assignee shall grant to any person the exclusive right to use or sell any subject invention in the United States unless the person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for an agreement may be waived by the agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States, or that under the circumstances domestic manufacture is not commercially feasible.

(h) March-in rights. The Contractor acknowledges that, with respect to any subject invention in which it has retained ownership, the agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of contract award.

(i) Special provisions for contracts with nonprofit organizations. If the Contractor is a nonprofit organization, it shall--

(1) Not assign rights to a subject invention in the United States without the written approval of the agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided, that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (but through their agency if the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions for the support of scientific research or education; and

(4) Make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business concerns, and give a preference to a small business concern when licensing a subject invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if

executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor.

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(j) Communications. (Complete according to agency instructions.)

(k) Subcontracts. (1) The Contractor shall include the substance of this clause, including this paragraph (k), in all subcontracts for experimental, developmental, or research work to be performed by a small business concern or nonprofit organization.

(2) The Contractor shall include in all other subcontracts for experimental, developmental, or research work the substance of the patent rights clause required by FAR Subpart 27.3.

(3) At all tiers, the patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor shall not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(4) In subcontracts, at any tier, the agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (h) of this clause.

(End of clause)

52.233-4 APPLICABLE LAW FOR BREACH OF CONTRACT CLAIM (OCT 2004)

United States law will apply to resolve any claim of breach of this contract.

(End of clause)

52.244-2 SUBCONTRACTS (JUN 2007)

(a) Definitions. As used in this clause--

Approved purchasing system means a Contractor's purchasing system that has been reviewed and approved in accordance with Part 44 of the Federal Acquisition Regulation (FAR).

Consent to subcontract means the Contracting Officer's written consent for the Contractor to enter into a particular subcontract.

Subcontract means any contract, as defined in FAR Subpart 2.1, entered into by a subcontractor to furnish supplies or services for performance of the prime contract or a subcontract. It includes, but is not limited to, purchase orders, and changes and modifications to purchase orders.
purchase orders.

(b) When this clause is included in a fixed-price type contract, consent to subcontract is required only on unpriced contract actions (including unpriced modifications or unpriced delivery orders), and only if required in accordance with paragraph (c) or (d) of this clause.

(c) If the Contractor does not have an approved purchasing system, consent to subcontract is required for any subcontract that—

(1) Is of the cost-reimbursement, time-and-materials, or labor-hour type; or

(2) Is fixed-price and exceeds—

(i) For a contract awarded by the Department of Defense, the Coast Guard, or the National Aeronautics and Space Administration, the greater of the simplified acquisition threshold or 5 percent of the total estimated cost of the contract; or

(ii) For a contract awarded by a civilian agency other than the Coast Guard and the National Aeronautics and Space Administration, either the simplified acquisition threshold or 5 percent of the total estimated cost of the contract.

(d) If the Contractor has an approved purchasing system, the Contractor nevertheless shall obtain the Contracting Officer's written consent before placing the following subcontracts:

(e)(1) The Contractor shall notify the Contracting Officer reasonably in advance of placing any subcontract or modification thereof for which consent is required under paragraph (b), (c), or (d) of this clause, including the following information:

(i) A description of the supplies or services to be subcontracted.

(ii) Identification of the type of subcontract to be used.

(iii) Identification of the proposed subcontractor.

(iv) The proposed subcontract price.

(v) The subcontractor's current, complete, and accurate cost or pricing data and Certificate of Current Cost or Pricing Data, if required by other contract provisions.

(vi) The subcontractor's Disclosure Statement or Certificate relating to Cost Accounting Standards when such data are required by other provisions of this contract.

(vii) A negotiation memorandum reflecting—

(A) The principal elements of the subcontract price negotiations;

(B) The most significant considerations controlling establishment of initial or revised prices;

(C) The reason cost or pricing data were or were not required;

(D) The extent, if any, to which the Contractor did not rely on the subcontractor's cost or pricing data in determining the price objective and in negotiating the final price;

(E) The extent to which it was recognized in the negotiation that the subcontractor's cost or pricing data were not accurate, complete, or current; the action taken by the Contractor and the subcontractor; and the effect of any such defective data on the total price negotiated;

(F) The reasons for any significant difference between the Contractor's price objective and the price negotiated; and

(G) A complete explanation of the incentive fee or profit plan when incentives are used. The explanation shall identify each critical performance element, management decisions used to quantify each incentive element, reasons for the incentives, and a summary of all trade-off possibilities considered.

(2) The Contractor is not required to notify the Contracting Officer in advance of entering into any subcontract for which consent is not required under paragraph (c), (d), or (e) of this clause.

(f) Unless the consent or approval specifically provides otherwise, neither consent by the Contracting Officer to any subcontract nor approval of the Contractor's purchasing system shall constitute a determination—

(1) Of the acceptability of any subcontract terms or conditions;

(2) Of the allowability of any cost under this contract; or

(3) To relieve the Contractor of any responsibility for performing this contract.

(g) No subcontract or modification thereof placed under this contract shall provide for payment on a cost-plus-a-percentage-of-cost basis, and any fee payable under cost-reimbursement type subcontracts shall not exceed the fee limitations in FAR 15.404-4(c)(4)(i).

(h) The Contractor shall give the Contracting Officer immediate written notice of any action or suit filed and prompt notice of any claim made against the Contractor by any subcontractor or vendor that, in the opinion of the Contractor, may result in litigation related in any way to this contract, with respect to which the Contractor may be entitled to reimbursement from the Government.

(i) The Government reserves the right to review the Contractor's purchasing system as set forth in FAR Subpart 44.3.

(j) Paragraphs (c) and (e) of this clause do not apply to the following subcontracts, which were evaluated during negotiations:

(End of clause)

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):

[www.com]

(End of clause)

52.252-6 AUTHORIZED DEVIATIONS IN CLAUSES (APR 1984)

(a) The use in this solicitation or contract of any Federal Acquisition Regulation (48 CFR Chapter 1) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the date of the clause.

(b) The use in this solicitation or contract of any insert regulation name (48 CFR _____) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the name of the regulation.

(End of clause)

252.204-7006 BILLING INSTRUCTIONS (OCT 2005)

When submitting a request for payment, the Contractor shall--

(a) Identify the contract line item(s) on the payment request that reasonably reflect contract work performance; and

(b) Separately identify a payment amount for each contract line item included in the payment request.

(End of clause)

252.235-7010 Acknowledgment of Support and Disclaimer. (MAY 1995)

(a) The Contractor shall include an acknowledgment of the Government's support in the publication of any material based on or developed under this contract, stated in the following terms: This material is based upon work supported by the [name of contracting agency(ies)] under Contract No. [Contracting agency(ies) contract number(s)].

(b) All material, except scientific articles or papers published in scientific journals, must, in addition to any notices or disclaimers by the Contractor, also contain the following disclaimer: Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the [name of contracting agency(ies)].

