

# Leavenworth-CMOP Unit of Use Automation (UUA) System Statement of Work

## Introduction

The Leavenworth Consolidated Mail Outpatient Pharmacy (L-CMOP) is a 70,000 square foot facility located at 5000 South 13<sup>th</sup>, Leavenworth KS, 66048. As a provider of outpatient pharmaceutical services to twenty-four VA Medical Centers and associated community clinics, the ChampVA Meds by Mail program, 1 DoD site, and 4 IHS sites, Leavenworth CMOP dispenses approximately 60,000 prescriptions in a 12 hour work day for direct to patient delivery by various mail carriers. Leavenworth CMOP operates one 12 hour shift, five days per week, and employs approximately 220 staff members.

## Statement of Need

The purpose of this procurement is to obtain a replacement Unit of Use Automation (UUA) System for the existing Leavenworth CMOP facility. L-CMOP requires a contractor to serve as a systems integrator who shall design a working, fully functional replacement UUA system, procure all system hardware and software components, provide a systems interface, and install and integrate them into the existing L-CMOP automated production systems. The contractor shall be required to remove, cleanup, store and dispose of the identified existing L-CMOP automated production systems. The contractor shall be responsible for storage, removal, cleanup, and disposal of the identified existing L-CMOP automated production systems. The replacement UUA system shall occupy the identified facility footprint, integrate with current operations software, and minimize changes/additions to the current hardware and support equipment.

L-CMOP requires the replacement UUA to have a minimum of 400 unique dispensers with price options to increase capacity up to 700 unique dispensers.

The timing for removal of the existing L-CMOP automated systems and delivery of replacement UUA system shall be coordinated with L-CMOP to allow completion and acceptance of a TCA upgrade before the UUA upgrade begins. Delivery shall not begin until the removal process provides adequate floor space for storage of the new UUA system components.

## PART I – SYSTEM DESIGN AND PERFORMANCE

1. The CMOP UUA System shall consist of an on-line dispensing system that provides a minimum throughput of 3,125 **totes**/orders per hour. A patient order consists of all of the prescriptions for a single patient in a specific order split. An order may contain a single prescription, multiple prescriptions filled by a single automated dispenser, or multiple prescriptions requiring more than one automated dispensing system for fulfillment. An order may contain prescriptions that are all filled by the UUA System and married to an empty bar coded tote or the order can arrive at the UUA already married to a bar coded tote with prescriptions from other filling systems. The current average is 1.8 prescriptions per order. L-CMOP shall require the replacement UUA to fully support the SuperTote process. A SuperTote consists of a user defined quantity of multiple, single patient orders, each consisting of one prescription item, and places them all into a single tote.
  - a. Installation will have minimal impact on current L-CMOP automated production system throughput.
  - b. Fit within identified square footage to be determined the VA will provide a PDF document of the available floor space
  - c. Replacement UUA system shall be designed to allow for disassembly and reassembly as a fully functional system to accommodate future production floor modifications.

- d. Fully integrate with Leavenworth CMOP's existing Operating System and order management and inventory control software, and conveyor routing systems. Implementation of interface/integration software must be compatible with systems written using the current MS Visual Studio development platform and provide real time data exchange.
- e. Signal an alert, visual and/or audible, when any operational programs malfunction or disengage.
- f. Provide fiber optic network cabling with at least a gigabyte backbone that seamlessly integrates into the existing CMOP network.
- g. Provide wireless devices where appropriate, ensure compatibility with current Cisco Access points wireless standards 802.11 (subject to change) and use the Windows Mobile PC operating system.
- h. Convey the order after filled and assigned to bar coded tote, as follows:
  - i. Labeling.
  - ii. Transport to the next stage of processing
  - iii. Pharmacy Verification.
  - iv. Packaging
- i. Design requirements shall include:
  - i. Redundancy – Multiple UUA units that operate independently of each other.
  - ii. Exception Station – Located next to operator station
  - iii. Labeling conveyor with workstations
  - iv. Multiple item locations
  - v. Inventory system
  - vi. Bar coded tote type
  - vii. Dump station
  - viii. Bar coded tote tracking

