PWS

PERFORMANCE WORK STATEMENT

OCCUPATIONAL MEDICAL EXAMINATIONS AND EVALUATIONS

LOCAL NATIONAL EMPLOYEES IN DARBY, ITALY (USAG)

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SECTION C-1

1. GENERAL

This is a non-personal services contract. The Contractor shall provide certified and credentialed Occupational Health Physician(s) (Medico Competente), medical examination facilities, management and supervision, administration, personnel, transportation, tools, equipment and materials to execute Local National (LN) Employees Occupational Health Services in accordance with the Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81 e s.m.i.), revision November 2020 (Technical Exhibit #1), to include all future amendments and supplements, as well as Conditions of Employment for Local National Employees of the U.S. Armed Forces in Italy (COE) effective 1 November 2018, to include all future updates and revisions (Technical

Exhibit #2).

1.1. SCOPE OF WORK: The Contractor shall perform preventive, scheduled occupational medical surveillance examinations and other special occupational medical evaluations of designated Darby Livorno Local National (LN) employees of the U.S. Armed Forces in Italy, in accordance with this Performance Work Statement (PWS) and the estimated monthly Level of Effort (LOE) in Technical Exhibit #4.

1.1.1. Occupational Health Surveillance examinations consist of initial pre-employment, periodic, termination, and ongoing examinations as outlined in Article 41 Sorveglianza Sanitaria, to include all related amendments and supplements, of Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81).

1.1.2. The Contractor assumes full accountability for responsibilities and obligations of the Employer's (U.S. Army) compliance with applicable Local National Employee Occupational Health Services Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81), to include future revisions and updates.

1.1.3. The Contractor’s Occupational Health Physician (OHP) (Medico Competente) shall perform Risk Assessments of LN employees’ worksites and activities in coordination with U.S. Government personnel to include, at a minimum, the Responsible for Services of Prevention and Protection (RSPP/ASPP) (Addetti e Responsabili del servizio di prevenzione e protezione dai rischi).

1.1.3.1. The Contractor’s OHP (Medico Competente) shall participate and perform Risk Assessments and evaluations of LN employees’ worksites at a minimum once a year or at

different frequency depending on the risk assessment evaluations, in accordance with Article 25 (Obblighi del medico competente) of the Italian Legislativ Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81).

1.1.3.2. ALLEGATO 3B art 40. The Contractor's OHP (Medico Competente) shall submit, no later than 31 March of the calendar year, to the Italian Safety agency the information through the form called allegato 3B in accordance with Article 40 (Rapporti del medico competente con il Servizio Sanitario Nazionale) medico competente) of the Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81).

1.1.4. The Contractor shall utilize a certified and accredited Laboratory for the performance of all laboratory examinations. The external Laboratory performing examinations shall be, at a minimum, accredited by the "Bureau Veritas Certification" or equivalent entity, and shall hold, at a minimum, a "Quality in Laboratory Medicine ISO 9001:2008 certificate (Qualità in medicina di Laboratorio, certificato ISO 9001:2008).

1.1.4.1. Laboratory results shall be made available in the Physician Statements "Giudizio d'Idoneità alla mansione specifica" within one (1) working day from the visit.

1.1.4.2. The Contractor shall notify within one working day the Contracting Officer Representative (COR) identified in Technical Exhibit #3, when results from additional examinations cannot be delivered within the timetable described in § 1.1.4.1.

1.2. ADMINISTRATION:

1.2.1. The Contractor shall provide sufficient organizational resources and management controls to ensure that this task is performed efficiently, accurately, on time, and in compliance with the requirements of this PWS and all Applicable Laws and Regulations,

1.2.2. The Contractor shall designate in writing a single Program Manager (PM) to oversee and supervise staff assigned to the performance of this contract. The name of this person, and an alternate or alternates, who shall act for the Contractor when the manager is absent, shall be designated in writing to the Contracting Officer. Both the PM and the alternate shall be able to converse in English and the host nation language to the degree that they understand oral and written communications and express themselves in matters pertaining to their duty.

1.2.2.1. The PM or alternate shall have full authority to act for the Contractor on all contract matters relating to the operation of this contract.

1.2.3. The Contractor shall designate an Occupational Health Surveillance Physician (Medico Competente), accountable for coordination, interpretation and implementation of

current and forthcoming Occupational Health Services requirements in the Italian and Toscana Region territory.

1.2.3.1. The Contractor shall designate and sustain, throughout the entire contract period, an Occupational Health Surveillance Physician (Medico Competente) with, at minimum, three (3) uninterrupted years of experience in organizations with 500 or more employees.

1.2.3.2. The PM, its Alternate and the Occupational Health Surveillance Physician (Medico Competente) designation letters shall be provided to the Contracting Officer prior to the contract start date. The Contractor shall notify the Contracting Officer of any changes, in writing, within one workday of the change.

1.2.4. Communication: The Contractor's OHP (Medico Competente) shall meet periodically with the designated U.S. Army RSPP and the Contracting Officer Representative (COR) and/or Technical Representative of the Contracting Officer (TRCO), identified in Technical Exhibit #3, to discuss compliance with Servizio Prevenzione Igiene Sicurezza Ambienti di Lavoro (SPISAL) directives and policies, to address problem areas and to track contract compliance by all parties or as agreed upon by all parties.

1.2.4.1. The COR and/or TRCO will provide an agenda to attendees within one week of the scheduled meeting. The meeting site and time will be confirmed with the agenda. Meetings will be conducted at the Darby Livorno Occupational Health Offices (OHO) in Caserma Darby.

1.2.4.2. Participants in the periodic meetings are, at a minimum: Employer (USAG Vicenza Garrison Commander and/or his Deputy), the Contractor's OHP (Medico Competente), the RSPP and Workers Safety Representatives (RLS Rappresentanti dei Lavoratori per la Sicurezza).

1.2.4.3. Participants to the periodic meetings may extend, among others, from representatives of: USARAF/SETAF Office of the Staff Judge Advocate; Civilian Personnel Advisory Center; Fire Department and Radiation Safety Officers.

1.2.4.4. Technical Exhibit # 3 is a living document, and the Authorized Government Personnel may be changed by the Government and the Contractor as necessary. Technical Exhibit # 3 revisions, signed by the COR and the Contractor, shall be submitted to the Contracting Officer for Final Approval within five (5) workdays upon concurrence of the changes.

1.2.5. Language: The Contractor shall provide during the performance of services under this contract, at least one individual who is able to read, write, speak, and understand Italian and English. Without prejudice to the obligation to provide all documentation in

English for contractual purposes, all documents, reports, or communications required by law for the Italian authorities must be produced in Italian according to the required official formats. An English translation of such documents must be provided to the COR.

1.3. KEY PERSONNEL:

1.3.1. The Contractor shall utilize for the performance of this contract only qualified physicians, fully licensed to practice medicine in Italy, with steady current credentials in Occupational Health Surveillance (Medico Competente) in accordance with Article 38 (Titoli e requisiti del medico competente) of the Legislative Decree 81/2008.

1.3.1.1. The PM or its Alternate shall submit copies of licenses and credentials to the Contracting Office, for the Contractor's OHP (Medico Competente) utilized for the performance on this contract.

1.3.1.2. The Contractor's OHP (Medico Competente) shall be registered and maintain registration in the Italy National List of OHPs (Elenco nazionale dei medici competenti) for the entire duration of the contract period of performance.

1.3.1.3. The Contractor's OHP (Medico Competente) shall maintain license and credentials in accordance with Article 38 (3) of the Legislative Decree 81/2008 (art. 38 comma 3 D.lgs. 81/2008).

1.3.2. The Contractor shall utilize, for the performance of laboratory examinations, only qualified, credentialed healthcare personnel, physicians and/or nurses.

1.3.2.1. The Contractor shall submit copies of licenses and credentials of healthcare personnel, physicians and/or nurses who will be dedicated to the performance of laboratory examination, to the Contracting Office.

1.3.3. Management of Key Personnel: The selection, assignment, reassignment, transfer, supervision, management,

and control of Contractor key personnel in the performance of this contract, shall be the sole responsibility of the Contractor.

1.3.4. The Contractor shall comply with the general intent and specific policies set forth in this PWS and the relevant U.S. and Italian Laws and regulations referenced in § 1. of this PWS

1.3.5. Sexual Harassment/Assault Response and Prevention (SHARP). The contractor shall comply with OTSG/MEDCOM Policy Memo 20-047, Sexual Harassment/Assault Response and Prevention Program, 28 August 2020, or superseding DHA or DOD policy once issued

and provided to the contractor. The SHARP reporting requirements apply only to knowledge obtained by contractor personnel while performing services under this contract.

1.3.5.1. The contractor shall require all CSPs with knowledge of an incident of sexual assault occurring on a Government facility, to include a Government leased facility, where the contractor is providing services under this contract, to report the incident to the contractor who shall immediately (within 24 hours, after gaining knowledge) report the incident in writing to the Government's COR. This reporting policy also applies to sexual assault incidents involving MEDCOM personnel that occur on the contractor's owned or leased facility under this contract. All incidents shall be reported whether they involve contractor personnel or Government personnel, or other individuals, when the incidents occur on a Government facility or a Government leased facility.

1.4. SECURITY REQUIREMENTS:

1.4.1. Contractor's personnel may be granted access to U.S. Army worksites and installations for official business, with the appropriate coordination of the Darby Livorno Occupational Health Offices (OHO.

1.4.2. Access and General Protection/Security Policy and Procedures: Contractor and all associated sub-Contractors' personnel (if any) shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by the COR and/or TRCO). The Contractor shall also provide all information required for background checks to meet installation access requirements to be accomplished by installation Provost Marshal Office, Director of Emergency Services or Security Office.

1.4.2.1. Contractor personnel shall comply with all personal identity verification requirements as directed by DOD, HQDA and/or local policy. In addition to the changes otherwise authorized by the changes clause of this contract, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in Contractor security matters or processes.

1.4.2.2. The Contractor must obtain clearance from the COR and/or TRCO pursuant to the Installation Pass requirements for contractors outlined in AR Army Regulation 190-16 entitled Installation Access Control and may be viewed at https://aepubs.army.mil/pdfpubs/AER190-16.pdf . An excerpt from this regulation is provided in Technical Exhibit #5.

1.4.2.3. Physical Security. The Contractor shall be responsible for safeguarding all Government equipment, information and property provided for Contractor use in accordance with Attachment # 1 (LRMC Memorandum 190-5 Security management).

NOTE: Due to the size of Attachment # 1, it is provided as separate file during solicitation and at award.

1.4.2.4. All Contractor personnel shall meet local site requirements for Base Access. All non-US Contractor personnel shall meet any Garrison or USAREUR required AT/Operations Security training and requirements as well as local host country background investigations.

1.4.2.5. Standard. Contractor personnel shall observe and comply with all rules, policies, and regulations prescribed by the installation Command and other federal authorities concerning eating and smoking areas, fire, safety, sanitation, security and possession of firearms or other lethal weapons.

1.4.2.6. Contractor personnel entering the Government installation shall abide by all security regulations for the installation which may be in effect during the contract period and shall be subject to such checks as may be deemed necessary to ensure that no violations occur. No employee will be permitted on the installation when such checks reveal that his/her presence would be detrimental to the security of the installation.