Section J - List of Documents, Exhibits and Other Attachments

ATTACHMENTS TABLE

DOCUMENT TYPE	DESCRIPTION	PAGES	DATE	COMMENTS
Attachment 1	Past Performance Questionnaire	3 Pages	Feb 2007	Attached

Section K - Representations, Certifications and Other Statements of Offerors

CLAUSES INCORPORATED BY REFERENCE

52.203-11	Certification And Disclosure Regarding Payments To Influence Certain Federal Transactions	SEP 2007
52.222-38	Compliance With Veterans' Employment Reporting Requirements	DEC 2001
52.222-52	Exemption from Application of the Service Contract Act to Contracts for Certain Services--Certification	NOV 2007
52.225-18	Place of Manufacture	SEP 2006
252.209-7001	Disclosure of Ownership or Control by the Government of a Terrorist Country	JAN 2009
252.225-7000	Buy American Act--Balance Of Payments Program Certificate	DEC 2009
252.225-7031	Secondary Arab Boycott Of Israel	JUN 2005

CLAUSES INCORPORATED BY FULL TEXT

52.204-3 TAXPAYER IDENTIFICATION (OCT 1998)

(a) Definitions.

Common parent, as used in this provision, means that corporate entity that owns or controls an affiliated group of corporations that files its Federal income tax returns on a consolidated basis, and of which the offeror is a member.

Taxpayer Identification Number (TIN), as used in this provision, means the number required by the Internal Revenue Service (IRS) to be used by the offeror in reporting income tax and other returns. The TIN may be either a Social Security Number or an Employer Identification Number.

(b) All offerors must submit the information required in paragraphs (d) through (f) of this provision to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M, and implementing regulations issued by the IRS. If the resulting contract is subject to the payment reporting requirements described in Federal Acquisition Regulation (FAR) 4.904, the failure or refusal by the offeror to furnish the information may result in a 31 percent reduction of payments otherwise due under the contract.

(c) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government (31 U.S.C. 7701(c)(3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror's TIN.

(d) Taxpayer Identification Number (TIN).

___ TIN:-----

___ TIN has been applied for.

___ TIN is not required because:

___ Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States;

___ Offeror is an agency or instrumentality of a foreign government;

___ Offeror is an agency or instrumentality of the Federal Government.

(e) Type of organization.

___ Sole proprietorship;

___ Partnership;

___ Corporate entity (not tax-exempt);

___ Corporate entity (tax-exempt);

___ Government entity (Federal, State, or local);

___ Foreign government;

___ International organization per 26 CFR 1.6049-4;

___ Other-----

(f) Common parent.

___ Offeror is not owned or controlled by a common parent as defined in paragraph (a) of this provision.

___ Name and TIN of common parent:

Name-----

TIN-----

(End of provision)

52.204-5 WOMEN-OWNED BUSINESS (OTHER THAN SMALL BUSINESS) (MAY 1999)

(a) Definition. Women-owned business concern, as used in this provision, means a concern that is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of its stock is owned by one or more women; and whose management and daily business operations are controlled by one or more women.

(b) Representation. [Complete only if the offeror is a women-owned business concern and has not represented itself as a small business concern in paragraph (b)(1) of FAR 52.219-1, Small Business Program Representations, of this solicitation.] The offeror represents that it () is a women-owned business concern.

(End of provision)

52.204-6 DATA UNIVERSAL NUMBERING SYSTEM (DUNS) NUMBER (APR 2008)

(a) The offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation "DUNS" or "DUNS+4" followed by the DUNS number or "DUNS+4" that identifies the offeror's name and address exactly as stated in the offer. The DUNS number is a nine-digit number assigned by Dun and Bradstreet, Inc. The DUNS+4 is the DUNS number plus a 4-character suffix that may be assigned at the discretion of the offeror to establish additional CCR records for identifying alternative Electronic Funds Transfer (EFT) accounts (see Subpart 32.11) for the same concern.

(b) If the offeror does not have a DUNS number, it should contact Dun and Bradstreet directly to obtain one.

(1) An offeror may obtain a DUNS number--

(i) Via the Internet at <http://fedgov.dnb.com/webform> or if the offeror does not have internet access, it may call Dun and Bradstreet at 1-866-705-5711 if located within the United States; or

(ii) If located outside the United States, by contacting the local Dun and Bradstreet office. The offeror should indicate that it is an offeror for a U.S. Government contract when contacting the local Dun and Bradstreet office.

(2) The offeror should be prepared to provide the following information:

(i) Company legal business name.

(ii) Tradestyle, doing business, or other name by which your entity is commonly recognized.

(iii) Company physical street address, city, state and Zip Code.

(iv) Company mailing address, city, state and Zip Code (if separate from physical).

(v) Company telephone number.

(vi) Date the company was started.

(vii) Number of employees at your location.

(viii) Chief executive officer/key manager.

(ix) Line of business (industry).

(x) Company Headquarters name and address (reporting relationship within your entity).

(End of provision)

52.204-8 ANNUAL REPRESENTATIONS AND CERTIFICATIONS (FEB 2009)

(a)(1) The North American Industry Classification System (NAICS) code for this acquisition is 325411

(2) The small business size standard is 750.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b)(1) If the clause at 52.204-7, Central Contractor Registration, is included in this solicitation, paragraph (d) of this provision applies.

(2) If the clause at 52.204-7 is not included in this solicitation, and the offeror is currently registered in CCR, and has completed the ORCA electronically, the offeror may choose to use paragraph (d) of this provision instead of completing the corresponding individual representations and certifications in the solicitation. The offeror shall indicate which option applies by checking one of the following boxes:

Paragraph (d) applies.

Paragraph (d) does not apply and the offeror has completed the individual representations and certifications in the solicitation.

(c)(1) The following representations or certifications in ORCA are applicable to this solicitation as indicated:

(i) 52.203-2, Certificate of Independent Price Determination. This provision applies to solicitations when a firm-fixed-price contract or fixed-price contract with economic price adjustment is contemplated, unless--

(A) The acquisition is to be made under the simplified acquisition procedures in Part 13;

(B) The solicitation is a request for technical proposals under two-step sealed bidding procedures; or

(C) The solicitation is for utility services for which rates are set by law or regulation.

(ii) 52.203-11, Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions. This provision applies to solicitations expected to exceed \$100,000.

(iii) 52.204-3, Taxpayer Identification. This provision applies to solicitations that do not include the clause at 52.204-7, Central Contractor Registration.

(iv) 52.204-5, Women-Owned Business (Other Than Small Business). This provision applies to solicitations that--

(A) Are not set aside for small business concerns;

(B) Exceed the simplified acquisition threshold; and

(C) Are for contracts that will be performed in the United States or its outlying areas.

(v) 52.209-5, Certification Regarding Responsibility Matters. This provision applies to solicitations where the contract value is expected to exceed the simplified acquisition threshold.

(vi) 52.214-14, Place of Performance--Sealed Bidding. This provision applies to invitations for bids except those in which the place of performance is specified by the Government.

(vii) 52.215-6, Place of Performance. This provision applies to solicitations unless the place of performance is specified by the Government.

(viii) 52.219-1, Small Business Program Representations (Basic & Alternate I). This provision applies to solicitations when the contract will be performed in the United States or its outlying areas.