2. The CMOP UUA Dispenser replenishment system shall:

- a. Provide a visual or audible warning that indicates that a dispenser is low on product.
- b. Provide a visual or audible warning that indicates that a dispenser is empty of product.
- c. Offline functionality to override empty or low alarms when product is not available.
- d. Allow for assignment of NDC and lot number to dispenser(s)
- e. Replenishment of dispenser while system is running
- f. Be adjustable

3. The CMOP UUA on-line production system shall:

- a. System shall be adjustable to allow for use of a variety of product shapes and sizes.
- b. Provide a minimum of 400 unique dispensers.
- c. Provide a verification of failsafe matching mechanism for dispenser replenishment to ensure product accuracy, to include strength and dosage form (correct NDC) without interrupting production.

- d. Ensure CMOP patients consistently receive the correct quantity of dispensed product by 100% count verification.
- e. Multiple dispensers may be assigned to one product to simultaneously dispense product for orders of multiple quantity and sequentially deplete dispensers at an even rate.
- f. Dispense without damage to product.
- g. Identify Errors and provide a mechanism for correction when required (i.e. Exceptions station(s)). A reject lane shall be provided from the conveyor that branches off from the main line to accommodate system detected exceptions. The UUA shall have a re-picking function that guides operators to add to incomplete requests. This re-pick function shall not solely rely on recirculation of bar coded totes through the UUA device. Re-picking of shorted bar coded totes shall be minimized with the expectation that total system throughput is maintained at the required rate.
- h. Provide dispensers which accommodate various Bottle/Box sizes and shapes and allow for multiple dispensers of identical medications for highly used items in order to meet throughput requirements. Current product ranges in size from 1" x 2" x 0.5" to 9" x 5" x 5".
- i. Computer workstations, bar code readers, and task lighting shall be included for all system operation work areas.
- j. The UUA shall have local user-definable parameters for operating and reporting purposes. Dispensing units shall monitor, track and report on all events which are electronically passed to the operating system upon completion of each event.
- k. The UUA subsystem shall consist of dispensers that operate independently of each other. Should there be a failure in any single dispenser, the other dispensers shall remain in continuous operations.

4. The UUA Labeling conveyor system shall:

- a. Route and convey each completed bar coded tote to a labeling workstation for processing
- b. Route and convey each bar coded tote to the next stage of processing after the labeling process is complete.
- c. Conveyor shall include ergonomic labeling workstations each workstation shall have a fiber network connection, quad 120vac outlet and task lighting to support the labeling process.
- d. Provide sufficient labeling workstation (average labeling rate is 165 labels per hour per workstation) throughput capacity to sustain hourly output of the system requirements.
- e. Be designed to allow labeling prescriptions in an ergonomic configuration to minimize repetitive motion.

7. To the extent possible, replacement parts shall be non-vendor specific and commercially available. Vendor specific replacement parts shall be readily available within 24 hours.

8. Environmental Considerations:

- a. Contractor is responsible for acquiring any permits, licenses or inspections required by local planning boards in conjunction with installation.

- b. Noise levels from the system shall not exceed 75 decibels (db) in any operator location. System design should minimize noise levels whenever possible.
- c. Noise levels in any location in the CMOP must not exceed levels specified in OSHA Safety and Health Standards 29 CFR 1910 for employees without personnel protection equipment.
- d. The system shall use a color scheme compliant with OSHA guidelines that emphasize safety hazards and safeguards.