1.5. MEDICAL RECORDS AND PRIVACY LAW COMPLIANCE:

1.5.1. The Contractor shall process and store all data necessary for the fulfillment of the contract's performance and for the maintaining of all accountability records in protected data processing systems in accordance with Italian Data Protection Authority (DPA) Laws, (Garante per la Protezione dei Dati Personali) as well as Health Insurance Portability and Accountability Act (HIPAA).

1.5.2. The Contractor obligates its physicians and ancillary staff to maintain strict confidentiality in accordance with Italian Laws and Regulations as well as HIPAA.

1.5.3. The Contractor shall deliver to the employer, at the termination of the employment, the medical records in accordance with Article 25 (d) Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81).

1.5.4. The Contractor shall deliver to the employee, at the termination of the employment, a copy of the medical record and risk assessment in accordance with Article 25 (e) Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81).

1.5.5. ALLEGATO 3B art 40. The Contractor's OHP (Medico Competente) shall submit, no later than 31 March of the calendar year, to the Italian Safety agency the information through the form called allegato 3B in accordance with Article 40 (Rapporti del medico competente con il Servizio Sanitario Nazionale) medico competente) of the Italian

Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81).

1.6. QUALITY CONTROL:

1.6.1. In compliance with the contract clause FAR 52.246 entitled "Inspection of Services-Fixed Price", the Contractor shall provide a Quality Control Plan that contains, at a minimum, the items listed in § C-1, C-3 and C-5 to the COR and Contracting Officer for acceptance not later than 10 days of the start of the contract. The Contracting Officer will notify the Contractor of acceptance or required modifications to the plan before the contract start date. The Contractor shall make appropriate modifications and obtain acceptance of the plan by the Contracting Officer.

1.6.2 The plan shall include:

1.6.2.1. A description of the inspection system to cover all services listed on the Performance Requirements Summary (PRS) listed in Technical Exhibit #6. Description shall include specifics as to the tasks to be inspected on both a scheduled and unscheduled basis, frequency of inspections, and the title and organizational placement of the inspectors.

1.6.2.2. A description of the methods to be used for identifying and preventing defects in the quality of service performed.

1.6.2.3. A description of the records to be kept to document inspections and corrective or preventive actions taken.

1.6.3. The records of inspections shall be kept and made available to the Government throughout the contract performance period and for the period after contract completion until final settlement of any claims under this contract.

1.7. HOURS OF OPERATION:

1.7.1. Contractor’s Program Manager and his/her alternate who shall be responsible for receiving service calls from the COR and/or TRCO, shall be available five (5) days a week from 0800 until 1700 each day. In case he/she is not reachable by phone, the Contractor shall take measures to ensure a call back to the COR and/or TRCO, within one (1) hour.

1.7.2. The Contractor shall provide the required services during the normal workweek hours Monday through Friday, exclusive of Italian holidays, U.S. Federal Holidays and officially conceded “bridge days “.

1.7.2.1. The Contractor shall designate, at a minimum, one (1) and/or two (2) days per week to accommodate Health Surveillance Examinations, Tests and Analysis requests.

1.7.2.2. The Contractor is not entitled to cost reimbursement for unused appointment slots for designated days and/or U.S. Army officially conceded days off duty due to official security measures. The OHO and the COR will promptly inform the Contractor Task manager(s) of examinations cancellations and re-scheduling plans.

1.7.2.3. The Contractor shall be available for scheduling appointments every Monday-Friday (except on Italian Holidays, as listed below) from 0800-1200 hrs at a telephone number provided by the Contractor to OHO and the COR. The following are recognized U.S. Federal and Italian holidays:

U.S. Federal Holidays

1st January New Year's Day

3rd Monday in January Martin Luther King Day

3rd Monday in February Washington's Birthday

Last Monday in May Memorial Day

4th July Independence Day

1st Monday in September Labor Day

2nd Monday in October Columbus Day

11th November Veteran's Day

Thursday November Thanksgivings Day

25th December Christmas Day

Italian Holidays

1 January New Year's Day

6 January Day of Epiphany

25 April Liberation Day

1 May Labor Day

2 June Republic Day

15 August Assumption Day

1 Tuesday in November All Saints' Day National Unity Day

8 December Immaculate Conception

25 December Christmas Day

26 December Saint Stephen's Day

1.7.3. EMERGENCY SERVICES: Services may be required to support an activation or exercise of contingency plans outside the normal duty hours described above. The Contractor's responsibilities for emergency support are specified in Section C-5, § 5.1.2.2.

1.8. PLACE OF PERFORMANCE

1.8.1. Place of Performance shall be the Contractor’s Examination Facility identified and listed by the Contractor in Technical Exhibit #7 in response to the mandated requirements of the solicitation.

SECTION C-2 DEFINITIONS

2. STANDARD DEFINITIONS:

2.1. Acceptable Quality Level (AQL). AQL is the maximum allowable percentage of deviation from perfect performance for an individual service output.

2.2. Contracting Officer (KO). The individual with the authority to enter into, administer, and/or terminate contracts. The KO is the exclusive Government official authorized to execute changes and authorize deviations or variations from the contract.

2.3. Contract Officer’s Representatives (COR): Administrative/technical representative assigned to Public Health Command-Europe (PHC-E) responsible for assisting in administration of the Government’s quality assurance portion of the contract. This person is designated in writing by the KO to be responsible for quality assurance, inspection, surveillance documentation and monthly acceptance of Contractor’s performance. A copy of the letter of designation will be provided to the Contractor.

2.4. Technical Representative of the Contracting Officer (TRCO): Administrative/technical representative assigned to Public Health Command-Europe (PHC-E) responsible for assisting the COR in administration of the Government’s quality assurance portion of the contract. This person is designated in writing by the KO to be responsible for quality assurance, inspection, surveillance documentation and monthly acceptance of Contractor’s performance. A copy of the letter of designation will be provided to the Contractor.

2.5. Occupational Medical Surveillance Examination: Preventive or periodic health examination IAW host nation standards performed to anticipate any disease before it occurs and avoid pathological consequence. This is anpreventive activity and not a diagnostic evaluation.

2.6. Performance of Work Statement (PWS): Scope and definition of occupational medical services provided under the contract.

2.7. Quality Assurance: Those actions taken by the Government to assure services meet the requirements of PWS.

2.8. Quality Control: Those actions taken by a Contractor to control the performance of services so that they meet the requirements of the PWS.

2.9. TECHNICAL DEFINITIONS PECULIAR TO THIS PWS:

2.9.1. Fitness for Duty evaluation, Fitness for Duty Examination: (Idoneità sanitaria per la mansione specifica). Objective assessment to determine if a current employee is or cannot perform essential job functions with particular emphasis on identification of characteristics that are associated with increased risk of harm to self or others.

2.9.2. Personal Protective Equipment (PPE): This includes, but is not limited to, gloves, aprons, goggles, respirators, clothing, hearing protection and other articles intended to protect the worker from exposure to various hazards of the workplace.

2.9.3. Occupational Health Offices (OHO): All activities whose requirements for occupational medical evaluations will be ordered under this contract.

2.9.4. Employee Health Database (EHD): This form is generated digitally, and it is used to document employee demographic and worksite hazard information for coordinating occupational health services from the Contractor.

NOTE: The Contractor provides the EHD digital form to the COR and/or TRCO, at the end of each day after examinations have occurred.

2.9.5. Physician Statement: This is the “Giudizio d’Idoneità alla mansione specifica” which the Contractor completes after the employee has been evaluated. The Physician Statement “Giudizio d’Idoneità alla mansione specifica” details the outcome of the services provided and any recommended follow-up.

2.9.6. Occupational Medical Surveillance Examination. Preventive or periodic health examination, in accordance with host nation. The objective of this monitoring is to anticipate any disease before it occurs and avoid pathological consequences. This is a

preventive activity and not a diagnostic evaluation. Frequency is based on host nation standards and determined by the occupational medicine physician.

2.9.7. ASPP (Addetti del Servizio di Prevenzione e Protezione). Designated Personnel to Prevention and Protection Services, in accordance with Articles 31, 32 and 33 of the Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81).

2.9.8. RSPP (Responsabile del Servizio di Prevenzione e Protezione). Responsible for Prevention and Protection Services in accordance with Articles 31, 32 and 33 of the Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81).

2.9.9. Occupational Health Physician (Medico Competente). Licensed and Credentialed Physicians specialized in Labor and Occupational Health Services in accordance with Articles 38 of the Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81).

2.9.10. SPISAL (Servizio Prevenzione Igiene Sicurezza Ambienti di Lavoro). The Service managing prevention of accidents and diseases and work-related through vigilance, care and promotion of health and safety in the workplace.

2.9.11. RLS (rappresentanti dei lavoratori per la sicurezza). Workers Safety representatives.

SECTION C-3

GOVERNMENT FURNISHED SERVICES

3. GENERAL: The Government will provide the Contractor with the services listed below at no cost.

3.1. WORKSITE EVALUATIONS:

3.1.1. General Worksite Risk Assessments and Evaluations: The U.S. Army personnel will facilitate and coordinate local LN worksites visits for Risk Assessment and Evaluations. The ASPP/RSPP, COR and TRCO, are recognized as the people responsible for coordinating all worksites visits. Worksite visits will be conducted on an average of four (4) per month with the expected time for completion of one hour.

3.1.2. Worksite Hazard Evaluations: The U.S. Army personnel will facilitate and coordinate local LN hazardous worksites visits for Risk Assessment and Evaluations. The ASPP/RSPP, the COR and the TRCO, are recognized as the people responsible for coordinating all hazardous worksites visits.

3.1.3. Worksite Risk Assessment and Evaluation visits must be coordinated through COR and/or TRCO, and ASPP/RSPP not later than 60 days prior to the visit. Complete worksite visit reports must be provided to the OHO and ASPP/RSPP within five (5) working days from the date of the visit.

3.1.4. The contractor shall ensure all service providers receive Sexual Harassment/Assault Response and Prevention (SHARP) training not later than 60 calendar days after contractor personnel begin performance under this contract. Training can be obtained either online or in person. Contractor personnel can attend SHARP training provided by MEDCOM on every other month basis by contacting (210) 221-6118 for class date/ time availability. If the employee has an AKO account, they can access online the Team Bound Self Study course through Army Learning Management System (ALMS) at http://www.atsc.army.mil/tadlp/delivery/alms.asp

SECTION C-4

CONTRACTOR FURNISHED ITEMS AND SERVICES

4. GENERAL: Except for those services specifically stated to be U.S. Army furnished in Section C-3, the Contractor shall furnish and maintain all equipment, supplies, records and all other items necessary to perform all services outlined in this PWS.

4.1. EXAMINATION FACILITIES: The Contractor shall perform all examinations at its facilities, within maximum twenty-five (25) kilometers of the U.S. Army Camp Darby. The Contractor’s examination facilities shall be suitable for the specific examinations and provide privacy for the examinee.

4.1.1. The Contractor's facilities shall be credentialed as ambulatory care clinic (studio medico o ambulatorio). The ambulatory care clinic shall comprise, at a minimum, a staffed dedicated reception desk, as well as distinct areas/ rooms, dedicated solely to laboratory tests and screenings (hearing, vision, PFT).

4.1.1.1. The ambulatory rooms dedicated to examinations and diagnostics shall comprise, at a minimum, of an Examination table; an Integrated Diagnostic System; Examination lights; ECG devices; a Spirometer; a Personal computer for patient information entries; a Storage cabinetry; a Sink and a counter.

