PRODUCT SPECIFICATION

FOR

HARKINS LABORATORY COMPLEX INFORMATION MANAGEMENT SYSTEM (HLCLIMS)

7 DECEMBER 2018

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1 **DESCRIPTION OF PRODUCT.**

1.1 Background.

Harkins Laboratory Complex (HLC) gas analysis program has been in operation for many years and enjoys a well-established reputation of unmatched low background gas analysis and reporting. Consistent and defensible data is at the core of our methods and policies. HLC understands the importance of consistent and defensible data, audit trails and traceability and has levied those requirements on our laboratory partners who assist and analyze a portion of our samples. To complete the process though, the gateway to our analytical system, the HLC, must be held to the same data-handling standard. A Laboratory Information Management System (LIMS) exemplifies HLC philosophy by capturing every record and traces the trustworthiness of all values.

1.2 <u>Scope.</u>

- 1.2.1 This requirement will deliver a commercial off-the-shelf software product very common to laboratory environments and tailored to HLC's needs. This product will achieve the following:
 - Eliminate file-sharing permission and access errors
 - Reduce data entry errors
 - Perform HLC scheduling functions
 - Permit automated notifications, via email when practical based process or userestablished parameters
 - Manage and control standard operating procedures (SOP)
 - Maintain chain-of-custody records
 - Allow full data audit capability
 - Permit and capitalize on the use of barcodes for item & sample management
 - Allow both standardized and customizable data reporting and graphing
 - Manage laboratory resources (which includes, but is not limited to)
 - Gas usage to include carrier and reference
 - Procurement, preparation, and consumption of supplies
 - Scheduling laboratory procedures (cleaning, processing, scheduled and unscheduled maintenance, calibrations, etc.)
 - Training technicians
 - Managing equipment calibrations
 - Storing and reporting radioactive source data
 - Storing sample location and status
 - Generating customizable reports
 - Calculate decay-corrected specific activity
 - Calculate counting uncertainty
 - Integrate current process generated excel files into data structure either by automated process or by user
 - Integrate historical process generated excel files into data structure either by automated process or by user

1.3 <u>Schedule.</u>

- 1.3.1 LIMS shall be delivered 6 months from contract award.
- 1.3.2 Demonstration of the LIMS product ninety (90) calendar days from period of performance (PoP) completion.
- 1.3.3 Training within 30 calendar days after LIMS delivery.

2 SYSTEM SPECIFICATION (CDRL A0001).

2.1 System Specifications

- 2.1.1 Acquire, install, and configure LabVantage LIMS 8.x for operation in one or more VMWare-compatible virtualized systems. LabVantage LIMS shall be the latest stable version in the 8.x series available at start of PoP.
- 2.1.2 All proposed code enhancements which will result in a custom LIMS uniquely suited for HLC's mission and data.
- 2.1.3 The data from the LIMS must be exportable to excel format.
- 2.1.4 Ability to incorporate all HLC's current and historical data, excel and .csv at the time of contract award.
- 2.1.5 The contractor shall test, debug, and validate all software prior to delivery to assure data accuracy and integrity, as well as assure the LIMS will function correctly.
- 2.1.6 The LIMS shall have the following specifications:
- 2.1.6.1 Audit trails:
 - Bar coding of samples, supplies, and equipment for positive tracking of over 1000 items per year.
 - Establishing sample custody chain within the laboratory from receipt through analysis at partner labs.
 - Document control on issuance and validity.
 - Inventory of stocks such as laboratory supplies, chemicals, radioactive sources, reference materials and radiation survey instruments. Warning messages can be generated when stocks begin to fall below a set value, instruments require recalibration, and technicians need to be recertified.
- 2.1.6.2 Calibration and maintenance tracking of instruments with provision for warning messages when calibration or maintenance becomes due.
- 2.1.6.3 Workload management of laboratory personnel.
- 2.1.6.4 Quality control to display warnings if non validated methods are adopted.
- 2.1.7 The LIMS shall provide system efficiencies to include:
- 2.1.7.1 Enter analytical results into the LIMS screens or using Excel spreadsheets for import into the LIMS, including legacy data. In either case, the data is only entered once and is

near-instantly available for queries, reports, and data exports.