## **PART II – EQUIPMENT AND SUPPLIES TO BE FURNISHED BY THE CONTRACTOR**

- 1. Conveyor system shall:
  - a. Provide a “smart” conveyor system which will monitor all automation queues and route Orders to the next stage of processing without damage to product.
  - b. Provide all required components, including but not limited to, transmitters and readers, necessary to route Orders.
  - c. Provide all required components to integrate with current mainline conveyor and bar coded bar coded tote system without disruption to existing systems.
  - d. Provide automatic visual and audible notification for operators to identify all jams and conditions that affect production.
- 2. Dispensing system shall:
  - a. Be of sufficient quantity as to achieve throughput requirements.
  - b. Dispensers shall be designed and installed to:
    - i. Accurately count and dispense pharmaceutical products.
    - ii. Provide redundant physical validation of count at dispense point.
    - iii. Provide ergonomically safe operation and replenishment.
    - iv. Provide easy access for regular and corrective maintenance and repair.
    - v. Allow for straightforward physical removal of dispenser set-up/calibration.
    - vi. Be provided in sufficient quantity to allow for replacement and repair.
- 3. Contractor shall provide all equipment and controls associated with the on-line production and labeling conveyor systems, including but not limited to:
  - a. Ergonomic workstations
  - b. Equipment to validate dispenser functionality
  - c. Docking stations
  - d. Scanning devices (wired or wireless depending on function)
  - e. CPUs, monitors and PDAs (UPS and surge protection)
  - f. Direct Thermal Printers (compatible with our labels and label format)
  - g. Task lighting

- h. Audible and visual notification devices
- i. Supplies and consumables not currently furnished by the VA required for testing.
- j. Contractor shall anticipate system support requirements, including but not limited to electrical, compressed air, and fiber optic, and augment present systems if necessary. Any modifications to the L-CMOP facility structure or infrastructure shall be coordinated through the contracting officer (CO) for approval.

### **PART III – SYSTEM FUNCTION AND INTEGRATION**

#### **1. Software control systems shall:**

- a. Provide a failsafe mechanism to validate bar coded tote/order match at marriage point.
- b. Provide a status change or hard stop to prohibit dispensing action for orders associated with mismatched bar coded tote/order and direct to exceptions.
- c. Direct bar coded totes containing dispensed incorrect quantities to an exceptions station prior to labeling
- d. Provide a failsafe mechanism within the exceptions function to correct detected quantity discrepancies and, if necessary, allow for physical return of excess quantities to stock through the off-line replenishment process and credit inventory accordingly.
- e. Confirm container/bar coded tote match after dispense, automatically provide a status change or hard stop prohibiting verification for both orders associated with mismatched container/bar coded tote, and direct to exceptions prior to verification.
- f. Direct filled and confirmed bar coded tote/order to an ergonomically sound Labeling station.
- g. Maintain system throughput independent of order profile (i.e. throughput should be maintained regardless if it processes single prescription orders or multiple prescription orders).
- h. Provide mechanism to meter release of back orders that will not impact or overload product dispensing.
- i. Display validation of the correct product during the replenishment, and return to stock processes.
- j. Fully integrate with current consolidated exceptions functionality to allow investigation and resolution of any issue related to prescription dispensing regardless of the dispensing system.

#### **2. Data capture and reporting functionality shall:**

- a. Store and maintain all operation events data in existing relational database system that can be queried in real time using TSQL Server, by CMOP personnel without degradation of performance using:
  - i. Automated report generators provided by the contractor
  - ii. Custom reports specified or created by CMOP personnel
- b. Store in the existing operation events table to capture all events in a manner that allows real time:

- i. Tracking of an order, prescription, or product (using a unique label instance) through the dispensing process and associated statuses for the purpose of system or software troubleshooting and error investigation.
  - c. Include in the existing operation events table, events relative to:
    - i. Exceptions processing
    - ii. Return to stock generation and utilization through replenishment
  - d. Log with each operation event data including but not limited to:
    - i. Date-time stamp
    - ii. Operator
    - iii. Product name and location
    - iv. NDC scanned or expected, CMOP ID, quantity when applicable
    - v. Type of transaction or event
    - vi. Order number, prescription number, container number, label instance number and bar coded tote number
  - e. Allow flexibility in generating ad hoc reports, in real time, to print, export, or save through a report generator application using a dashboard format with selectable filters and data ranges as specified by CMOP personnel.
  - f. Provide pertinent real time dispensing activity data in a format to be used to monitor system efficiency based on production location including but not limited to product name, CMOP ID, zone and location.
  - g. Provide pertinent real time production data in a format to be used to monitor system and operator performance including but not limited to: date/time range, UUA prescriptions filled, product dispensed, UUA prescriptions labeled.
4. Dispensing system shall alert and allow for correction of any source of “out of sequence” orders.
5. Dispensers shall:
- a. Accurately count and dispense various product sizes and shapes.
  - b. Provide physical validation of count.
  - c. Require minimal set-up/calibration time and technical skill.
6. The dispenser replenishment system shall:
- a. Provide an error-free mechanism to accommodate product (NDC) changes to prevent inaccurate dispenser loading.
  - b. Sequence replenishment activities to prevent interruption of dispensing.
  - c. Provide a unique physical identifier on each dispenser.
  - d. Provide mechanism to display, assign and track status for each dispenser in real time (for example: low on product, empty, jammed, not dispensing, product assigned).
  - e. Require operator log-on to initiate process.

- f. Track all replenishment actions to every dispenser.
  - g. Ensure that only one NDC can be assigned to a dispenser at a time.
  - h. Require a valid bar code scan for product used to replenish or restock a dispenser.
  - i. Electronically transfer inventory, to include NDC and lot information, from storage to dispenser location and update existing inventory management system accordingly.
  - j. Electronically transfer inventory, to include NDC and lot information, associated with return to stock product.
7. The dispenser loading and refilling system shall:
- a. Track all loading and refilling actions to every dispenser. Require independent operator log-on for loading and refilling when accomplished separately.
  - b. Prioritize refill requirements and provide a visual replenishment alert for operator action.

#### **PART IV – QUALITY ASSURANCE**

To ensure prescription accuracy and patient safety, the UUA System shall be required to:

- 1. Provide and track in real time internal electronic validation of dispenser match with failsafe mechanism that prevents dispensing if mismatched.
- 2. Provide and track physical validation of count at dispensing point, routing bar coded tote/order directly to an exceptions station if dispensed incorrect quantities.
- 3. Track all replenishment actions to every dispenser in real time.
- 4. Utilize and capture in the existing operation events table electronic forcing functions to ensure safety and require supervisory intervention when unexpected events occur that may compromise the integrity of the on-line dispensing/labeling processes.
- 5. Include failsafe mechanisms to prevent operator workarounds when bar code scanning is required. For example: operators may not manually key an NDC in place of a valid NDC bar code scan.
- 6. Electronically capture in real time all operation events which impact the integrity of the finished product.
- 7. Provide a mechanism to prevent mixing brands of same pharmaceuticals or variation in appearance of the same NDC, and prevent user from loading the wrong NDC into the UUA System.
- 8. Log in real time details of all unexpected events.
- 9. Provide a mechanism to electronically account for product identified as waste. (i.e. Product decremented, but not dispensed or eligible to return to stock, such as spillage, must be tracked for inventory control purposes.)
- 10. Provide real time event logging and data capture of labeling events and allow for retrieval using TSQL Server.
- 11. Undergo a five-phase testing program by the contractor and the CMOP.

## **PART V - Installation/Support:**

### **1. Progress Meetings and Progress Reports**

- a. The contractor shall attend bi-monthly progress meetings to brief Government personnel on the progress of design, installation and integration of the UUA. The contractor shall be responsible for providing briefing notes after each meeting. Meeting location will be determined by VA.
- b. The contractor shall submit to the VA Contracting Officer, written bi-weekly progress reports. Each report shall include information as to 1) percentage of the work completed by phase and trade, 2) a statement as to expected UUA completion and system go-live (operational) date; 3) any approved changes introduced into the work; and 4) general remarks on such items as material shortages, strikes, weather, etc.