4.1.1.2. The ambulatory rooms dedicated to hearing examinations shall be conformed to standards ISO 8253-1:2010 or ANSI S3.6-1996, conducive to noise reduction.

4.1.1.3. Vision screening examinations shall be performed with the support of Vision Screeners. Examinations with Eye charts may be performed temporarily yet conformed to the guidelines of the Eye Chart manufacturer.

4.1.2. The ambulatory care clinic should have separate bathrooms for public use. The ambulatory care clinic shall include a bathroom, away from the waiting room area, dedicated solely to drug tests.

4.1.2.1. During drug tests procedure, employees may choose that the observer be of their same gender. The Contractor shall make available responsible chaperones of the requested gender, upon employees' request.

4.1.3. Contractor's Occupational Health Physician (OHP) and all healthcare personnel dedicated to the examinations and lab tests should wear medical apparel, to always include identification name tags with titles.

4.1.4. All examinations shall be performed using calibrated equipment conformed to manufacturer operational standards. The ambulatory care clinic shall have the capability to make examinations and tests results available to employees on site, in printed format.

4.1.5. The Contractor's facilities shall be visible to pedestrians and motorists by a signpost on the building. The Contractor's facilities shall offer, at a minimum, three (3) dedicated parking spaces, within one hundred meters from the facilities.

4.2. The Contractor is not authorized to provide occupational health services in any U.S. Army building or facility.
Note: Exception is made for unannounced, random Alcohol testing described in §5.4.12.

4.3. Re-Referrals: The Contractor is to fully provide all required examinations on its premises. Specialty examinations not offered at the Contractor site may be outsourced to medical facilities within maximum 10 kilometers of the Contractor's site.

4.3.1. The Contractor shall coordinate Specialty examinations and/or care with the local - OHO and COR, prior to scheduling of Re-referrals.

4.4. Reporting: The Contractor's OHP (Medico Competente) shall provide to the Contractor Task Manager(s) worksite visit reports and any applicable worksite personal or site monitoring results for inclusion in the affected employee's medical records, to facilitate appropriate performance of the scheduled medical examinations.

SECTION C-5 SPECIFIC TASKS

5. SPECIFIC TASKS: This section specifies details as to the scope of work to be performed under the contract:

5.1. The Contractor shall provide Occupational and Environmental Health Surveillance Services to the Darby Livorno Local National (LN) employees of the U.S. Armed Forces in Italy, except for Local Nationals employed by AAFES. The Contractor shall provide

specialized Occupational Health Surveillance expertise and support to Local National employees.

5.1.1. The Contractor shall organize and perform Occupational Health Surveillance in accordance with the Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81 e s.m.i.), revision November 2020, to include all future amendments and supplements.

5.1.2. The Contractor shall guarantee the performance of Occupational Health Surveillance and Examinations in accordance with Article 41 (Sorveglianza Sanitaria) of the Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81 e s.m.i.), revision November 2020, to include all future amendments and supplements. Here below a summary excerpt from Article 41:

a. Preventive Health Examination aimed at proving the absence of counter-indications to the task that the worker will have to perform to evaluate his or her suitability to the specified task.

b. Periodic Health Examinations to verify employees' health suitability for specific tasks.

c. Health Examinations at employees' request.

d. Health Examinations when changing duty position, to verify the suitability in the specific tasks.

e. Health Examinations upon termination of employment.

f. Pre-Placement Health Examinations.

f.1. The Contractor shall, in accordance with U.S. Army employment directives, provide a summary of health suitability (sommario di Giudizio d'idoneità) in Pre-Placement form OPF 178 July 2009 (Attachment # 2).

g. Health Examinations after a period exceeding sixty consecutive sick leave days in order to verify fitness duty in the specific tasks.

5.1.2.1. The Contractor's OHP (Medico Competente) shall be available to conduct Health Examinations, at a minimum, for five (5) days per calendar month.

5.1.2.2. Flexible Dates. The Contractor's OHP (Medico Competente) shall be available to conduct Health Examinations during emergency circumstances (i.e. Pre-Placement actions § 5.1.2 (f), Sick Leave § 5.1.2 (g).

5.1.2.3. The Contractor's OHP (Medico Competente) shall have the capability to perform, at a minimum, up to twenty (20) Health Examinations per day, to include all laboratory tests

and screenings required for each employeein accordance with the OHO schedule of appointments, in accordance with estimated LOE in Technical Exhibit #4.

5.1.2.4. The OHO, in coordination with the COR and/or TRCO will forward updated schedules of appointments to the Contractor on a quarterly basis.

5.1.2.4.1. The OHO, in coordination with the COR and/or TRCO will confirm 24 hours prior to the Health Examination date, the list of scheduled employees to include the types of testing as described in § 5.4 of this PWS.

5.1.2.5. The Contractor shall provide to the-OHO the list of availability dates for each month, at a minimum, sixty (60) days before the beginning of the month.

5.1.3. The Contractor's OHP (Medico Competente) shall provide individual counseling and information to LN employees with specific reference to their area of responsibilities. (i.e. workplace hazards, use of Personal Protective Equipment (PPE).

5.1.4. The Contractor's OHP (Medico Competente) shall perform Risk Assessments of LN employees' worksites in coordination with U.S. Army Government personnel to include, at a minimum, the Representatives of Prevention and Protection Service, RSPP/ASPP, (Addetti e Responsabili del servizio di prevenzione e protezione dai rischi).

5.1.4.1. The Contractor's OHP (Medico Competente) shall participate and perform Risk Assessments and evaluations of LN employees' worksites at a minimum once a year or at different frequency depending on the risk assessment evaluations, in accordance with Article 25 (Obblighi del medico competente) of the Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81), as well as in accordance with SPISAL directives and regulations (Servizio Prevenzione, Igiene e Sicurezza negli Ambienti di Lavoro).

5.1.4.2. The Contractor's OHP (Medico Competente) shall submit Worksite Visit Reports in the English language to the COR or TRCO, to the ASPP/RSPP, and to the PHC-E Occupational Health Nurse Consultant, no later than 5 calendar days after worksite visits.

5.2. REPORTING OF EXAMINATION RESULTS

5.2.1. The Contractor shall submit a Daily Report, electronically, to OHO within one (1) business day after employees have been examined. The Daily Report shall include, at a minimum, employees' name, type of examination performed and types of laboratory test(s) and screening(s).

5.2.2. The Contractor shall submit an electronic Monthly Report to-OHO within five (5) working days of month end, detailing the number of Occupational Health Examinations, to include numbers and dates of examinations and tests performed and completed.

5.2.3. The Contractor shall transmit copies of the Physician Statements "Giudizio d'Idoneità alla mansion specifica" in the Italian and in the English language, in PDF format, within one (1) working day from the visit, to:

a) the Civilian Personnel Office; b) the Employee; c) the OHO.

5.2.3.1. The Contractor shall utilize a door-to-door traceable shipment method using the commercial addresses listed in Technical Exhibit # 3.

5.2.3.2. The Contractor shall mail medical records or documents covered under privacy laws, by labeling them 'confidential', packaged, sealed and mailed with the package contents to arrive intact.

5.2.3.3. For examinations requiring testing for which results cannot be expected within one (1) working day from the visit, the Contractor shall notify the OHO, within one (1) business day of the timetable for expected results.

5.2.4. The Contractor shall submit the aggregate annual report indicating, at a minimum, Occupational Health summary results, frequency and Risk Assessments in accordance with Article 25 (Obblighi del medico competente) of the Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81).

5.2.5. The Contractor shall update and maintain employees' medical records (Cartella Sanitaria), in accordance with Article 25 (Obblighi del medico competente), of the Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81).

5.2.5.1. The Contractor shall process, store and maintain safeguard employees' data and medical records (Cartella Sanitaria), in a secure environment, in accordance with Italian Data Protection Authority (DPA) Laws, (Garante per la Protezione dei Dati Personali) as well as Health Insurance Portability and Accountability Act (HIPAA), as referred in § 1.5.1 of this PWS.

5.2.6. The Contractor shall promptly report to the appropriate Italian authorities, (SPISAL, INAIL, ISPESL, etc.) cases of occupational illnesses discovered during employees' examinations.

5.2.7. The Contractor shall, simultaneously, inform the U.S. Government personnel, the -OHO, the COR, and/or Technical Representative of the Contract Officer, the ASPP/RSPP

and the Civilian Personnel Office, of the submission in § 5.2.6. of cases of occupational illnesses discovered during employees' examinations.

5.3. MEETINGS/CONFERENCES

5.3.1. The Contractor's OHP (Medico Competente) shall attend annual meetings in accordance with article 35 (Riunione periodica) of the Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81).

5.3.2. The Contractor's OHP (Medico Competente) shall attend, at a minimum, three (3) periodic meetings to review Risk Assessments, update the database, and update the health surveillance protocol (Protocollo Sanitario), in coordination with the ASPP//RSPP, the Civilian Personnel Office Representative, and -OHO personnel

5.3.3. The Contractor's OHP (Medico Competente) shall participate in the development of Risk Assessment Document meetings in accordance with article 29 Modalities for performing the evaluation of risks (Modalità di effettuazione della valutazione dei rischi) of the Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81).

5.4. WORK SITE VISITS

5.4.1. Contractor shall conduct work site visits as described in paragraph 3.1.1. of the PWS.

5.5. EXAMINATIONS / TESTS

5.5.1. LNs HEALTH EXAMINATIONS

5.5.1.1. Contractor shall provide Health Examinations as described in paragraph 5.1.2. of the PWS. Contractor shall provide Health Examinations as described in paragraph 5.1.2. The examination shall include filling out medical record as per annex 3A following law changes, vital signs, spinal examination and upper limb when it is requested by the type of work and the lifting required by the job.

5.5.2. EKG (Electrocardiogram Test)

5.5.2.1. The Contractor shall perform EKG in accordance with employees' worksite, duty position and established Risk Assessments reports.

5.5.2.2. The Contractor may forward EKG reports, in coordination with the COR, to a Cardiologist for the evaluation of the results. Cardiologist shall return results to the Contractor for determination of the employee's fitness for duty.

5.5.3. VISION SCREENING

5.5.3.1. The Contractor shall perform vision screening in accordance with employee's worksite, duty position and established Risk Assessments reports.

5.5.4. AUDIOGRAMS

5.5.4.1. The Contractor shall perform Audiograms in accordance with employee's worksite, duty position and established Risk Assessments reports.

5.5.5. PULMONARY FUNCTION TESTING (PFT)

5.5.5.1. The Contractor shall perform PFT testing in accordance with employees' workplace, duty position and established Risk Assessments reports.

5.5.6. SPECIALIST EXAMINATION AND CERTIFICATION

5.5.6.1. The Contractor shall refer employees to a specialist to complete more extensive testing and evaluation not available at the Contractor's facility. Unit price to include testing and evaluation performed by Specialist.

5.5.7. BLOOD LAB ANTIBODY TITERS

5.5.7.1. The Contractor shall conduct blood antibody titer tests in accordance with employee's worksite, duty position and established Risk Assessments reports.

a) Hepatitis B Titer: Performed as a one-time test on employees who require proof of Hepatitis B immunity.

b) Hepatitis C Titer (HCV): Performed as a one-time test on employees who require proof of Hepatitis C immunity

c) Varicella Titer: Performed as a one-time test on employees who require proof of Varicella immunity.

d) MMR Titer: Performed as a one-time test on employees who require proof of MMR immunity.