(A) The basic provision applies when the solicitations are issued by other than DoD, NASA, and the Coast Guard.

(B) The provision with its Alternate I applies to solicitations issued by DoD, NASA, or the Coast Guard.

(ix) 52.219-2, Equal Low Bids. This provision applies to solicitations when contracting by sealed bidding and the contract will be performed in the United States or its outlying areas.

(x) 52.222-22, Previous Contracts and Compliance Reports. This provision applies to solicitations that include the clause at 52.222-26, Equal Opportunity.

(xi) 52.222-25, Affirmative Action Compliance. This provision applies to solicitations, other than those for construction, when the solicitation includes the clause at 52.222-26, Equal Opportunity.

(xii) 52.222-38, Compliance with Veterans' Employment Reporting Requirements. This provision applies to solicitations when it is anticipated the contract award will exceed the simplified acquisition threshold and the contract is not for acquisition of commercial items.

(xiii) 52.223-1, Biobased Product Certification. This provision applies to solicitations that require the delivery or specify the use of USDA-designated items; or include the clause at 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts.

(xiv) 52.223-4, Recovered Material Certification. This provision applies to solicitations that are for, or specify the use of, EPA-designated items.

(xv) 52.225-2, Buy American Act Certificate. This provision applies to solicitations containing the clause at 52.225-1.

(xvi) 52.225-4, Buy American Act--Free Trade Agreements—Israeli Trade Act Certificate. (Basic, Alternate I, and Alternate II) This provision applies to solicitations containing the clause at 52.225-3.

(A) If the acquisition value is less than \$25,000, the basic provision applies.

(B) If the acquisition value is \$25,000 or more but is less than \$50,000, the provision with its Alternate I applies.

(C) If the acquisition value is \$50,000 or more but is less than \$67,826, the provision with its Alternate II applies.

(xvii) 52.225-6, Trade Agreements Certificate. This provision applies to solicitations containing the clause at 52.225-5.

(xviii) 52.225-20, Prohibition on Conducting Restricted Business Operations in Sudan--Certification.

(xix) 52.226-2, Historically Black College or University and Minority Institution Representation. This provision applies to--

(A) Solicitations for research, studies, supplies, or services of the type normally acquired from higher educational institutions; and

(B) For DoD, NASA, and Coast Guard acquisitions, solicitations that contain the clause at 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns.

(2) The following certifications are applicable as indicated by the Contracting Officer:

(Contracting Officer check as appropriate.)

----(i) 52.219-19, Small Business Concern Representation for the Small Business Competitiveness Demonstration Program.

----- (ii) 52.219-21, Small Business Size Representation for Targeted Industry Categories Under the Small Business Competitiveness Demonstration Program.

----- (iii) 52.219-22, Small Disadvantaged Business Status.

----- (A) Basic.

----- (B) Alternate I.

----- (iv) 52.222-18, Certification Regarding Knowledge of Child Labor for Listed End Products.

----- (v) 52.222-48, Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment Certification.

----- (vi) 52.222-52 Exemption from Application of the Service Contract Act to Contracts for Certain Services-- Certification.

----- (vii) 52.223-9, with its Alternate I, Estimate of Percentage of Recovered Material Content for EPA- Designated Products (Alternate I only).

----- (viii) 52.223-13, Certification of Toxic Chemical Release Reporting.

----- (ix) 52.227-6, Royalty Information.

----- (A) Basic.

----- (B) Alternate I.

----- (x) 52.227-15, Representation of Limited Rights Data and Restricted Computer Software.

(d) The offeror has completed the annual representations and certifications electronically via the Online Representations and Certifications Application (ORCA) website at <http://orca.bpn.gov>. After reviewing the ORCA database information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below (offeror to insert changes, identifying change by clause number, title, date). These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR Clause	Title	Date	Change
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Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on ORCA.

(End of Provision)

52.209-5 CERTIFICATION REGARDING RESPONSIBILITY MATTERS (DEC 2008)

(a)(1) The Offeror certifies, to the best of its knowledge and belief, that-

(i) The Offeror and/or any of its Principals-

(A) Are () are not () presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have () have not (), within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, state, or local) contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property; and

(C) Are () are not () presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in paragraph (a)(1)(i)(B) of this provision.; and

(D) Have [ballot], have not [ballot], within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds \$3,000 for which the liability remains unsatisfied.

(1) Federal taxes are considered delinquent if both of the following criteria apply:

(i) The tax liability is finally determined. The liability is finally determined if it has been assessed. A liability is not finally determined if there is a pending administrative or judicial challenge. In the case of a judicial challenge to the liability, the liability is not finally determined until all judicial appeal rights have been exhausted.

(ii) The taxpayer is delinquent in making payment. A taxpayer is delinquent if the taxpayer has failed to pay the tax liability when full payment was due and required. A taxpayer is not delinquent in cases where enforced collection action is precluded.

(2) Examples. (i) The taxpayer has received a statutory notice of deficiency, under I.R.C. Sec. 6212, which entitles the taxpayer to seek Tax Court review of a proposed tax deficiency. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek Tax Court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(ii) The IRS has filed a notice of Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. Sec. 6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(iii) The taxpayer has entered into an installment agreement pursuant to I.R.C. Sec. 6159. The taxpayer is making timely payments and is in full compliance with the agreement terms. The taxpayer is not delinquent because the taxpayer is not currently required to make full payment.

(iv) The taxpayer has filed for bankruptcy protection. The taxpayer is not delinquent because enforced collection action is stayed under 11 U.S.C. 362 (the Bankruptcy Code).

(ii) The Offeror has () has not (), within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(2) Principal, for the purposes of this certification, means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a subsidiary, division, or business segment; and similar positions).

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

(End of provision)

52.219-1 SMALL BUSINESS PROGRAM REPRESENTATIONS (MAY 2004)

(a)(1) The North American Industry Classification System (NAICS) code for this acquisition is 325411.

(2) The small business size standard is 750.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b) Representations. (1) The offeror represents as part of its offer that it () is, () is not a small business concern.

(2) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents, for general statistical purposes, that it () is, () is not a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents as part of its offer that it () is, () is not a women-owned small business concern.

(4) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents as part of its offer that it () is, () is not a veteran-owned small business concern.

(5) (Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (b)(4) of this provision.) The offeror represents as part of its offer that it () is, () is not a service-disabled veteran-owned small business concern.

(6) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents, as part of its offer, that--

(i) It () is, () is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material change in ownership and control, principal office, or HUBZone employee percentage has occurred since it was certified by the Small Business Administration in accordance with 13 CFR part 126; and

(ii) It () is, () is not a joint venture that complies with the requirements of 13 CFR part 126, and the representation in paragraph (b)(6)(i) of this provision is accurate for the HUBZone small business concern or concerns that are participating in the joint venture. (The offeror shall enter the name or names of the HUBZone small business concern or concerns that are participating in the joint venture:_____.) Each HUBZone small business concern participating in the joint venture shall submit a separate signed copy of the HUBZone representation.