- 2.1.7.2 Retrieve very specific information from vast amounts of data swiftly and simply, using standard queries available.
- 2.1.7.3 Minimize paper records and eliminate the occurrence of lost or misfiled data, worksheets, and files. Save time previously spent searching for data or retrieving lost information.
- 2.1.7.4 Rapidly generate routine reports with a click or two of the mouse. Easily produce non-routine reports by specifying data and report features.
- 2.1.7.5 Prepare both standard and customizable trend studies, reports, and historical analysis using easily accessed archived data. Access archived data using the full complement of screens, queries and reports available with the production database.
- 2.1.7.6 Easily add new sample types, units of measure, customers, sampling locations, etc.
- 2.1.8 The LIMS shall provide system productivities to include:
- 2.1.8.1 Generate productivity reports which allow lab managers to track processing times, number of samples or analyses completed per unit of time, expired reagents or supplies, and non-standard mission tasks; sortable by equipment, technician, lab, etc.
- 2.1.8.2 Increase efficiency by using LIMS scheduling features to control routine samples, analysis, instrument calibration and maintenance tasks.
- 2.1.8.3 Eliminate tedious paper-handling tasks, such as placing SOPs in the LIMS, so technicians may spend more productive time in the laboratory.
- 2.1.8.4 Establish read-only access for personnel outside the lab. This feature allows authorized personnel such as higher level management to directly pursue their own questions dynamically, effectively eliminating nonproductive data search, retrieval, and copying time by technicians.
- 2.1.9 The LIMS shall provide system accuracy to include:
- 2.1.9.1 Significantly reduce data entry and transcription error by pulling data from processing and measurement equipment. Virtually all data entry is done using selections from predefined pull-down lists and menus whenever possible.
- 2.1.9.2 Validation protocols on many fields, allowing technicians to catch data input errors before they are entered.
- 2.1.9.3 Document data accuracy and precision referencing the QC program. Lab managers shall be able to set QC limits for both individual analytical methods and instrument calibration. Associated control charts can be maintained and updated as necessary.
- 2.1.9.4 Use the automated scheduling prompts to notify personnel in advance of facility & laboratory events, sample deadlines, quality program separations/loads/measurements and other upcoming tasks as needed.
- 2.1.9.5 Screen data thoroughly through validation protocols to eliminate illogical data conditions prior to generating reports.

- 2.1.10 The LIMS shall adhere to AFTAC / AF security policies by establishing individual accounts with tiered access privileges, controlled by the LIMS administrator. The most up-to-date requirements can be found on the unclassified network at iase.disa.mil. The contractor shall ensure that the Security Technical Implementation Guide (STIG) version is appropriate for the environment and that the current version is being utilized at all times.
- 2.1.11 Constraints:
 - Virtualization: VMware 6.5 or newer compatible .ova or .ovf format for import
 - Operating System: Windows Server 2012 R2 or newer
 - Database: Oracle 12c or newer running on Windows 2012 R2 or newer
 - Application Server: JBoss (newest version compatible with LabVantage LIMS)
 - Oracle Java: JDK (newest version compatible with LabVantage LIMS)
 - Bartender Server: (newest version compatible with LabVantage LIMS)
- 2.1.12 Integration Points:
 - User Authentication: Active Directory
 - Email: Microsoft Exchange
 - Client Systems:
 - o Microsoft Windows 7 or newer with Google Chrome
 - RedHat Linux 5.5 or newer with Google Chrome
 - $\circ~$ Google Chrome version shall be the latest stable version available at the start of PoP
 - Virtualization Platform: VMware 6.5
- 2.2 Data Deliverables
- 2.2.1 Contractor shall provide a System Development Plan which the contractor will follow to meet laboratory objectives using LIMS software by LabVantage. This will involve a site visit to AFTAC/HLC's work area at Cheyenne Mountain Air Force Station, Colorado, interviewing HLC employees, and watching the work being performed. The contractor shall provide a LIMS Design Report to detail the proposed plan for the HLC LIMS. (CDRL A002 applies).
- 2.2.2 The Contractor shall provide Monthly Status Reports with list open issues being worked with description and options for resolution. (CDRL A001 applies)
- 2.2.3 The contractor shall provide a Systems Administration Guide, System Installation Guide, and Architecture Source Code with the system delivery, within thirty (30) days prior to end of PoP. (CDRLs A003, A004, A005 apply)
- 2.2.3.1 These deliverables shall include:
 - Virtual machine image(s)

- Installation media
- Software component license files
- Provisioning, installation, and configuration instructions for each virtual machine image

- Build environment, instructions, and source code for installer and/or installation scripts (if used)

2.3 <u>Software and Hardware Deliverables</u>

The contractor shall provide the following:

- 2.3.1 Fourteen (14) concurrent full user licenses and two (2) named full user licenses of the LabVantage software thirty (30) days prior to end of PoP.
- 2.3.2 Two (2) label printers. The printer should be equivalent to Zebra GX-430t or GX-420t (if no Ethernet is required) with the following characteristics:
- 2.3.2.1 Must print labels in the size range: 1" X 2" to 4" X 6"
- 2.3.2.2 Must print using Thermal Transfer method for label longevity/permanence
- 2.3.2.3 Hardware must be suitable for laboratory setting, i.e. not generate lots of particles, easily cleaned, etc.
- 2.3.2.4 Labels and printer supplies must be easily obtained through regular commercial supply sources
- 2.3.2.5 Must be compatible with Windows-7 or higher, Red Hat 5.5 operating systems and LabVantage software
- 2.3.2.6 Must have USB/Ethernet* connectivity
- 2.3.2.7 Must print 200 dpi resolution or better
- 2.3.2.8 Printing is not expected to exceed 30 labels per week.
- 2.3.2.9 The printer shall have no wireless functions.
- 2.3.3 The contractor shall provide twenty (20) label scanners with the following characteristics:
- 2.3.3.1 Must be hand-held with ability to be self-supported or stand-mounted for hands free use
- 2.3.3.2 Must be capable of scanning barcodes up to 14 inches from the face of the scanner
- 2.3.3.3 Must be capable of scanning 1D & 2D (QR) barcodes
- 2.3.3.4 Must be compatible with Windows-7 or higher, Red Hat 5.5 operating systems and LabVantage software.
- 2.3.3.5 Must be capable of reading labels printed by the printer selected in Section 2.1.10 The scanner shall have no wireless functions.

2.4 <u>LIMS Training</u>

2.4.1 The contractor shall provide one (1) training session after delivery of the LIMS product at the Government facility after delivery of the final LIMS within thirty (30) days. One (1) electronic and one (1) physical copy of the Software User Manual shall be provided five (5) days prior to the training class. (CDRLs A006 & A007 apply)

3 GOVERNMENT FURNISHED PROPERTY AND SERVICES.

- 3.1.1 <u>Services:</u> The Government will provide
- 3.1.2 Escorts to accompany the contractor while working at any Government facilities in service of this PWS
- 3.1.3 <u>Facilities:</u> The Government will provide
- 3.1.4 Access to Cheyenne Mountain Air Force Station on two (2) occasions as described in Section 5.2
- 3.1.5 <u>Materials</u>: The Government will provide
- 3.1.6 Sample data and reports which the delivered system will need to be able to read, convert, process, produce, etc.
- 3.1.7 HLC SOPs relevant to the scope of the work being performed in this PWS
- 3.1.8 Example printer labels upon which the deliverables described in section 2.2.4 will be based

4 GENERAL INFORMATION.

4.1 <u>Contractor Identification in the Government Workplace.</u>

When conversing with Government personnel during business meetings, over the telephone or via electronic mail, the contractor shall identify themselves as such to avoid situations arising where sensitive topics might be better discussed solely between Government employees. The contractor shall identify themselves on any attendance sheet or any coordination documents they may review. Electronic mail signature blocks shall identify their company affiliation.

4.2 Location(s) of Work.

- 4.2.1 The Contractor will be given access to Cheyenne Mountain Air Force Station in Colorado Springs, CO on two (2) occasions.
- 4.2.1.1 Initial Assessment: Contractor will meet with key personnel and subject matter experts to discuss current methods, requirements, limitations, unique factors, etc.
- 4.2.1.2 Training: Contractor Representative(s) will perform the training covered in Section 2.3
- 4.2.2 All other work to be performed under this contract shall be performed at the contractor facility.

4.3 Contractor Manpower Reporting.

The below information is for informational purposes only and shall not be initiated by the contractor without written direction from the Contracting Officer:

- 4.3.1 Overview. In accordance with Section 8108 of the National Defense Appropriations Act of Fiscal Year 2011 the contractor shall report, annually, for performing services on Department of Defense installations in support of this contract, all required prime contract and subcontract data, or require any subcontractors to report separately using the Enterprise-wide Contractor Manpower Reporting Application (eCRMA) located at http://www.ecmra.mil. There are four separate eCMRA tools: Army, Air Force, Navy and All Other Defense Components. The appropriate eCMRA reporting tool to use is determined by the requiring activity being supported (e.g., if DISA awards a contract for an Air Force requiring activity, the contractor shall load the required reporting data in the "Department of Air Force CMRA" tool). The contractor shall report ALL contractor direct labor hours and direct labor dollars (including subcontractor labor hours) required for performance of services provided under this contract. The contractor is only responsible for entering the Order, Contact, and Location Data. The contractor may view user manuals and frequently asked questions (FAQs) at https://cmra.army.mil/Help/help.html.
- 4.3.2 Initial Contract/Order Creation. The contractor shall enter initial data (Order and Contact Data only) into the appropriate eCMRA tool to establish the basic contract record no later than 30 calendar days after receipt of contract award. The contractor shall notify the COR and the CO when the basic contract record has been established in the appropriate eCMRA tool.