5.5.8. CHEMISTRY 6

5.5.8.1. Chemistry 6 includes the following: CBC/Diff; Lipoprotein Panel; GGT; Urea Nitrogen/Creatinine; Hepatic Function Panel; Glucose Fasting.

5.5.8.2. The Contractor shall conduct Chemistry 6 tests in accordance with employees' worksite, duty position and established Risk Assessments report.

5.5.8.3. Chemistry 6 shall be conducted in coordination with scheduled appointments prepared by the Darby Military Community-OHO personnel and COR

5.5.9. URINALYSIS (UA)

5.5.9.1. The Contractor shall conduct Urinalysis (UA) tests in accordance with employees' worksite, duty position and established Risk Assessments reports.

5.5.10. METAL SCREENING

5.5.10.1. Metal Screening includes the following: Hippuric Acid (Urine); Methyl-Hippuric Acid (Urine); Alau-Delta Aminolevulinic Acid (Urine); ZPP-Zinc Protoporphyrin (Blood); Lead (Blood)

5.5.11. BLOOD COLLECTION

5.5.11.1. The Contractor shall conduct Blood Collection in accordance with employees' worksite, duty position and established Risk assessment reports.

5.5.12. DRUG TESTING

5.5.12.1. The Contractor shall conduct Drug Testing in accordance with Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81), Toscana Regional and local procedures directives and laws.

5.5.12.2. The Contractor shall conduct drug testing randomly in accordance with employees' worksite, duty position and established Risk Assessments reports.

5.5.12.3. Drug Testing shall be conducted in coordination with scheduled appointments prepared by OHO personnel, COR and ASPP/RSPP, during the periodic visits, during the fitness for duty physical, upon return to work after a positive test, and/or after an on-the-job injury.

5.5.12.4. The Contractor shall submit urine samples to a certified laboratory when the drug tests performed are positive.

5.5.12.5. Laboratory Referral (Positive Drug testing). The Contractor shall immediately forward a Positive resulting test to a specialized health facility for the execution of a second level assessment.

5.5.13. ALCOHOL TESTING

5.5.13.1. The Contractor shall conduct Alcohol Testing in accordance with Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81), Toscana Regional and local procedures directives and laws.

5.5.13.2. The Contractor shall conduct alcohol testing, breathalyzer, randomly in accordance with employees' worksite, duty position and established Risk Assessments reports, in coordination with the -OHO personnel, COR and ASPP/RSPP.

5.5.13.3. Alcohol Testing may be also conducted in conjunction with the medical examination. Positive results will be reported to CPAC POC and follow up will be conducted IAW with Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81), Toscana Regional and local procedures directives and laws.

5.5.14. ENTOMOLOGIST SCREENING

5.5.14.1. Entomolitist Screening includes the following: Total Protein (Serum) Electrophoresis and RBC Cholinesterase.

5.5.15. HIV.

5.5.15.1. The Contractor shall conduct HIV Testing in accordance with Italian Legislative Decree 81/2008 (Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9 Aprile 2008, n. 81), Toscana Regional and local procedures directives and laws.

SECTION C-6

APPLICABLE REGULATIONS, MANUALS, TECHNICAL DOCUMENTS, SPECIFICATIONS, AND

FORMS

6.1. LIST OF APPLICABLE PUBLICATIONS - ITALY:

a. Technical Arrangement between the Ministry of Defense of the Italian Republic and the Department of Defense of the United States of America regarding the installations / infrastructure in use by the US Forces in Italy, 16 April

2008 para VIII (2).

b. Decreto Legislativo 9 aprile 2008 n. 81 – Testo unico sulla salute e sicurezza sul Lavoro e s.m.i.

LIST OF APPLICABLE PUBLICATIONS – U.S.:

c. 29 CFR 1910 Occupational Safety and Health Standards, General Industry, last updated 28 Feb 2006

http://www.osha.gov/pls/oshaweb/owastand.display_standard_group?p_toc_level=1&p_part_number=1910

d. 29 CFR 1910.1020 Access to Employee Exposure and Medical Records.

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10027

e. AR 40-5, Preventive Medicine 25 May 2007., 1-7, d. Occupational Health.

http://www.army.mil/usapa/epubs/pdf/r40_5.pdf

f. AR 40-66, Medical Record Administration and Healthcare Documentation, 4 January 2010

http://www.army.mil/usapa/epubs/pdf/r40_66.pdf

g. AR 40-562, Immunizations and Chemoprophylaxis, 29 September 2006

http://www.army.mil/usapa/epubs/pdf/r40_562.pdf

h. DA Pam 40-11, Preventive Medicine, 19 October 2009, Chapter 5, Occupational Health

http://www.army.mil/usapa/epubs/pdf/p40_11.pdf

USAPHC, PHRE requires English translation of applicable Contractor unique Italian publications that affect the

implementation of this contract.

SECTION C-7

QUALITY MANAGEMENT

7.1 QUALITY CONTROL. In compliance with the contract clause FAR 52.246 entitled "Inspection of Services-

Fixed Price", the Contractor is responsible for the development, implementing and maintaining of its own Quality Control Plan (QCP) to ensure that the requirements of this

contract are performed in accordance with this PWS. The Contractor's QCP is the means by which the Contractor assures that his work complies with the requirement of the contract and procedures to identify, prevent, and ensure non-recurrence of defective services are implemented.

7.1.1 The Contractor shall provide a QCP that contains, as a minimum, the items listed in C-1, C-3. and C-5., to the COR and Contracting Officer for acceptance not later than 10 days of the start of the contract. The Contracting Officer will notify the Contractor of acceptance or required modifications to the plan before the contract start date.
The Contractor shall make appropriate modifications and obtain acceptance of the plan by the Contracting Officer.

7.1.2 The plan shall include, at a minimum, a description of the inspection system to cover all services listed on the Performance Requirements Summary (PRS) listed in Technical Exhibit #6. Description shall include specific details as to the areas to be inspected on both a scheduled and unscheduled basis, frequency of inspections, and the title and organizational placement of the inspectors.

7.1.3 The records of inspections shall be kept and made available to the Government throughout the contract performance period and for the period after contract completion until final settlement of any claims under this contract.

7.1.4 Methods of communication with the U.S. Army regarding performance of the contract. The communications shall include verbal, written and electronic communication and formal meetings with U.S. Army agencies and personnel. Electronic communication regarding examinees must safeguard privacy and be in conformance with confidentiality laws.

7.1.5 The QCP shall address corrective action. The Contractor shall respond promptly and affirmatively to deficiencies discovered in the performance of this contract The Contractor shall identify and correct problem areas.

Corrective actions shall not depend on Government direction. Records shall be kept of any deficiencies discovered and corrective action taken. Short-term remedial actions and long-term solutions shall be described. A summary report of this will be forwarded to the COR. If medical information is involved, the report will be forwarded instead to the occupational medicine physician at PHC.

7.1.6 The Contractor QCP shall include a customer complaint program. This program must describe how commanders, employees, or other interested parties may identify problem areas and situations to the Contractor. The customer complaint system shall be compatible with the reporting and communication systems of the plan.

7.2. Contractor shall provide a QCP during the pre-performance conference. The QCP is not subject to approval by the Government. The COR or other Government representative may offer suggestions of items for inclusion in the QCP, but any such suggestions are strictly advisory and not mandatory. However, the Contractor shall request Contracting Officer's acceptance in writing of any proposed change to his QC system.

7.3. QUALITY ASSURANCE: The Government will evaluate the contractor's performance under this contract in accordance with the Quality Assurance Surveillance Plan (QASP). All surveillance observations will be recorded.

When an observation indicates defective performance, the COR will request the Program Manager to acknowledge the observation in writing.

7.4 MONITORING METHODS. Monthly QASP Surveillance Activity Checklist. The COR will use the Monthly QASP Activity Checklist 7.4.1-1 to monitor contractor performance. The COR will upload the completed QASP Surveillance Activity Checklist in the Wide Area Workflow – COR Tool. https://wawf.eb.mil

7.4.1

-1 Quality Assurance Surveillance Plan (QASP):

Performance Objective	**PWS Section**	**Acceptable Quality Level AQL**	**Surveillance Method**	**Compliance**
Meetings Attendance	Para. 1.2.4	100%	100% Inspection	Positive/Negative Performance Report
Provide English and Italian language proficiency	Para 1.2.5.	100%	100% Inspection	Positive/Negative Report
Qualified physicians, fully licensed to practice Occupational Health medicine in Italy (*medico competente*), with steady current credentials	Para 1.3.	100%	Random Inspection / Customer Complaint	Positive/Negative Performance Report
Medical Records and Privacy Law Compliance	Para 1.5.	100%	Random Inspection / Customer Complaint	Positive/Negative Performance Report

Hygienic and confidential facilities	Para 4.1.	99%	Customer Complaints/ Random Inspection	Positive/Negative Performance Report
Return Daily Report in digital format to the OHO within one working day after LNs examinations. WSV report within five (5) working days after worksite visits occurred.	Para 5.2.1	100%	100% Inspection	Re-Performance
Monthly Report detailing the Occupational Health Examinations, within five (5) days of the close of the previous month to OHO.	Para 5.2.2	100%	100% Inspection	Re-Performance

Provide Physician Statements "*Giudizio d'Idoneità alla mansione specifica"* within one (1) working day from the visit. Exams requiring testing that cannot be resulted within this time, OHO must be notified within one (1) business day with timeline of expected results.	Para 5.2.2	100%	100% Inspection	Performance
Worksite visit reports must be submitted to OHO within five (5) working days from date of visit	Para 3.1.4	100%	100% Inspection_	Performance
Coordinate all worksite visits and periodic physical examinations with OHO and RSPP NLT 60 days prior to visit/exam.	Para 3.1.4	100%	100% Inspection	Positive/Negative Performance Report
Compliance: Periodic medical exams to including testing	Para 5.1 Para 5.4	100%	100% Inspection	Performance

SECTION C-8

SEXUAL ASSAULT PREVENTION AND RESPONSE PROGRAM (SHARP)

The Contractor shall comply with OTSG/MEDCOM Policy Memo 13-062, Policy for Reporting Incidents of Sexual Assault and Sexual Harassment under the Sexual Assault Prevention and Response Program (SHARP), 12 Nov

2013. The SHARP reporting requirements apply only to knowledge obtained by Contractor personnel while performing services under this contract.

A Contractor with knowledge of an incident of sexual assault occurring on a government facility, to include a government leased facility, where the Contractor is providing services under this contract, to report the incident immediately (within 24 hours) in writing to the

Government's COR. All incidents shall be reported whether they involve Contractor personnel or Government personnel, or other individuals.

The Contractor shall with knowledge of an incident of sexual harassment occurring on a Government facility, to include a Government leased facility, where the Contractor is providing services under this contract, to report the incident to the immediately (within 24 hours) incident in writing to the Government's COR. All incidents shall be reported whether they involve contractor personnel or Government personnel, or other individuals.

Sexual Assault Reporting. The Contractor will immediately (within 24 hours) report an incident of sexual assault to the COR.Sexual Harassment Reporting. The Contractor will immediately (within 24 hours) report an incident of sexual harassment to the COR.