(c) Definitions. As used in this provision--

Service-disabled veteran-owned small business concern--

(1) Means a small business concern--

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

"Small business concern," means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and the size standard in paragraph (a) of this provision.

Veteran-owned small business concern means a small business concern--

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

"Women-owned small business concern," means a small business concern --

(1) That is at least 51 percent owned by one or more women; in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

(d) Notice.

(1) If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

(2) Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a small, HUBZone small, small disadvantaged, or women-owned small business concern in order to obtain a contract to be awarded under the preference programs established pursuant to section 8(a), 8(d), 9, or 15 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall--

(i) Be punished by imposition of fine, imprisonment, or both;

(ii) Be subject to administrative remedies, including suspension and debarment; and

(iii) Be ineligible for participation in programs conducted under the authority of the Act.

(End of provision)

52.219-1 SMALL BUSINESS PROGRAM REPRESENTATIONS (MAY 2004) - ALTERNATE I (APR 2002)

(a)(1) The North American Industry Classification System (NAICS) code for this acquisition is () (insert NAICS code).

(2) The small business size standard is () (insert size standard).

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b) Representations. (1) The offeror represents as part of its offer that it () is, () is not a small business concern.

(2) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents, for general statistical purposes, that it () is, () is not a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents as part of its offer that it () is, () is not a women-owned small business concern.

(4) (Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.) The offeror represents as part of its offer that it () is, () is not a veteran-owned small business concern.

(5) (Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (b)(4) of this provision.) The offeror represents as part of its offer that it () is, () is not a service-disabled veteran-owned small business concern.

(6) [Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.] The offeror represents, as part of its offer, that--

(i) It () is, () is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material change in ownership and control, principal office, or HUBZone employee percentage has occurred since it was certified by the Small Business Administration in accordance with 13 CFR part 126; and

(ii) It () is, () is not a joint venture that complies with the requirements of 13 CFR part 126, and the representation in paragraph (b)(6)(i) of this provision is accurate for the HUBZone small business concern or concerns that are participating in the joint venture. (The offeror shall enter the name or names of the HUBZone small business concern or concerns that are participating in the joint venture: _____.) Each HUBZone small business concern participating in the joint venture shall submit a separate signed copy of the HUBZone representation.

(7) (Complete if offeror represented itself as disadvantaged in paragraph (b)(2) of this provision.) The offeror shall check the category in which its ownership falls:

___ Black American.

___ Hispanic American.

___ Native American (American Indians, Eskimos, Aleuts, or Native Hawaiians).

___ Asian-Pacific American (persons with origins from Burma, Thailand, Malaysia, Indonesia, Singapore, Brunei, Japan, China, Taiwan, Laos, Cambodia (Kampuchea), Vietnam, Korea, The Philippines, U.S. Trust Territory of the Pacific Islands (Republic of Palau), Republic of the Marshall Islands, Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands, Guam, Samoa, Macao, Hong Kong, Fiji, Tonga, Kiribati, Tuvalu, or Nauru).

___ Subcontinent Asian (Asian-Indian) American (persons with origins from India, Pakistan, Bangladesh, Sri Lanka, Bhutan, the Maldives Islands, or Nepal).

___ Individual/concern, other than one of the preceding.

(c) Definitions. As used in this provision--

Service-disabled veteran-owned small business concern--

(1) Means a small business concern--

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

"Small business concern," means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and the size standard in paragraph (a) of this provision.

Veteran-owned small business concern means a small business concern--

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

"Women-owned small business concern," means a small business concern --

(1) That is at least 51 percent owned by one or more women or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; or

(2) Whose management and daily business operations are controlled by one or more women.

(d) Notice.

(1) If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

(2) Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a small, HUBZone small, small disadvantaged, or women-owned small business concern in order to obtain a contract to be awarded under the preference programs established pursuant to section 8(a), 8(d), 9, or 15 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall--

(i) Be punished by imposition of fine, imprisonment, or both;

(ii) Be subject to administrative remedies, including suspension and debarment; and

(iii) Be ineligible for participation in programs conducted under the authority of the Act.

(End of provision)

52.219-22 SMALL DISADVANTAGED BUSINESS STATUS (OCT 1999)

(a) General. This provision is used to assess an offeror's small disadvantaged business status for the purpose of obtaining a benefit on this solicitation. Status as a small business and status as a small disadvantaged business for general statistical purposes is covered by the provision at FAR 52.219-1, Small Business Program Representation.

(b) Representations.

(1) General. The offeror represents, as part of its offer, that it is a small business under the size standard applicable to this acquisition; and either--

___ (i) It has received certification by the Small Business Administration as a small disadvantaged business concern consistent with 13 CFR 124, Subpart B; and

(A) No material change in disadvantaged ownership and control has occurred since its certification;

(B) Where the concern is owned by one or more disadvantaged individuals, the net worth of each individual upon whom the certification is based does not exceed \$750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and

(C) It is identified, on the date of this representation, as a certified small disadvantaged business concern in the database maintained by the Small Business Administration(PRO0Net); or

___ (ii) It has submitted a completed application to the Small Business Administration or a Private Certifier to be certified as a small disadvantaged business concern in accordance with 13 CFR 124, Subpart B, and a decision on that application is pending, and that no material change in disadvantaged ownership and control has occurred since its application was submitted.

(2)___ For Joint Ventures. The offeror represents, as part of its offer, that it is a joint venture that complies with the requirements at 13 CFR 124.1002(f) and that the representation in paragraph (b)(1) of this provision is accurate for the small disadvantaged business concern that is participating in the joint venture. [The offeror shall enter the name of the small disadvantaged business concern that is participating in the joint venture: _____.]

(c) Penalties and Remedies. Anyone who misrepresents any aspects of the disadvantaged status of a concern for the purposes of securing a contract or subcontract shall:

- (1) Be punished by imposition of a fine, imprisonment, or both;
- (2) Be subject to administrative remedies, including suspension and debarment; and
- (3) Be ineligible for participation in programs conducted under the authority of the Small Business Act.

(End of provision)

52.219-28 POST-AWARD SMALL BUSINESS PROGRAM REREPRESENTATION (APR 2009)

(a) Definitions. As used in this clause--

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is "not dominant in its field of operation" when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall rerepresent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

- (1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

(c) The Contractor shall rerepresent its size status in accordance with the size standard in effect at the time of this rerepresentation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at <http://www.sba.gov/services/contractingopportunities/sizestandardstopics/>.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the rerepresentation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete the following rerepresentation and submit it to the contracting office, along with the contract number and the date on which the rerepresentation was completed:

The Contractor represents that it () is, () is not a small business concern under NAICS Code 325411 assigned to contract number _____.

(Contractor to sign and date and insert authorized signer's name and title).

(End of clause)

52.222-22 PREVIOUS CONTRACTS AND COMPLIANCE REPORTS (FEB 1999)

The offeror represents that --

(a) () It has, () has not participated in a previous contract or subcontract subject to the Equal Opportunity clause of this solicitation;

(b) () It has, () has not, filed all required compliance reports; and

(c) Representations indicating submission of required compliance reports, signed by proposed subcontractors, will

be obtained before subcontract awards.