### **2. Materials and installation:**

- a. Installation shall be accomplished with minimal impact on current UUA system throughput.
- b. All installed equipment shall meet OSHA requirements, including but not limited to identifying all pinch points, electrical hazards, and personal protective equipment (PPE) requirements.
- c. All materials shall be FDA compliant where contact with dispensed product exists.
- d. All wiring shall meet or exceed NEC standards.
- e. All structures and platforms shall meet or exceed applicable UBC requirements.
- f. Contractor is responsible for acquiring any licenses, permits or inspections required by governing authorities in conjunction with the installation of their equipment.
- g. Contractor shall be responsible for all aspects of demolition, removal and disposal of existing equipment/conveyance. CMOP Leavenworth will identify and determine which removed equipment parts, if any, to keep prior to disposal by contractor.
- h. Contractor shall be responsible for rigging and special handling costs, if required, to move the equipment from the dock area to the installation site.
- i. Contractor shall be responsible for providing an on-site dumpster as well as removing the dumpster after job completion.
- j. Contractor shall be responsible for all aspects of delivery and installation
- k. Demolition, removal and installation shall be scheduled with minimal impact to current L-CMOP Automated Prescription Filling system throughput and minimize interference with ancillary processes, including but not limited to receiving and shipping operations.
- l. All items for consideration must conform to current standards, to include but not limited to, OSHA, local/state and federal codes, National Fire Protection Association codes, Underwriters



Laboratories (UL) 544 and 1950, Medical Device Amendments of 1976, and Safe Medical Device Amendments of 1998.

- m. Contractor shall provide surge protection and battery back-up systems to protect all electronics, computers, readers, canisters, etc

### 3. Documentation

Provide to CMOP Supervisory Engineer (COR) all engineering documentation, including but not limited to, mechanical drawings, electrical/wiring diagrams, and support system layouts.

- a. All documentation shall be delivered to the VA in the English language and with unlimited rights as defined by FAR 52.227-14.
- b. Provide to CMOP Supervisory Engineer two (2) operational/service (technical maintenance) manuals (one may be in electronic format, provided the ability to read this format exists at the customer facility separate from the installed system) for the overall system and any component subsystems as necessary (components that will require troubleshooting and maintenance by CMOP personnel). Sections of these manuals shall include, but not limited to:
  - i. Equipment nomenclature and technical specifications
  - ii. General description
  - iii. Installation instructions
  - iv. Operating instructions, including a separate basic user guide and help screens in all user software
  - v. Maintenance (both preventive and corrective, special tools, troubleshooting, and testing/calibration)
  - vi. Replacement parts list and recommended source
  - vii. Drawings
  - viii. Copy of PLC code with documentation
  - ix. Tool to program dispensers
- c. Contractor shall supply two (2) copies of Service Bulletins affecting the safety or maintenance of equipment furnished under this contract for a period of ten (10) years after date of acceptance.
- d. All required documentation, annotated above in paragraphs 2.a. and 2.b., shall be provided to the Contracting Officer's Representative (COR) prior to the time of acceptance.

### 4. Logistics:

- a. Contractor shall supply a list of spare parts (prior to the time of acceptance) to include:
  - i. Master list of all parts
  - ii. Recommended list of high failure components to stock for repairs
  - iii. List of long lead time order parts
  - iv. Recommended list of on hand spares

- b. Contractor shall supply 2% excess dispensing units as on hand spares.
- c. Contractor shall ensure a supply of parts is available for a minimum of 10 years from acceptance.
- d. All equipment and peripherals shall be "state of the art" technology. "State of the art" is defined as the most recently designed components that are announced for marketing purposes, available, maintained and supported in accordance with mandatory requirements specified in the scope of work. Components and products with a manufacturer's planned obsolescence within the first year of contract award are not acceptable.

5. Training:

- a. Contractor shall provide initial on-site training for operators, supervisors, engineers, and IT.
- b. Contractor shall provide on-site training for maintenance personnel to include standard preventive maintenance, routine adjustments to maintain proper operation, and adjustments and actions in the event of failure that will not jeopardize the guarantee.
- c. Contractor shall provide continuing training and system upgrade training to the system during the guarantee period.