Army Regulation 600-20, Army Command Policy, 20 Sep 2012

OTSG/MEDCOM Policy Memo 13-062, Policy for Reporting Incidents of Sexual Assault and Sexual

SECTION C-9

9. Personally Identifiable Information, Protected Health Information, and Federal Information Requirements

(Revised May 23, 2017)

9.1 General Requirements Overview - Personally Identifiable Information (PII), Protected Health Information (PHI) and Federal Information Laws

This Section addresses the Contractor’s requirements under The Privacy Act of 1974 (Privacy Act), The Freedom of Information Act (FOIA), and The Health Insurance Portability and Accountability Act (HIPAA) as set forth in applicable statutes, implementing regulations and Department of Defense (DoD) issuances. In general, the Contractor shall comply with the specific requirements set forth in this Section and elsewhere in this Contract. The Contractor shall also comply with requirements relating to records management as described herein.

This Contract incorporates by reference the federal regulations and DoD issuances referred to in this Section. If any authority is amended or replaced, the changed requirement is effective when it is incorporated under contract change procedures. Where a federal regulation and any DoD issuance govern the same subject matter, the Contractor shall first follow the more specific DoD implementation unless the DoD issuance does not address or is unclear on that matter. DoD issuances are available at http://www.dtic.mil/whs/directives.

For purposes of this Section, the following definitions apply.

DoD Privacy Act Issuances means the DoD issuances implementing the Privacy Act, which are DoDD 5400.11

(October 29, 2014) and DoD 5400.11-R (May 14, 2007).

HIPAA Rules means, collectively, the HIPAA Privacy, Security, Breach and Enforcement Rules, issued by the U.S.

Department of Health and Human Services (HHS) and codified at 45 Code of Federal Regulations (CFR) Part 160

and Part 164, Subpart E (Privacy), Subpart C (Security), Subpart D (Breach) and Part 160, Subparts C-E

(Enforcement), as amended. Additional HIPAA rules regarding electronic transactions and code sets (45 CFR Part

162) are not addressed in this Section and are not included in the term HIPAA Rules.

DoD HIPAA Issuances means the DoD issuances implementing the HIPAA Rules in the DoD Military Health

System (MHS). These issuances are DoD 6025.18-R (January 24, 2003), Department of Defense Instruction (DoDI)

6025.18 (December 2, 2009), and DoDI 8580.02 (August 12, 2015).

Defense Health Agency (DHA) Privacy Office means the DHA Privacy and Civil Liberties Office. The DHA Privacy Office Chief is the HIPAA Privacy and Security Officer for DHA, including the National Capital Region Medical Directorate (NCRMD).

9.2 Records Management

When creating and maintaining official government records, the Contractor shall comply with all federal requirements established by 44 United States Code (U.S.C.) Chapters 21, 29, 31, 33 and 35, and by 36 CFR, Chapter

XII, Subchapter B – Records Management. The Contractor shall also comply with DoD Administrative Instruction

No. 15 (DoD AI-15), “OSD Records and Information Management Program” (May 3, 2013) and Records Management requirements outlined in the current TRICARE Operations Manual (TOM).

9.3 Freedom of Information Act (FOIA)

The Contractor shall comply with the following procedures if it receives a FOIA request and immediately contacts the DHA FOIA Officer for evaluation/action:

The Contractor shall inform beneficiaries that DHA FOIA procedures require a written request addressed to the DHA Freedom of Information Service Center, 7700 Arlington Boulevard, Suite 5101, Falls Church, Virginia 22042-

5101 (or email requests addressed to DHA.FOIA@mail.mil), and that the request shall describe the desired record as completely as possible (ideally with Contract or modification number) to facilitate its retrieval from files and to reduce search fees which may be borne by the requestor. Although the administrative time limit to grant or deny a request (ten working days after receipt) does not begin until the request is received by DHA, the Contractor shall act as quickly as possible.

In response to requests received by the Contractor for the release of information, unclassified information, documents and forms which were previously provided to the public as part of routine services shall continue to be made available in accordance with previously established criteria. All other requests from the public for release of DHA records and, specifically, all requests that reference FOIA shall be immediately forwarded to DHA,

ATTENTION: Freedom of Information Officer, for appropriate action. Direct contact, including interim replies, between TRICARE contractors and such requestors is not authorized. The Contractor shall process requests by individuals for access to records about themselves in accordance with directions from the DHA Freedom of Information Service Center. If such a requestor specifically makes the request under the Privacy Act or does not make clear whether the request is made under FOIA or the Privacy Act, the Contractor shall process the request in accordance with directions from the DHA Privacy Office. If requestor specifically seeks PHI under HIPAA, the Contractor shall follow paragraph 8.1.6, relating to individual rights of access to PHI.

9.4 Systems of Records

To meet the requirements of the Privacy Act and the DoD Privacy Act Issuances, the Contractor shall identify to the DHA Contracting Officer (CO) systems of records that are or will be maintained or operated for DHA where records of PII collected from individuals are maintained and specifically retrieved using a personal identifier.

Upon identification of such systems to the CO, and prior to the lawful operation of such systems, the Contractor shall coordinate with the DHA Privacy Office to complete systems

of records notices (SORNs) for submission and publication in the Federal Register as coordinated by the Defense Privacy, Civil Liberties, and Transparency Division, and as required by the DoD Privacy Act Issuances. Following proper SORN publication and Government confirmation of Contractor authority to operate the applicable system(s), the Contractor shall also comply with the additional systems of records and SORN guidance, in coordination with the DHA Privacy Office, regarding periodic system review, amendments, alterations, or deletions set forth by the DoD Privacy Act Issuances, Office of Management and Budget (OMB) Memorandum 99-05,

Attachment B, and OMB Circular A-130. The Contractor shall promptly advise the DHA Privacy Office of changes

in systems of records or their use that may require a change in the SORN.

9.5 Privacy Impact Assessment (PIA)

Contractors are not required to submit PIAs to DHA.

9.6 Data Sharing Agreement (DSA)

9.6.1 (Applies if contract requirements involve the use of DHA data (including PII/PHI, a limited data set, or identified data)

The Contractor shall consult with the DHA Privacy Office to determine if the Contractor must obtain a DSA or Data Use Agreement (DUA), when DHA data will be accessed, used, disclosed or stored, to fulfil the requirements of this Contract.

The Contractor shall comply with the permitted uses established in a DSA/DUA to prevent the unauthorized use and/or disclosure of any PII/PHI, in accordance with the HIPAA Rules and DoD HIPAA Issuances. Likewise, the Contractor shall comply with the DoD Privacy Act Issuances.

Prior to using any data involving PHI for research purposes, as defined by HIPAA, the Contractor must gain approval from the DHA Privacy Board. Thus, the Contractor shall comply with DHA Privacy Board requests for additional documentation.

To begin the DSA request process, the Contractor shall submit a DSA Application (DSAA) to the DHA Privacy Office. Upon approval, the requestor shall enter into one of the following agreements, depending on the data involved:

- DSA for De-Identified Data
- DSA for PHI
- DSA for PII Without PHI

• DUA for Limited Data Set

DSAs executed for contract support will expire after 1 year or at the end of the contract option year, whichever comes first. If the contractual use of DHA data continues after the DSA expiration date, the Contractor shall submit a DSA Renewal Request template to the Privacy Office; however, if the DSA is not renewed, the Contractor shall close the DSA by providing a Certificate of Data Disposition (CDD) to the DHA Privacy Office.

9.6.2 (Applies if contract requirements may include human subject research)

This Contract incorporates by reference the Protection of Human Subject Research clause in the Defense Federal Acquisition Regulation Supplement (DFARS) at 48 CFR 252.235-7004. A separate DFARS provision, 48 CFR

235.072(e), requires that the clause be incorporated in contracts that include or may include research involving human subjects in accordance with 32 CFR 219, DoDI 3216.02, and 10 U.S.C. 980, including research that meets exemption criteria under 32 CFR 219.101(b), the clause applies to solicitations and contracts awarded by any DoD component, regardless of mission or funding Program Element Code. Thus, in the event a contractor participates in a study or demonstration project or other activity that involves human subject research, then the contractor shall comply with Protection of Human Research clause. COs may not determine whether an activity is exempt from human subject research requirements. If contractor activity appears to involve human subject research, then the contractor shall consult the DHA Privacy Office, which may contact the Research Regulatory Oversight Office in the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)).

9.7 Privacy Act and HIPAA Training

The Contractor shall ensure that its entire staff, including subcontractors and consultants that perform work on this Contract receive training on the Privacy Act, HIPAA, and the federal regulations on confidentiality of alcohol and drug abuse patient records, 42 CFR Part 2. Refer to FAR 52.224-3 regarding specific requirements for Privacy

Training appropriate to the Contractor’s scope of involvement with DHA’s PHI and its regulatory responsibilities as either a Covered Entity, or Business Associate.

The Contractor shall ensure all employees and subcontractors supply a certificate of all training completion to the Contracting Officer's Representative (COR) within 30 days of being assigned and on an annual basis based on the trainee's birth month thereafter.

9.8 HIPAA Business Associate Provisions

9.8.1 Business Associate – General Provisions

The Contractor meets the definition of Business Associate, and DHA meets the definition of a covered entity under the HIPAA Rules and the DoD HIPAA Issuances. Therefore, a Business Associate Agreement (BAA) between the Contractor and DHA is required to comply with the HIPAA Rules and the DoD HIPAA Issuances. This paragraph 8 serves as the required BAA. As a Business Associate, the Contractor shall comply with the HIPAA Rules and the DoD HIPAA Issuances applicable to a business associate performing under this Contract.

9.8.1.1 Catch-All Definition

The following terms used, but not otherwise defined in paragraph 8.1, shall have the same meaning as those terms have in the DoD HIPAA Issuances: Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices (NoPP), Protected Health Information (PHI), Required By Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information (Unsecured PHI), and Use.

9.8.1.2 The Contractor shall not use or further disclose PHI other than as permitted or required by the Contract or as Required by Law.

9.8.1.3 The Contractor shall use appropriate safeguards and comply with the HIPAA Security Rule with respect to electronic PHI, to prevent use or disclosure of PHI other than as provided for by the Contract.

9.8.1.4 The Contractor shall report to DHA any breach of which it becomes aware, and shall proceed with breach response steps as required by paragraph 9 (if this Contract incorporates by reference the TOM, then all references to paragraph 9 shall be deemed to refer to the breach response provisions of the TOM, Ch. 1, Sec. 5, paragraphs 2.1-

2.2). With respect to electronic PHI, the Contractor shall also respond to any security incident of which it becomes aware in accordance with any applicable DoD cybersecurity and National Institute of Standards and Technology (NIST) requirements. If at any point the Contractor becomes aware that a security incident involves a breach, the contractor shall immediately initiate breach response as required by paragraph 9.

9.8.1.5 In accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), respectively, as applicable, the Contractor shall ensure that any subcontractors that create, receive, maintain, or transmit PHI on behalf of the Contractor agree to the same restrictions, conditions, and requirements that apply to the Contractor with respect to such PHI.