(End of provision)

52.222-25 AFFIRMATIVE ACTION COMPLIANCE (APR 1984)

The offeror represents that

(a) it has developed and has on file, has not developed and does not have on file, at each establishment, affirmative action programs required by the rules and regulations of the Secretary of Labor (41 CFR 60-1 and 60-2), or

(b) has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

(End of provision)

52.223-13 CERTIFICATION OF TOXIC CHEMICAL RELEASE REPORTING (AUG 2003)

(a) Executive Order 13148, of April 21, 2000, Greening the Government through Leadership in Environmental Management, requires submission of this certification as a prerequisite for contract award.

(b) By signing this offer, the offeror certifies that--

(1) As the owner or operator of facilities that will be used in the performance of this contract that are subject to the filing and reporting requirements described in section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) (42 U.S.C. 11023) and section 6607 of the Pollution Prevention Act of 1990 (PPA) (42 U.S.C. 13106), the offeror will file and continue to file for such facilities for the life of the contract the Toxic Chemical Release Inventory Form (Form R) as described in sections 313(a) and (g) of EPCRA and section 6607 of PPA; or

(2) None of its owned or operated facilities to be used in the performance of this contract is subject to the Form R filing and reporting requirements because each such facility is exempt for at least one of the following reasons: (Check each block that is applicable.)

(i) The facility does not manufacture, process, or otherwise use any toxic chemicals listed in 40 CFR 372.65;

(ii) The facility does not have 10 or more full-time employees as specified in section 313.(b)(1)(A) of EPCRA 42 U.S.C. 11023(b)(1)(A);

(iii) The facility does not meet the reporting thresholds of toxic chemicals established under section 313(f) of EPCRA, 42 U.S.C. 11023(f) (including the alternate thresholds at 40 CFR 372.27, provided an appropriate certification form has been filed with EPA);

(iv) The facility does not fall within the following Standard Industrial Classification (SIC) codes or their corresponding North American Industry Classification System sectors:

(A) Major group code 10 (except 1011, 1081, and 1094.

(B) Major group code 12 (except 1241).

(C) Major group codes 20 through 39.

(D) Industry code 4911, 4931, or 4939 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce).

(E) Industry code 4953 (limited to facilities regulated under the Resource Conservation and Recovery Act, Subtitle C (42 U.S.C. 6921, et seq.), 5169, 5171, or 7389 (limited to facilities primarily engaged in solvent recovery services on a contract or fee basis); or

() (v) The facility is not located within the United States or its outlying areas.

(End of clause)

52.230-1 COST ACCOUNTING STANDARDS NOTICES AND CERTIFICATION (OCT 2008)

Note: This notice does not apply to small businesses or foreign governments. This notice is in three parts, identified by Roman numerals I through III.

Offerors shall examine each part and provide the requested information in order to determine Cost Accounting Standards (CAS) requirements applicable to any resultant contract.

If the offeror is an educational institution, Part II does not apply unless the contemplated contract will be subject to full or modified CAS coverage pursuant to 48 CFR 9903.201-2(c)(5) or 9903.201-2(c)(6), respectively.

I. DISCLOSURE STATEMENT--COST ACCOUNTING PRACTICES AND CERTIFICATION

(a) Any contract in excess of \$650,000 resulting from this solicitation will be subject to the requirements of the Cost Accounting Standards Board (48 CFR Chapter 99), except for those contracts which are exempt as specified in 48 CFR 9903.201-1.

(b) Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of 48 CFR Chapter 99 must, as a condition of contracting, submit a Disclosure Statement as required by 48 CFR 9903.202. When required, the Disclosure Statement must be submitted as a part of the offeror's proposal under this solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If an applicable Disclosure Statement has already been submitted, the offeror may satisfy the requirement for submission by providing the information requested in paragraph (c) of Part I of this provision.

CAUTION: In the absence of specific regulations or agreement, a practice disclosed in a Disclosure Statement shall not, by virtue of such disclosure, be deemed to be a proper, approved, or agreed-to practice for pricing proposals or accumulating and reporting contract performance cost data.

(c) Check the appropriate box below:

(1) Certificate of Concurrent Submission of Disclosure Statement.

The offeror hereby certifies that, as a part of the offer, copies of the Disclosure Statement have been submitted as follows: (i) original and one copy to the cognizant Administrative Contracting Officer (ACO) or cognizant Federal agency official authorized to act in that capacity (Federal official), as applicable, and (ii) one copy to the cognizant Federal auditor.

(Disclosure must be on Form No. CASB DS-1 or CASB DS-2, as applicable. Forms may be obtained from the cognizant ACO or Federal official and/or from the loose-leaf version of the Federal Acquisition Regulation.)

Date of Disclosure Statement: _____ Name and Address of Cognizant ACO or Federal Official Where Filed: _____

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement.

(2) Certificate of Previously Submitted Disclosure Statement.

The offeror hereby certifies that the required Disclosure Statement was filed as follows:

Date of Disclosure Statement: _____ Name and Address of Cognizant ACO or Federal Official Where Filed: _____

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the applicable Disclosure Statement.

(3) Certificate of Monetary Exemption.

The offeror hereby certifies that the offeror, together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated prime contracts and subcontracts subject to CAS totaling more than \$50 million (of which at least one award exceeded \$1 million) in the cost accounting period immediately preceding the period in which this proposal was submitted. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

(4) Certificate of Interim Exemption.

The offeror hereby certifies that (i) the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted and (ii) in accordance with 48 CFR 9903.202-1, the offeror is not yet required to submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period, the offeror will immediately submit a revised certificate to the Contracting Officer, in the form specified under subparagraph (c)(1) or (c)(2) of Part I of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

CAUTION: Offerors currently required to disclose because they were awarded a CAS-covered prime contract or subcontract of \$50 million or more in the current cost accounting period may not claim this exemption (4). Further, the exemption applies only in connection with proposals submitted before expiration of the 90-day period following the cost accounting period in which the monetary exemption was exceeded.

II. COST ACCOUNTING STANDARDS--ELIGIBILITY FOR MODIFIED CONTRACT COVERAGE

If the offeror is eligible to use the modified provisions of 48 CFR 9903.201-2(b) and elects to do so, the offeror shall indicate by checking the box below. Checking the box below shall mean that the resultant contract is subject to the Disclosure and Consistency of Cost Accounting Practices clause in lieu of the Cost Accounting Standards clause.

() The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 48 CFR 9903.201-2(b) and certifies that the offeror is eligible for use of the Disclosure and Consistency of Cost Accounting Practices clause because during the cost accounting period immediately preceding the period in which this proposal was submitted, the offeror received less than \$50 million in awards of CAS-covered prime contracts

and subcontracts. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

CAUTION: An offeror may not claim the above eligibility for modified contract coverage if this proposal is expected to result in the award of a CAS-covered contract of \$50 million or more or if, during its current cost accounting period, the offeror has been awarded a single CAS-covered prime contract or subcontract of \$25 million or more.