- 4.3.3 Annual Reporting. Reporting inputs will be for the direct labor executed during the period of performance (PoP) for each Government fiscal year (FY), which runs 1 October through 30 September. While inputs may be reported any time during the FY, all data shall be reported no later than 31 October of each calendar year. The contractor shall provide reporting inputs for the final PoP of this contract no later than 30 calendar days after contract expiration. The contractor may direct technical questions about the eCMRA tool to the CMRA help desk.
- 4.3.4 Uses and Safeguarding of Information. Information from the secure website is considered to be proprietary in nature when the contract number and contractor identity are associated with the direct labor hours and direct labor dollars. At no time will any data be released to the public with the contractor name and contract number associated with the data.

4.4 Security Guidance.

- 4.4.1 In order for contractors to be allowed access to this Government facility, all contractors working on this effort shall be US citizens and be free of any criminal history that would prevent access to a military installation.
- 4.4.2 The contractor shall be responsible for safeguarding all government equipment, information and property provided for contractor use.
- 4.5 <u>Contractor Travel.</u>
- 4.5.1 Contractor will be required to travel CONUS during the performance of this contract to attend meetings, conferences, and/or training. The contractor may be required to travel to off-site training locations and to ship training aids to these locations in support of this PWS. The contractor shall provide all travel required for delivery of the HLCLIMS product. All travel requires Government approval/authorization and notification to the COR

4.6 Data Rights.

4.6.1 The Government shall have unlimited rights to all documents/material produced under this contract. All documents and materials, to include the source codes of any software, produced under this contract shall be Government owned and are the property of the Government with all rights and privileges of ownership/copyright belonging exclusively to the Government. These documents and materials may not be used or sold by the contractor without written permission from the Contracting Officer. All materials supplied to the Government shall be the sole property of the Government and may not be used for any other purpose. This right does not abrogate any other Government rights.

4.7 <u>Deliverables.</u>

Reports and other data required in this PWS shall be submitted IAW the Contract Data Requirements List (CDRL) in Exhibit A of the contract.

CDRL #	Data Item Number	Data Item Description	PWS Para.	Delivery Schedule
A001	DI-MGMT- 80368A	Monthly Status Report	Section 2	First submission of report will be the 15th working day of the month following contract award. Subsequent submissions due 15th working day of the month following the reporting period.
A002	DI-MISC- 80508A	LIMS Design Report	2.2.1	Draft due fifteen (15) business days after on-site visit. Government comments shall be provided within five (5) business days of receipt. Final document due ten (10) business days after receipt of Government comments.
A003	DI-MISC- 80508A	System Administration Guide	2.2.3	Draft due thirty (30) calendar days prior to end of contract. Government comments shall be provided within five (5) business days of receipt. Final copy shall be provided last business day prior to end of PoP.
A004	DI-MISC- 80508A	System Installation Guide	2.2.3	Draft due forty-five (45) calendar prior to end of contract. Government comments shall be provided within five (5) business days. Final copy shall be provided on thirty (30) calendar days prior to end of PoP.
A005	DI-MISC- 80508A	Architecture Source Code	2.2.3	Due thirty (30) calendar days prior to end of contract.
A006	DI-MISC- 80508A	Software User Manual	2.4.1	Draft due five (5) business days prior to training session. Government comments shall be provided within five (5) business days. Final copy shall be provided on last

				business day prior to end of PoP.
7	DI-MISC-	Training Materials	2.4.1	Due three (3) business days
	80508A	Č		prior to training session

APPENDIX A - ACRONYMS AND ABBREVIATIONS LIST

Acronym/Abbreviation	Definition		
AF	Air Force		
AFB	Air Force Base		
CDRL	Contract Data Requirements List		
СО	Contracting Officer		
COR	Contracting Officer's Representative		
DOD	Department of Defense		
FAR	Federal Acquisition Regulation		
IAW	In accordance with		
NDA	Non-Disclosure Agreement		
OSHA	Occupational Safety and Health Act		
PBSA	Performance Based Service Acquisition		
PWS	Performance Work Statement		
QA	Quality Assurance		
QASP	Quality Assurance Surveillance Plan		
SS	Services Summary		
SOP	Standard Operating Procedure		
USAF	United States Air Force		