9.8.1.6 With respect to individual rights of access to PHI, the Contractor shall make available PHI in a designated record set to the individual or the individual's designee as necessary to satisfy DHA's obligations under the DoD HIPAA Issuances and the corresponding 45 CFR 164.524. If the Contractor intends to deny the individual's request, the Contractor shall forward it (within seven working days of receipt) to the CO. The CO shall decide within 20 calendar days (50 calendar days for justified delays) of the request. The CO shall notify the individual, with a copy to the Contractor, of any approved or denied access determinations and the reason for any denial. The individual may appeal the denial determination to the DHA Privacy Office.

9.8.1.7 The Contractor shall make any amendment(s) to PHI in a designated record set as directed or agreed to by DHA or take other measures as necessary to satisfy DHA's obligations under the DoD HIPAA Issuances and the corresponding 45 CFR 164.526.

9.8.1.8 The Contractor shall maintain and make available to the Government the information required to provide an accounting of disclosures to the MHS or to the individual as necessary to satisfy DHA's obligations under the DoD HIPAA Issuances and the corresponding 45 CFR 164.528.

9.8.1.9 To the extent the Contractor is to carry out one or more of DHA's obligation(s) under the HIPAA Rules, the Contractor shall comply with the requirements of the HIPAA Rules.

9.8.1.10 The Contractor shall make its internal practices, books, and records available to the HHS Secretary for purposes of determining compliance with the HIPAA Rules.
Permitted Uses and Disclosures

9.8.2 General Use and Disclosure Provisions

The Contractor may only use or disclose PHI as necessary to perform the services set forth in this Contract or as required by law. The Business Associate is not permitted to de-identify PHI under DoD HIPAA Issuances or the corresponding 45 CFR 164.514(a)-(c), nor is it permitted to use or disclose de-identified PHI, except as provided by the Contract or directed by DHA. The Contractor agrees to use, disclose and request PHI only in accordance with the HIPAA Privacy Rule "minimum necessary" standard and

corresponding DHA policies and procedures as stated in the DoD HIPAA Issuances. The Contractor shall not use or disclose PHI in a manner that would violate the DoD HIPAA Issuances or HIPAA Privacy Rules if done by the covered entity, except uses and disclosures for the Contractor's own management and administration and legal responsibilities or for data aggregation services as set forth in paragraphs 8.3.1 – 8.3.3.

9.8.3 Specific Use and Disclosure Provisions

9.8.3.1 Except as otherwise limited in this Section, the Contractor may use PHI for the proper management and administration of the Contractor or to carry out the legal responsibilities of the Contractor. The foregoing authority to use PHI does not apply to disclosure of PHI, which is covered in the next paragraph.

9.8.3.2 Except as otherwise limited in paragraph 8.3, the Contractor may disclose PHI for the proper management and administration of the Contractor or to carry out the legal responsibilities of the Contractor, provided that disclosures are required by law, or the Contractor obtains reasonable assurances from the person to whom the PHI is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person, and the person notifies the Contractor of any instances of which it is aware in which the confidentiality of the information has been breached.

9.8.3.3 Except as otherwise limited in this Section, the Contractor may use PHI to provide Data Aggregation services relating to DHA's health care operations.

9.8.4 Contractor Compliance with DHA Notices and Restrictions

9.8.4.1 DHA will provide the Contractor with the notice of privacy practices that DHA produces in accordance with the DoD HIPAA Issuances and the corresponding 45 CFR 164.520.

9.8.4.2 Upon notification by DHA of any changes in, or revocation of, permission by an individual to use or disclose his or her PHI, the Contractor shall comply to the extent that such changes may affect the Contractor's use or disclosure of PHI.

9.8.4.3 Upon notification by DHA, the Contractor shall comply with any restriction on the use or disclosure of PHI that the Government has agreed to or is required to abide by under the DoD HIPAA Issuances or the corresponding 45 CFR 164.522, to the extent that such restriction may affect Contractor's use or disclosure of PHI.

9.8.5 Permissible Requests by DHA

The Government will not request the Contractor to use or disclose PHI in any manner that would not be permissible under the HIPAA Rules or any applicable Government regulations (including without limitation, DoD HIPAA Issuances) if done by the Government, except for providing Data Aggregation services to the Government and for management and administrative activities of the Contractor as otherwise permitted by this Contract.

9.8.6 Termination

9.8.6.1 Effect of Noncompliance

Noncompliance by the Contractor (or any of its staff, agents, or subcontractors) with any requirement in these HIPAA Business Associate Provisions (paragraph 8) may subject the Contractor to termination under any applicable default or other termination provision of this Contract.

9.8.6.2 Effect of Termination

9.8.6.2.1 If this Contract has records management requirements, the Contractor shall handle such records in accordance with the records management requirements. If this Contract does not have records management requirements, the Contractor shall handle such records in accordance with paragraphs 8.6.2.2 and 8.6.2.3 below. If this Contract has provisions for transfer of records and PII/PHI to a successor contractor, or if DHA gives directions for such transfer, the Contractor shall handle such records and information in accordance with such Contract provisions or DHA direction.

9.8.6.2.2 If this Contract does not have records management requirements, except as provided in paragraph 8.6.2.3 below, upon termination of the Contract, for any reason, the Contractor shall return or destroy all PHI received from the Government or created or received by the Contractor on behalf of the Government that the Contractor still maintains in any form. This provision shall apply to PHI that is in the possession of subcontractors or agents of the Contractor. The Contractor shall retain no copies of the PHI.

9.8.6.2.3 If this Contract does not have records management provisions and the Contractor determines that returning or destroying the PHI is infeasible, the Contractor shall provide to the Government notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Government and the Contractor that return, or destruction of PHI is infeasible, the Contractor shall extend the protection of the Contract to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as the Contractor maintains such PHI.

9.8.7 Miscellaneous

9.8.7.1 Survival

The obligations of the Contractor under the “Effect of Termination” provision of Paragraph 9 shall survive the termination of this Contract.

9.8.7.2 Interpretation

Any ambiguity in this Contract shall be interpreted in a manner to permit compliance with the HIPAA Rules and the DoD HIPAA Issuances.

9.9 Breach Response

[This paragraph 9 is inoperative, and all references herein to “paragraph 9” shall be deemed to refer to the TOM breach responses provisions, if the contract incorporates the TOM by reference. See paragraph 8.1.4 above]

9.9.1 Definitions Related to Breach response

9.9.1.1 Breach means a loss of control, compromise, unauthorized disclosure, unauthorized acquisition, unauthorized access, or any similar term referring to situations where persons other than authorized users and for other than an authorized purpose have access or potential access to PII, whether physical or electronic. The foregoing definition is based on the definition of breach in DoDD 5400.11. Breaches are classified as either possible or confirmed (see the following two definitions) and as either cyber or non-cyber (i.e., involving either electronic PII/PHI or paper/oral PII/PHI).

9.9.1.2 A possible breach is an incident where the possibility of unauthorized access is suspected (or should be suspected) and has not been ruled out. For example, if a laptop containing PII/PHI is lost, and the contractor does not initially know whether or not the PII/PHI was encrypted, then the incident must initially be classified as a possible breach, because it is impossible to rule out the possibility of unauthorized access to the PII/PHI. In contrast, that possibility can be ruled out immediately, and a possible breach has not occurred, when misdirected postal mail is returned unopened in its original packaging. However, if the intended recipient informs the contractor that an expected package has not been received, then a possible breach exists until and unless the unopened package is returned to the contractor. In determining whether unauthorized access should be suspected, the contractor shallconsider at least the following factors:

• How the event was discovered.

• Did the information stay within the covered entity’s control.

• Was the information accessed/viewed; and

• Ability to ensure containment (e.g., recovered, destroyed, or deleted).

9.9.1.3 A confirmed breach is an incident in which it is known that unauthorized access could occur. For example, if a laptop containing PII/PHI is lost and the contractor knows that the PII/PHI is unencrypted, then the contractor should classify and report the incident as a confirmed breach, because unauthorized access could occur due to the lack of encryption (the contractor knows this even without knowing whether or not unauthorized access to the PII/PHI has actually occurred). If the laptop is subsequently recovered and forensic investigation reveals that files containing PII/PHI were never accessed, then the possibility of unauthorized access can be ruled out, and the contractor should re-classify the incident as a non-breach incident.

9.9.1.4 A HIPAA breach is an incident that satisfies the definition of breach in 45 CFR 164.402.

9.9.1.5 A cybersecurity incident is a violation or imminent threat of violation of computer security policies, acceptable use policies, or standard security practices, with respect to electronic PII/PHI. A cybersecurity incident may or may not involve a breach of PII/PHI. For example, a malware infection would be a possible breach if it could cause unauthorized access to PII/PHI. However, if malware only affects data integrity or availability (not confidentiality), then a non-breach cybersecurity incident has occurred.

9.9.2 General

9.9.2.1 The breach response requirements set forth in paragraph 9 are designed to satisfy both the DoD Privacy Act Issuances and the HIPAA Breach Rule, 45 CFR Part 164, Subpart D, as applicable. The definition of breach above is based on the definition of breach in the DoD Privacy Act Issuances. This Privacy Act definition is broader than a HIPAA breach as defined above. Thus, a Privacy Act breach would not constitute a HIPAA breach if the PII involved does not include PHI or if it involves PHI but is excluded from the definition of HIPAA breach. If a breach is not a HIPAA breach, then the Contractor has no HIPAA breach response obligations. In such cases, the Contractor must still comply with breach response requirements under the DoD Privacy Act Issuances, as stated in this paragraph 9.

9.9.2.2 Because DoD defines “breach” to include possible (suspected), as well as actual (confirmed) breaches, the Contractor shall implement these breach response requirements immediately upon the Contractor’s discovery of a possible breach. These procedures focus on the first two steps (breach identification and reporting) of a comprehensive breach response program, but also require addressing the remaining steps: containment, mitigation (which includes individual notification), eradication, recovery, and follow-up.

9.9.2.3 The contractor shall establish internal processes for carrying out the procedures set forth below. These processes shall assign responsibility for investigating, classifying, reporting and otherwise responding to breaches and cybersecurity incidents. The contractor should consult with the DHA Privacy Office where guidance is needed, such as when the contractor is uncertain whether a discovered breach is the contractor'sresponsibility (e.g., if thecontractor discovers a breach not caused by the contractor), or how the contractor is to classify an incident (breach vs. non-breach, confirmed vs. possible, cyber vs. non-cyber). Under no circumstances will a contractor delay reporting a confirmed or possible breach to the DHA Privacy Office beyond the 24-hour deadline (see paragraph

9.3.2) while waiting for the DHA Privacy Office guidance or while investigating the incident. In conjunction with its initial investigation, the contractor shall immediately take steps to minimize any impact from the occurrence, proceed with further investigation of any relevant details (such as root causes, vulnerabilities exploited), and initiate further breach response steps.

9.9.2.4 In the event of a cybersecurity incident not involving a PII/PHI breach, the contractor shall follow applicable DoD cybersecurity and NIST requirements, which include United States- Computer Emergency Readiness Team (US-CERT) reporting (see paragraph 9.3). If at any point a contractor finds that a cybersecurity incident involves a PII/PHI breach (possible or confirmed), the contractor shall immediately initiate the reporting procedures set forth below. The contractor shall also continue to follow any required cybersecurity incident response procedures and other applicable DoD cybersecurity requirements.

9.9.2.5 Contractors shall require subcontractors who discover a possible breach or cybersecurity incident to initiate the incident response requirements herein by reporting the incident to the contractor immediately after discovery.