III. ADDITIONAL COST ACCOUNTING STANDARDS APPLICABLE TO EXISTING CONTRACTS

The offeror shall indicate below whether award of the contemplated contract would, in accordance with subparagraph (a)(3) of the Cost Accounting Standards clause, require a change in established cost accounting practices affecting existing contracts and subcontracts.

() YES () NO

(End of clause)

252.225-7035 BUY AMERICAN ACT--FREE TRADE AGREEMENT --BALANCE OF PAYMENTS PROGRAM CERTIFICATE (DEC 2009)

(a) Definitions. "Bahrainian end product," "commercially available off-the-shelf (COTS) item," "component," "domestic end product," "Free Trade Agreement country," "Free Trade Agreement country end product," "foreign end product," "Moroccan end product," "qualifying country end product," and "United States," as used in this provision, have the meanings given in the Buy American Act--Free Trade Agreements--Balance of Payments Program clause of this solicitation.

(b) Evaluation. The Government--

(1) Will evaluate offers in accordance with the policies and procedures of part 225 of the Defense Federal Acquisition Regulation Supplement; and

(2) For line items subject to Free Trade Agreements, will evaluate offers of qualifying country end products or Free Trade Agreement country end products other than Bahrainian end products or Moroccan end products without regard to the restrictions of the Buy American Act or the Balance of Payments Program.

(c) Certifications and identification of country of origin.

(1) For all line items subject to the Buy American Act--Free Trade Agreements--Balance of Payments Program clause of this solicitation, the offeror certifies that--

(i) Each end product, except the end products listed in paragraph (c)(2) of this provision, is a domestic end product; and

(ii) Components of unknown origin are considered to have been mined, produced, or manufactured outside the United States or a qualifying country.

(2) The offeror shall identify all end products that are not domestic end products.

(i) The offeror certifies that the following supplies are qualifying country (except Australian or Canadian) end products:

(Line Item Number) (Country of Origin)

(ii) The offeror certifies that the following supplies are Free Trade Agreement country end products other than Bahrainian end products or Moroccan end products:

(Line Item Number) (Country of Origin)

(iii) The following supplies are other foreign end products, including end products manufactured in the United States that do not qualify as domestic end products, i.e., an end product that is not a COTS item and does not meet the component test in paragraph (ii) of the definition of "domestic end product":

(Line Item Number)-----

(Country of Origin (If known))-----

(End of provision)

Section L - Instructions, Conditions and Notices to Bidders

CLAUSES INCORPORATED BY REFERENCE

52.214-34	Submission Of Offers In The English Language	APR 1991
52.214-35	Submission Of Offers In U.S. Currency	APR 1991
52.222-24	Preaward On-Site Equal Opportunity Compliance Evaluation	FEB 1999
52.222-46	Evaluation Of Compensation For Professional Employees	FEB 1993
52.237-10	Identification of Uncompensated Overtime	OCT 1997

CLAUSES INCORPORATED BY FULL TEXT

52.215-1 INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION (JAN 2004)

(a) Definitions. As used in this provision--

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

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

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

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

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

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

(c) Submission, modification, revision, and withdrawal of proposals. (1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

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

(i) The solicitation number;

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

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

item;

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

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

(3) Submission, modification, or revision, of proposals.

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

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

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

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

(3) It is the only proposal received.

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

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

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

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

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

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

included in the solicitation.

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

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

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

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

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

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

(2) Mark each sheet of data it wishes to restrict with the following legend: Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

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

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

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

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

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

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

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

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced

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

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

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

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

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

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

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

(iv) A summary of the rationale for award.

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

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

(End of provision)

52.215-6 PLACE OF PERFORMANCE (OCT 1997)

(a) The offeror or respondent, in the performance of any contract resulting from this solicitation, () intends, () does not intend (check applicable block) to use one or more plants or facilities located at a different address from the address of the offeror or respondent as indicated in this proposal or response to request for information.

(b) If the offeror or respondent checks "intends" in paragraph (a) of this provision, it shall insert in the following spaces the required information:

Place of Performance(Street Address, City, State, County, Zip Code)

Name and Address of Owner and Operator of the Plant or Facility if Other Than Offeror or Respondent

(End of provision)

52.216-1 TYPE OF CONTRACT (APR 1984)

The Government contemplates award of a Cost-Plus-Fixed-Fee contract resulting from this solicitation.

(End of provision)

52.233-2 SERVICE OF PROTEST (SEP 2006)

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from

U.S. Army Medical Research Acquisition Activity
820 Chandler Street
Fort Detrick, MD 21702-5014

ATTN: Mr. Aaron J. Wade
Aaron.wade1@us.army.mil

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of provision)

52.252-1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (FEB 1998)

This solicitation incorporates one or more solicitation provisions 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. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es):

<http://www.usamraa.army.mil>

(End of provision)

52.252-5 AUTHORIZED DEVIATIONS IN PROVISIONS (APR 1984)

(a) The use in this solicitation of any Federal Acquisition Regulation (48 CFR Chapter 1) provision with an authorized deviation is indicated by the addition of "(DEVIATION)" after the date of the provision.

(b) The use in this solicitation of any [Defense Federal Acquisition Regulation Supplement](#) (48 CFR Chapter 48 [CFR Chapter 2](#)) provision with an authorized deviation is indicated by the addition of "(DEVIATION)" after the name of the regulation.

(End of provision)

PROPOSAL PREPARATION

1. PROPOSAL PREPARATION INSTRUCTIONS

Offeror Definition

“Offeror,” as used in this solicitation, encompasses either a single entity, or a consortium of entities including subcontractors or teaming partners, that submit a proposal in response to this solicitation. If the offeror consists of a consortium of entities, one shall be clearly designated as the prime offeror.

Proposal Page Limitation

There is a maximum page limitation of **100 pages** for the complete proposal (Volumes I-II) submitted in response to this solicitation. Addenda may be submitted as necessary. A page is defined as one side of a sheet, 8-1/2" x 11", with at least one inch margins on all sides, using not smaller than **11 point Arial or 12 point Times New Roman font**. Foldouts count as an equivalent number of 8-1/2" x 11" pages. The metric standard format most closely approximating the described standard 8-1/2" x 11" size may also be used. Pages submitted in excess of the limitations specified in this provision will not be evaluated by the Government. Title Pages, Cover Sheets, Tables of Contents, Resumes and/or Curriculum Vitae, and Past Performance Questionnaires are not included in the page counts. If final proposal revisions are requested, separate page limitations and the color of paper for the revisions will be specified in the Government's request for that submission.

Proposal Content Style

Proposals shall be clear, specific, complete, and concise, presenting complete effective methods and approaches for satisfying the RFP's requirements. Content shall be indexed (cross-indexed, as appropriate) and logically assembled.

The overall proposal shall consist of the following separate, individually titled volumes. Each copy of each volume shall be separated with appropriate identification.

Volume I – Business/Cost Proposal

Volume II – Technical Proposal

2. PROPOSAL SUBMISSION REQUIREMENTS

Offerors shall submit proposals to the office indicated in Block 7 of Standard Form (SF) 33 to arrive no later than the date and time specified in Block 9 of SF 33.

Offerors shall submit their proposal in accordance with the instructions outlined in Section L of this RFP. Failure to submit all documents concurrently and in accordance with the instructions outlined in Section L of this RFP may render a proposal NON-RESPONSIVE.

In order to be considered for possible contract award, the offeror shall submit an (i) business/cost proposal volume and a (ii) technical proposal volume as well as a solicitation coversheet and addenda as necessary.

One Proposal

The Government will evaluate only one proposal from each prime offeror.

Award on Initial Offer

The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost/price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. (FAR 52.215-1 (f)4)

Proposal Revisions

Should the Government determine that discussions are necessary, the Contracting Officer will provide proposal revision instructions to the offeror, as required.

Proposal Incorporation into the Contract

The Government will incorporate into the resultant contract any and/or all commitments made in the offeror's proposal.

3. PROPOSAL CONTENT**Solicitation Cover Page, Fill-in Pages and Other Submittals of the Offer**

All indicated offeror data on the Solicitation cover page and all required fill-in sections must be completed. The signed Cover Page, the pages with the required fill-in's, and all of the representations and certifications must be submitted. The balance of the solicitation need not be returned unless the offeror has made changes to other pages that will constitute part of the contract. Any such changes must be separately identified as set forth in a Summary of Exceptions.

VOLUME I – BUSINESS/COST PROPOSAL *Submit original and five (5) copies as well as 1 CD with 1 Backup of the CD.*

Offerors shall identify costs per contract year for the basic contract. The cost shall include as a minimum Direct Labor, Travel, Overhead, Subcontract Cost, Materials, G&A, Fee and Total Cost. The offeror will provide a basis of estimate that explains methodologies, sources, calculations, estimating approaches, and key drivers for the cost estimate. Offeror's shall address at a minimum all escalation factors applied to the base costs, the basis for estimating labor utilization, and the current audit status of all indirect cost factors. This information is considered to be other than cost or pricing data and is required by the Government in order to conduct a cost analysis to determine price reasonableness and to conduct a cost realism analysis to ensure costs in the proposal are realistic for the work to be done, reflect a clear understanding of the requirement, and are consistent with the various elements of the offeror's technical proposal.

The Business/Cost Proposal shall include the Request for Proposals – Solicitation, Offer and Award (Standard Form 33) and the completed Section K.

Offerors shall submit their proposals in accordance with the format requirements of FAR 15.408, Table 15-2. Offerors are also referred to <http://www.dcaa.mil> Information for Contractors Pamphlet, Chapter 3, found under "Publications," for a model proposal.

VOLUME II – TECHNICAL PROPOSAL *Submit original and five (5) copies as well as 1 CD with 1 Backup of the CD.*

The offeror shall submit information that demonstrates the ability of their firm and personnel to perform this requirement. The technical proposal shall not contain any reference to cost. However, information concerning labor hours and categories, consultants, subcontracts, travel, materials, equipment, and other information of interest to technical reviewers shall be contained in the technical proposal in sufficient detail so that the offeror's understanding of the statement of work may be adequately evaluated.

- (c) Cover Page – should contain RFP title, solicitation number, name and location of offeror, and name of Principal Investigator.
- (d) Table of Contents – the technical proposal shall be indexed and pages numbered consecutively.
- (e) The technical proposal shall address the following categories (also see section M):

a. **Facilities.**

Factor 1 - The offeror will demonstrate evidence of availability and access to facilities capable of manufacturing cGMP compliant medicinal gum, as per 21 CFR 210 and 211 and as required by the statement of work of the RFP.

b. **Past Performance.**

Factor 2 - The offeror's proposal must present a listing of all current/past contracts of a same or similar nature performed within the last three (3) years, or if the length of time the contractor has been in business is less than three (3) years, provide a listing of all past contracts of a same or similar nature. The information shall contain the principal point of contact, telephone number, contract number, and a brief summary of services provided. Attachment 1 to the solicitation is provided so that offerors may request individuals/companies to complete and submit past performance information directly to Mrs. Dana L. Herndon at dana.herndon@us.army.mil for evaluation of the offeror's past performance. Forms which have been completed and are submitted by the offeror will not be accepted for review. Past performance questionnaires shall be submitted no later than the due date and time for offers submitted in response to this RFP.

c. **Technical Experience/Managerial/Personnel/Technical Approach.**

Factor 3 – Experience in performing work similar to the requirements of APCG. Experience in working with peptides, such as peptide antimicrobials, the active ingredient in the antiplaque chewing gum, is a plus. Other experience includes having established analytical protocols for assaying peptides in general and other adjuncts in formulations.

Factor 4 - The offeror will address the managerial/personnel factor by demonstrating the ability and competency of the proposed principal investigator and technical support personnel, including any proposed subcontractor. Complete resumes for all proposed personnel should accompany and be a part of the offer. A resume is complete if it includes a summary of each individual's background, education, and past experience, and describes how these fit the individual for his/her proposed responsibilities. The offeror will include a verification of current employment and availability for dedication to the contract. The offeror's proposal should show that the staff is competent and experienced in the Statement of Work. Resumes shall reflect length and variety of experience in similar and relevant tasks.

Factor 5 - This factor shall be addressed by the offeror in a detailed written technical proposal that refers to the technical excellence and the appropriateness of the techniques, methods, processes, and tests the offeror plans to use to successfully accomplish the major tasks specified in the SOW. The offeror's proposal shall also demonstrate an understanding of the Statement of Work by describing technical approaches that clearly show a grasp of the range and complexity of the work and a thorough understanding of the requirements

d. **Regulatory/Quality.**

Factor 6 - The offeror shall demonstrate their comprehension and compliance with associated FDA regulatory requirements for medical product development and have internal regulatory support.

Factor 7 – The offeror shall demonstrate their internal quality assurance and control programs and plans for product development and manufacturing approach.

Factor 8 – The offeror shall demonstrate the qualities of the facilities, which will be utilized for this requirement, capable of producing cGMP compliant gum.

Section M - Evaluation Factors for Award

BASIS FOR AWARD**1. OVERALL BASIS FOR AWARD**

a. The candidate contractor/organization for contract award shall be presented to the Source Selection Authority (SSA)/Contracting Officer (CO/KO) on the basis of an integrated assessment of the strengths, weaknesses, and risks associated with each proposal.

b. The SSA/CO/KO shall consider all relevant factors and make the selection on the basis of the proposal deemed to be the most advantageous to the Government. The SSA/CO/KO will determine the best value by comparing the differences (strengths, weaknesses, and risks) in the features and attributes of the technical proposal with the difference in the evaluated cost proposal. In making this comparison, the Government will be more concerned with (a) Facilities, (b) Past Performance, (c) Technical/Managerial/ Personnel, and (d) Regulatory/Quality than overall evaluated cost. However, the Government will not make an award at a significantly higher overall cost if the other merit factors are only slightly higher. Evaluated cost may become the determining factor for award of a contract as proposals become more equal based on other factors. The degree of equality between proposals will be measured by the nature, significance, and applicability of the features proposed and not by the ratings received.