The time of that report to the contractor shall trigger the contractor's DHA Privacy Office reporting deadline (24 hours) under paragraph 9.3.2. If a cybersecurity incident is involved, the contractor's deadline for US-CERT reporting (1 hour) runs from the time the incident is confirmed. The contractor shall require the subcontractor to cooperate as necessary to meet these deadlines, maintain records, and otherwise enable the contractor to complete

the breach response requirements herein. Alternatively, the contractor and subcontractor may agree that the subcontractor shall report directly to US-CERT and the DHA Privacy Office, and that the subcontractor shall be responsible for completing the response

process, provided that such agreement requires the subcontractor to inform the contractor of the incident and the subsequent response actions.

9.9.2.6 Contractors shall maintain records of all breach and cybersecurity incident investigations, regardless of the outcome. Investigations identifying unauthorized disclosures must be logged for HIPAA and Privacy Act disclosure accounting purposes, whether individual notification is required under the HIPAA Breach Rule.

9.9.2.7 Contractors, when acting as HIPAA-covered entities (rather than as business associates), are not subject to the breach response requirements herein. However, such contractors are subject to both the HIPAA Breach Rule (applicable to them in their capacity as covered entities) and DoD cybersecurity requirements (applicable to them in their capacity as DoD contractors).

9.9.3 Reporting Provisions

9.9.3.1 Immediately upon discovery of a possible or confirmed breach or cybersecurity incident, the contractor shall initiate an investigation. If the incident involves electronic PII/PHI, and if the investigation finds a confirmed breach or cybersecurity incident, the contractor shall report it, within 1 hour of confirmation, to the US-CERT Incident Reporting System at https://forms.us-cert.gov/report/, as required by the Department of Homeland Security (DHS).

Note: DHS no longer requires US-CERT reporting of non-cyber breaches or unconfirmed electronic breaches.

However, DHS permits US-CERT reporting of unconfirmed cyber-related incidents on a voluntary basis. Thus, if a contractor is uncertain whether a possible cyber-related incident should be treated as confirmed and thus reportable, the contractor may voluntarily report the incident.

Before submission to US-CERT, the contractor shall save a copy of the on-line report. After submitting the report, the contractor shall record the US-CERT incident reporting number, which shall be included in the initial report to the DHA Privacy Office as described in paragraph 9.3.2.

Note: Regardless of whether an incident is confirmed as a breach, the contractor must also investigate whether the incident impacts data integrity or availability of PII/PHI. If such impact is confirmed, then the incident is reportable to US-CERT as a cybersecurity incident. For guidance on investigating the impact on data integrity and availability, refer to DoD cybersecurity and NIST guidance.

The contractor shall provide any updates to the initial US-CERT report by email to soc@us-cert.gov, with the Reporting Number in the subject line. The contractor shall provide a copy of the initial or updated US-CERT report to the DHA Privacy Office if requested. Contractor questions about US-CERT reporting shall be directed to the DHA Privacy Office, not the US-CERT office.

9.9.3.2 In addition to US-CERT reporting, the contractor shall report to the DHA Privacy Office by submitting the form specified below within 24 hours of discovery of a breach (possible or confirmed), unless the breach falls within a category that the Privacy Office has determined to be not reportable. This 24-hour period runs from the time of discovery, unlike the 1-hour US- CERT reporting period, which runs from the time a cybersecurity incident is confirmed. Thus, depending on the time needed to confirm, the report to the DHA Privacy Office may be due either before or after the US-CERT report.

The breach report form required within the 24-hour deadline shall be sent by e-mail to:

DHA.PrivacyOfficer@mail.mil. The contractor shall also e-mail the report to the CO, the COR and its usual point of contact at the applicable Program Office. Encryption is not required, because reports and notices shall not contain

PII/PHI. If electronic mail is not available, telephone notification is also acceptable (at 703-275-6363), but all notifications and reports delivered telephonically must be confirmed in writing as soon as technically feasible.

Contractors shall prepare the breach reports required within the 24-hour deadline by completing the Breach Reporting Department of Defense (DD) Form DD 2959 (Breach of PII Report), available at the Breach Response link on the DHA Privacy Office web site, http://www.health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/Breaches-of-PII-and-PHI. For non-cyber incidents without a US-CERT number, the contractor shall assign an internal tracking number and include that number in Box 1.e of the DD Form 2959. The contractor shall coordinate with the DHA Privacy Office for subsequent action, such as beneficiary notification, and mitigation. The contractor must promptly update the DD Form 2959 as new information becomes available.

When a Breach Report Form initially submitted is incomplete or incorrect due to unavailable information, or when significant developments require an update, the Contractor shall submit a revised form or forms promptly after the new information becomes available, stating the updated status and previous report date(s) and showing any revisions or additions in red text. The Contractor shall provide updates to the same parties as required for the initial Breach Report Form.

9.9.4 Individual Notification Provisions

9.9.4.1 If the DHA Privacy Office determines that individual notification is required, the Contractor shall provide written notification to beneficiaries affected by the breach as soon as possible, but no later than 10 working days after the breach is discovered and the identities of the beneficiaries are ascertained. The 10-day period begins when the Contractor is able to determine the identities (including addresses) of the beneficiaries whose records were impacted. If notification cannot be completed within 10 working days, the contractor shall notify the DHA Privacy Office.

9.9.4.2 The Contractor's proposed notification to be issued to the affected beneficiaries shall be submitted to the DHA Privacy Office for approval. The notification to beneficiaries shall include, at a minimum, the following:

• Specific data elements,

• Basic facts and circumstances,

• Recommended precautions the beneficiary can take,

• Federal Trade Commission (FTC) identity theft of hotline information, and

• Any mitigation support services offered, such as credit monitoring.

Contractors shall ensure any envelope containing written notifications to affected individuals are clearly labeled to alert the recipient to the importance of its contents, e.g., "Data Breach Information Enclosed," and that the envelopeis marked with the identity of the Contractor and/or subcontractor organization that suffered the breach.

If media notice is required, the contractor will submit a proposed notice and suggested media outlets for the DHA Privacy Office review (which will include coordination with the DHA Communications Division) and approval.

9.9.5 In the event the Contractor is uncertain on how to apply the above requirements, the Contractor shall consult with the CO, who will consult with the Privacy Office as appropriate when determinations on applying the above requirements are needed.

The Contractor shall, at no cost to the government, bear any costs associated with a breach of PII/PHI that the Contractor has caused or is otherwise responsible for addressing.

SECTION C-10

Exclusion from Participation in Federal Health Care Programs (October 2015)

10.1. The Contractor shall not employ or contract with any individual or entity (hereinafter collectively referred to as“person”) to provide items or services that will be included in invoices submitted to the Government under this contract if such person is listed on the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) List of Excluded Individuals and Entities (LEIE) or the TRICARE Sanctioned Provider List. The Government is legally prohibited from paying for provision of items or services by such people. The prohibition extends to services beyond direct patient care, such as services of people in executive or leadership roles and administrative and management services, whether or not such services are billed separately. The LEIE may be found at http://oig.hhs.gov/fraud/exclusions.asp, and the TRICARE Sanctioned Provider list at

http://www.health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Quality-And-Safety-of- Healthcare/Program-Integrity/Sanctioned-Providers. The LEIE and TRICARE Sanctioned Provider List are hereinafter collectively referred to as “the Lists.”

10.2. Prior to start of contract performance, the Contractor shall

(a) query the Lists to determine whether the name of any person the Contractor employs or contracts with to provide services or items for which payment may be made under this contract appears on the Lists and certify to the Contracting Officer that the Contractor has queried the Lists and no such names appear on either of the Lists.

10.3. During performance of the contract, and prior to persons other than those whose names were queried in accordance with paragraph 2, above, (hereinafter “new persons”) providing services or items under the contract, the Contractor shall

(a) query the Lists as in paragraph 2, and

(b) certify to the Contracting Officer that the names of such new persons do not appear on either of the Lists.

10.4. The Contractor is advised that during performance of the contract, MTF personnel will perform a recurrent recheck of the names of contractor personnel working in the MTF against the Lists, as specified in OTSG/MEDCOM Policy Memo 15-037. The Government will notify the Contractor in the event any contractor personnel working in the MTF appear on either of the Lists.

10.5. Should any person providing items or services under the contract appear on either of the Lists at any time during contract performance, the Contractor shall

(a) in cases where the Contractor identified the person, notify the Contracting Officer, and

(b) promptly remove that person from the contract.

10.6. Violation of any aspect of the above paragraphs shall be considered a material breach of the contract and may result in termination of the contract.

10.7. The Contractor is further advised that, in accordance with Civil Monetary Penalties Law [CMP] (codified at 42

USC § 1320a-7a):

a. There are steep civil monetary penalties associated with billing the Government for providing items or services by a person on either of the Lists, and with failing to return to the Government any overpayments received for provision of such items or services.

b. Billing under the contract for provision of items or services by a person on either List may also result in exclusion of the person that employs or contracts with such person.

10.8. HHS OIG has issued a Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs with additional information on the CMP. The Special Advisory Bulletin may be found at

http://oig.hhs.gov/exclusions/files/sab-05092013.pdf.

TECHNICAL EXHIBIT # 1

* Due to size and type, Italian Legislative Decree 81/2008 (*Testo Unico sulla Salute e Sicurezza sul Lavoro, D.lgs. 9*

Aprile 2008, n. 81 e s.m.i.), revision November 2020, is made available separately in PDF format.

“End of Technical Exhibit # 1”

TECHNICAL EXHIBIT # 2

* Due to size and type, Conditions of Employment for Local National Employees of the U.S. Armed Forces in Italy

(COE) effective 1 November 2018, is made available separately in PDF format.

“End of Technical Exhibit # 2”

TECHNICAL EXHIBIT # 3

AUTHORIZED GOVERNMENT PERSONNEL

NAME EMAIL ADDRESS TEL. Nr. (DSN) MAILING ADDRESS

CONTRACTING OFFICER REPRESENTATIVES:

NAME EMAIL ADDRESS Phone Nr. Commercial

CONTRACTING OFFICER REPRESENTATIVES (COR):

Emilio Marchesin emilio.marchesin.ln@health.mil **00390444619426**

Nicolo' De Toffoli nicolo.detoffoli.ln@health.mil **00390444619448**

Mailing Address:

Public Health Command Europe - U.S. Army Occupational Health System Specialist - Vicenza, Italy

Rappresentante del Contratto da contattare direttamente per qualsiasi informazione.

Contracting Officer Representative to be contacted directly for any information

UFFICIO MEDICINA DEL LAVORO (OHO) OCCUPATIONAL HEATH OFFICE (OHO)

Invio documenti e relazioni richieste dal contratto

Point of contact send here the documents requested

Emilio Marchesin emilio.marchesin.ln@health.mil **00390444619426**

Public Health Command Europe - U.S. Army Occupational Health System Specialist - Vicenza, Italy

Contracting Officer Technical Representative:

Nicolo' De Toffoli nicolo.detoffoli.ln@health.mil **00390444619448**

Public Health Command Europe - U.S. Army Occupational Health Technician - Vicenza, Italy

UFFICIO DEL PERSONALE/ OFFICE OF PERSONNEL

Per invio "Giudizio di idoneita' alla mansione Specifica"

Send here "Fitness for duty Certification and translation required.