2. EVALUATION OF PROPOSALS

Offerors are placed on notice that any unrealistic proposal in terms of technical commitment or unreasonably low or high in cost or price, will be deemed reflective of inherent lack of technical competence or indicative of failure to comprehend the complexity and risk of the contract requirements and may be grounds for rejection of the proposal. The Government reserves the right to make a competitive range cut of proposals at the outset of the Source Selection Activity immediately after initial review and evaluation.

3. SOURCE SELECTION AND EVALUATION FACTORS--GENERALSource Selection

This competitive acquisition shall be conducted in accordance with the Federal Acquisition Regulation and the DoD and Army Supplements that are applicable to a "Source Selection."

Evaluation Factors

Responses shall be rated technically on the factors listed below in the following order of precedence:

Rating of the factors listed below with the exception of the cost factor will be based on the demonstrated ability of each offeror as represented in his/her proposal, to adequately address the evaluation considerations contained in the factors listed below. Factor 1 is the most important factor. Factors 2 and 4 are the next most important factors. Factors 2 and 4 are equal in importance. Factors 3 and 8 are the next most important factors. Factor 3 is slightly more important than Factor 8. Factors 5, 6, and 7 are the next most important factors. Factors 5, 6, and 7 are equal in importance. Factors 1, 2, and 4 are more important than Factors 3, 8, 5, 6, and 7.

Cost will be considered as an independent variable in making the final selection. Technical ratings will be based upon the information contained in the technical proposal.

Non-Cost Evaluation Factors

Facility:

Factor 1 - Facility must be capable of manufacturing cGMP¹ compliant medicinal gum, as per 21 CFR² 210 and 211.

Past Performance:

Factor 2 - Prior experience demonstrating the technical and developmental ability to produce cGMP compliant medical gum.

Technical Experience/Managerial/Personnel/Technical Approach:

Factor 3 - Experience in performing work similar to the requirements of APCG³. Experience in working with peptides, such as peptide antimicrobials, the active ingredient in the antiplaque chewing gum, is a plus. Other experience includes having established analytical protocols for assaying peptides in general and other adjuncts in formulations.

Factor 4 - Qualifications of Technical and Managerial Personnel in Research and Development and manufacturing. These include technical approaches to performing the work including experience in the development of gum formulations for optimizing the chewing gum platform; release kinetics of API in selected gum platform; ability to perform stability testing of the final APCG product according to ICH⁴ Guidelines. Prior experience in manufacturing gums for taste (sensory) and texture is critical to the developmental process.

Factor 5 - Understand the proposed project and scope of work requirement.

Regulatory/Quality:

Factor 6 - Comprehension and compliance with associated FDA⁵ regulatory requirements for medical product development and have internal regulatory support.

Factor 7 - Internal Quality Assurance and Control Programs and Plans for product development and manufacturing approach.

Factor 8 - Qualities of Facilities (capable of producing cGMP compliant gum).

Cost Evaluation Factor:

Cost will not receive a rating in this evaluation.

Footnote:

¹ Current Good Manufacturing Practice

² Code of Federal Regulations

³ Antiplaque Chewing Gum

⁴ International Conference on Harmonization

⁵ Food and Drug Administration

PAST PERFORMANCE QUESTIONNAIRE INSTRUCTIONS

U.S. ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY
FORT DETRICK, MD

The information obtained from this questionnaire will be utilized to evaluate the past and present performance of offerors submitting proposals in response to Request for Proposals No. W81XWH-10-R-0029. The information you provide will be instrumental in allowing the Government to evaluate how well the contractor performed under your contract(s).

- a. Please complete all sections of the attached questionnaire. Include your name and title, organizational address, e-mail address, telephone and fax number.
- b. Include the contractor's name and address, the title and/or description of the type of work performed, the award number, the value of the contract (including options), the award and completion date of the project and the type of award/solicitation.
- c. Use the rating scale found on the bottom left corner of the questionnaire to rate each performance element.
- d. Comments are encouraged and would be appreciated. The last page may be used if additional space is needed for comments. Clear handwritten responses are sufficient.
- e. Please FAX or e-mail your response to the Contract Specialist whose number and address is shown at the bottom right corner of the questionnaire.

Thank you for your time and participation.

FOR OFFICIAL USE ONLY - SOURCE SELECTION SENSITIVE WHEN COMPLETED

USAMRAA Form 74-R-E (FEB 2007)

PAST PERFORMANCE QUESTIONNAIRE

YOUR NAME & TITLE		YOUR ORGANIZATIONAL ADDRESS						
TEL NO. FAX :		E-MAIL:						
CONTRACTOR'S NAME & ADDRESS		TITLE OR DESCRIPTION OF REQUIREMENT:						
CONTRACT NUMBER:		CONTRACT VALUE (INCLUDING OPTIONS):						
CONTRACT TYPE: <input type="checkbox"/> FIXED PRICE <input type="checkbox"/> COST + FEE <input type="checkbox"/> COMPETITIVE <input type="checkbox"/> NON-COMPETITIVE <input type="checkbox"/> SET-ASIDE <input type="checkbox"/> SEALED BID <input type="checkbox"/> NEGOTIATED		CONTRACT AWARD & COMPLETION DATE:						
PAST PERFORMANCE ELEMENT		RATING						
		1	2	3	4	5	6	NA
1. Contractor demonstrated a thorough understanding of technical requirements of the contract/task.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:								
2. Contractor anticipated/identified and resolved problems effectively.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:								
3. Contractor managed and directed resources (i.e. personnel, subcontractors, equipment, etc.) effectively.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:								
4. Contractor provided the necessary skilled personnel to perform the required work.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:								
5. Contractor retained the necessary skilled personnel and maintained a low turnover rate.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:								

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PAST PERFORMANCE QUESTIONNAIRE

6. Contractor met scheduled contract delivery dates.	<input type="checkbox"/>						
Comments:							
7. Contractor provided accurate, complete and high quality deliverables.	<input type="checkbox"/>						
Comments:							
8. Contractor complied with the terms of the contract.	<input type="checkbox"/>						
Comments:							
9. Contractor was diligent in forecasting and controlling contract cost.	<input type="checkbox"/>						
Comments:							
10. I would recommend award to this contractor again.	<input type="checkbox"/>						
Comments:							

1	0 – 25% of the time	Strongly Disagree	PLEASE RETURN COMPLETED RESPONSE TO: U.S. Army Medical Research Acquisition Activity ATTN: MCMR-AAA-W/Mrs. Dana L. Herndon 820 Chandler Street Fort Detrick, MD 21702-5014 EMAIL:dana.herndon@us.army.milFAX:301619300
2	26 – 40% of the time	Disagree	
3	41 – 55% of the time	Somewhat Disagree	
4	56 – 70% of the time	Somewhat Agree	
5	71 – 85% of the time	Agree	
6	86 – 100% of the time	Strongly Agree	
NA		No Knowledge of This Element	

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