Non e' possibile conttattare o farsi contattare dall'Ufficio del personale senza autorizzazione COR It is not possible to contact or be contacted from Civialian Personnel Office without COR autorization

Grazia Angeli grazia.angeli.ln@mail.mil 0039050547427 Camp Darby Italy

UFFICIO RSPP/SAFETY OFFICES

Per invio “Giudizio di idoneita’ alla mansione Specifica”

Send here “Fitness for duty Certification and translation required.

Non e’ possibile conttattare o farsi contattare dall’Ufficio del personale senza autorizzazione COR.

It is not possible to contact or be contacted from Civialian Personnel Office without COR authorization.

AFSBn AFRICA - Leghorn Army Depot

Marco Ruberti marco.ruberti4.ln@mail.mil +0039050548134

Lucia Gullo lucia.gullo3.ln@mail.mil +0039050548323

USAG ITALY -

Chiara Chelossi chiara.chelossi2.ln@mail.mil +0039050547814

“End of Technical Exhibit # 3”

TECHNICAL EXHIBIT #4.

U.S. ARMY LOCAL NATIONAL EMPLOYEES - MONTHLY LEVEL OF EFFORT (LOE)

U.S. Army Local National Employees - Monthly Level of Effort (LOE**)**

Description Estimated Monthly

(average)

LNs Health Examinations 45

EKG Examination and Reporting 3

Visual Screening 12

Audiogram 37

Pulmonary Function Testing 25

Specialist Referrals Examinations 2

Urinalysis 37

Blood Collection 37

Work Site Visits 6

Meetings/Conferences (hr) 20 minutes

Drug Testing 37

Laboratory Referral (Positive Drug testing) 2

Risk Assessment Meetings (hr) 2

Risk Assessment Meetings Alcohol (hr) 1

Alcohol Testing 20

Hepatitis B Titer 3

Hepatitis C Titer (HCV) 3

HIV 3

Glucose Fasting 37

Chemistry 5:

- CBC/diff (emocromo con formula) 37

- Lipoprotein Panel (triglyceride, cholesterol, HDL, LDL, Cholestero/HDL) 37

- GGT (gamma-glutamyl transferase) 37

- Urea Nitrogen/Creatinine (urea Nitrogen, creatinine, urea nitrogen/creatinine) 37

- Hepatic Function Panel (albumin, bilirubin, bilirubin direct, alkaline phosphatase, protein, alanine aminotransferase, aspartate aminotransferase) 37

Hippuric Acid (Urine) end work shifts 1

Methyl-Hippuric Acid (Urine) end work shifts 1

Alau-Delta Aminolevulinic Acid (Urine) Plastic urine container with 0.5ml of 30% glacial acetic acid and amber plastic frozen transport tube and cap 1

ZPP-Zinc Protoporphyrin (Blood) 1

Lead (blood) 1

Antibody Titers (Hep A, MMR, Varicella) Only 1 per year

“End of Technical Exhibit # 4”

TECHNICAL EXHIBIT # 5

ARMY in EUROPE Regulation 190-16 Excerpt

Chapter 11 - CONTRACTOR (RESIDENT OF EUROPEAN UNION (EU) OR NATO-MEMBER COUNTRY)

• **Definition:** An individual without NATO SOFA status who lives in the EU or a NATO-member country and is contracted to work for DOD in Europe. Contractors who are trying to establish a contract with DOD may be granted access only through an individual who has visitor-sponsor privileges or through access-roster procedures.

b. Types of Passes Authorized:

(1) Temporary Installation Pass: Authorized after all required background checks have been completed and, for individuals in Germany, an LNSP screening has been initiated.

(2) Regular Installation Pass: Authorized after all background checks have been completed and returned with no entries.

c. Length of Time the Passes are Valid:

(1) Temporary Installation Pass: Valid for the length of the contract or up to 90 days, whichever is less.

(2) Regular Installation Pass: Valid for the length of the contract, up to 2 years, or until the expiration date of the supporting document that was used to obtain the installation pass (for example, passport), whichever is earliest.

d. Sponsors:

(1) Individuals appointed in writing as KOs, contracting officer's representatives (CORs), alternate contracting officer's representatives (ACORs), or site contracting officer's representatives (SCORs). If a KO, COR, ACOR, or SCOR is not available to perform the sponsor function (for example, if based in CONUS), he or she may appoint in writing an individual assigned to the USAREUR AOR as his or her USAREUR representative for sponsoring installation access.

(2) Individuals appointed in writing as sponsors for contractors by an OPM-approved agency or organization (for example, the 266th Financial Management Support Center sponsors Community Bank contractors).

NOTE: All appointment letters will be on file on the USAREUR IACS portal.

e. Background Checks:

(1) GCC: Required before a temporary or regular installation pass may be issued.

(2) U.S. Security Check: Required for U.S. citizens before a temporary or regular installation pass may be issued.

(3) HN Background Check: Required, if available, for both non-U.S. citizens and U.S. citizens who have lived in the HN for more than 12 consecutive months without NATO SOFA status. In Germany, this is the LNSP screening.

The LNSP screening must be initiated before a temporary installation pass may be issued. The screening must be completed and returned with no entries before a regular installation pass may be issued.

f. Residence and Work Permits: Required for non-EEA citizens. (The USAREUR IACS SharePoint site provides current guidance.)

NOTE: In Germany, separate work permits are no longer issued to individuals who are not citizens of an EEA member country. Authorization to work must be included in and explicitly indicated on the *Aufenthaltstitel*.

g. Installations a Passholder May Enter: Limited to the minimum number required for a contractor to perform his or her duties according to the contract performance work statement (PWS). A copy of the applicable portion of the PWS must be submitted with the application package. A vague or incomplete PWS limits an applicant's access to a single USAG until the PWS is revised.

h. Days and Times Access is Authorized: As specified in the PWS. A vague or incomplete PWS limits an applicant's access to Monday through Friday, 0800–1700 hours, until the PWS is revised.

i. Visitor-Sponsor Privileges:

(1) Visitor-sponsor privileges normally are not granted to contractors. USAG commanders or their designated appointees may approve visitor-sponsor privileges based on the justification provided on AE Form 190-16A as supported by the PWS.

(2) Visitor-sponsor privileges are not authorized at FPCON Delta.

(3) Only third-party contractors and vendors who support the sponsor's contract may be sponsored for an escorted-visitor paper pass.

(4) Visitor-sponsor privileges are not authorized for temporary-installation-pass holders.

j. FPCON Restrictions:

(1) Temporary-installation-pass holders: Bravo.

(2) Regular-installation-pass holders identified as—

(a) Nonessential personnel: Bravo.

(b) Essential personnel: Charlie.

(c) Essential personnel who are also first or emergency responders (glossary), and personnel

required to perform duties in times of crisis or war: Delta.

“End of Technical Exhibit 5”

TECHNICAL EXHIBIT # 6

PERFORMANCE REQUIREMENTS SUMMARY

1. The purpose of this section is to:

a. List the contract requirements considered most critical to acceptable contract performance.

b. Show the maximum allowable degree of deviation from perfect performance for each requirement or Minimum Acceptable Standards (MAS) that shall be allowed by the U.S. Army before contract performance is considered unsatisfactory.

c. Explain the Quality Assurance methods the U.S. Army will use to evaluate the Contractor’s performance in meeting the contract requirements.

d. Show the percentage of the major elements of the contract price that each contract requirement listed represents.

e. Define the procedure the U.S. Army shall use in reducing the Contractor’s monthly payment if satisfactory performance is not rendered by the Contractor.

2. The U.S. Army primary quality assurance procedures are based on customer complaints, periodic inspections, and 100% Inspection.

3. Monthly payments to the Contractor shall be reduced for unsatisfactory performance using the following methods:

a. Each month, Contractor performance will be compared to contract standards and MAS’s using the U.S. Army Quality Assurance Surveillance Plan.

b. If the performance in any required service is unsatisfactory and the poor performance is clearly the fault of the Contractor, any amount of money up to the percentage cost of

service, as stated in the fifth column of the Performance Requirements Summary shall be withheld.

c. Monetary deductions for unsatisfactory performance will be computed by deducting the percentage shown from the monthly invoice when the MAS was not achieved.

Performance Objective	**PWS Section**	**Acceptable Quality Level AQL**	**Surveillance Method**	**Compliance**
Meetings Attendance	Para. 1.2.4	100%	100% Inspection	Positive/Negative Performance Report
Provide English and Italian language proficiency	Para 1.2.5.	100%	100% Inspection	Positive/Negative Report
Qualified physicians, fully licensed to practice Occupational Health medicine in Italy (*medico competente*), with steady current credentials	Para 1.3.	100%	Random Inspection / Customer Complaint	Positive/Negative Performance Report
Medical Records and Privacy Law Compliance	Para 1.5.	100%	Random Inspection / Customer Complaint	Positive/Negative Performance Report
Hygienic and confidential facilities	Para 4.1.	99%	Customer Complaints/ Random Inspection	Positive/Negative Performance Report
Return Daily Report in digital format to the OHO within one working day after LNs examinations. WSV report within five (5) working days after worksite visits occurred.	Para 5.2.1	100%	100% Inspection	Re-Performance

Monthly Report detailing the Occupational Health Examinations, within five (5) days of the close of the previous month to OHO.	Para 5.2.2	100%	100% Inspection	Re-Performance

Provide Physician Statements "*Giudizio d'Idoneità alla mansione specifica"* within one (1) working day from the visit. Exams requiring testing that cannot be resulted within this time, OHO must be notified within one (1) business day with timeline of expected results.	Para 5.2.2	100%	100% Inspection	Performance
Worksite visit reports must be submitted to OHO within five (5) working days from date of visit	Para 3.1.4	100%	100% Inspection_	Performance
Coordinate all worksite visits and periodic physical examinations with OHO and RSPP NLT 60 days prior to visit/exam.	Para 3.1.4	100%	100% Inspection	Positive/Negative Performance Report
Compliance: Periodic medical exams to including testing	Para 5.1 Para 5.4	100%	100% Inspection	Performance

SURVEILLANCE ACTIVITY CHECKLISTS GUIDANCE

1. Applicability. Checklists will be used to record surveillance results of contract requirements that will be surveyed on a periodic (daily, weekly, or monthly) basis.

2. Inspection Procedures. The Contractor will be permitted to accompany the COR during inspections. Every defect will be thoroughly documented by the COR to specifically identify the deficiency and the way the deficiency is not in conformity with the contract requirement. The Contractor and Contracting Officer will be provided with a copy of such documented reports. Requirements to be inspected under this procedure are listed in Section 5.

3. Record of Observations. The Contracting Officer's Representative will inspect all services provided and review all invoices to ensure they have met Minimum Acceptable Standards (MAS). Services will be monitored by the COR. Results will be recorded on the invoice and receiving report.

"End of Technical Exhibit 6"

TECHNICAL EXHIBIT #7.

U.S. Army LIVORNO FACILITIES –

US. Army LOCATION Contractor's Place of Performance Distance in Kilometers

Camp Darby Tirrenia

56128 Tirrenia (PI)

Via Giovanni Battista Picotti 1

Pisa, Pisa 56124 21

ARMY DEPOT

Via Aurelia Sud

56121 Tombolo (PI)

Via Giovanni Battista Picotti 1

Pisa, Pisa 56124 25

“End of Technical Exhibit 7”

“End of Performance Work Statement”