6. Maintenance:

- a. Contractor shall provide a list of required Preventive Maintenance items and specify requirements for each item, to include but not limited to, list of required parts/tools/test equipment, detailed instructions to complete the PM, minimum number of technicians and man-hours required to complete the PM, and periodicity. The written documentation shall be received prior to acceptance.
- b. Contractor shall provide guidance in writing and as part of the on-site training delineating what corrective maintenance is reasonable for on-site CMOP maintenance personnel to complete and what items need to be repaired by contractor specified technicians. Any maintenance activities that would invalidate the guarantee shall be identified in the maintenance documentation provided.
- c. Contractor shall provide quarterly on-site visits during the guarantee period to conduct Preventive Maintenance, continued training for maintenance personnel, and equipment groom. These visits shall be done on a not to interfere with production basis. Any maintenance items that require system shutdown shall be done outside of production hours.
- d. All written documentation described above in paragraphs 5.a., 5.b., and 5.c. shall be received prior to acceptance.

7. Warranty

- a. The contractor shall provide a 1 year warranty providing UUA operational and available for use 99% of the operational time. Warranty period will begin at final system acceptance.
- b. Technical Assist on-site support shall be provided by the contractor within four (4) hours in the event of a failure that cannot be corrected by CMOP maintenance personnel.
- c. The contractor shall supply technical "Helpdesk" support to CMOP maintenance personnel 24 hours per day, 7 days per week.

## **PART VI - TESTING AND ACCEPTANCE**

### **1. General Requirements**

- a. The contractor shall provide a five-phase testing program that is designed to fully evaluate UUA performance and demonstrate that the system meets the requirements of this Statement of Work.
- b. Each phase of testing shall consist of evaluations designed for the UUA system and tailored to its unique integration into the L-CMOP automated production system. Each phase of testing shall be mutually performed and evaluated by the contractor and the government. VA will approve or disapprove each element of phased testing.

### **2. System Design and Performance. The contractor shall validate, verify, and test the UUA and demonstrate that each element conforms to the requirements within the Statement of Work. These elements include but are not limited to the following:**

- a. The system shall successfully interface with the existing automated production system database structure including order acknowledgement and return completed dispensing data.
- b. The workflow process shall detail throughput and performance requirements for all subsystems.
- c. The contractor shall provide dimensioned prints that show system footprint and how the UUA system incorporates all applicable fire and safety codes, secondary stock storage, and ergonomic work flow.
- d. The contractor shall provide complete and acceptable staffing plan required to operate the automation including the number of pharmacy technicians, labelers, and other ancillary personnel needed.

### **3. Technical Quality. The contractor shall validate, verify, and test the UUA and demonstrate that each technical element conforms to requirements within this Statement of Work. The contractor shall provide:**

- a. Detail that outlines how the system meets patient safety requirements, including system data integrity checks, prevention of cross contamination of products, product storage, and prevention of spillage of contents before, during, or after filling
- b. A UUA that prevents out of sequence processing and possesses other system safeguards that act as a barrier to prevent or determine system malfunction
- c. Other system safeguards such as operator and system tracking logs, locking mechanisms, and verification systems
- d. A UUA ergonomically designed that includes workstations designed for functional area and workstations designed to minimize unnecessary operator reaching, twisting, or repetitive motion
- e. SCADA and HMI (control systems, status, displays, and alerts, audible and visible alarms). The contractor shall generate activity reports and traceable logs
- f. Operator safety is achieved with system design including minimization of operator exposure to airborne and other contaminants

- g. A UUA that will allow the interchangeable use of consumable supplies including bottles and boxes.
4. Subsystem Requirements. The contractor shall validate, verify, and test the UUA and demonstrate that each sub-system element conforms to requirements within the Statement of Work. The contractor shall demonstrate:
- a. The operation of the conveyance system is detailed including item tracking and item location during normal system operation.
  - b. The UUA meets dispensing needs including throughput, accuracy, and storage security.
  - c. The UUA accomplishes patient safety including prevention of cross contamination of product, wrong product selection, and wrong product dispensing.
  - d. Off-line UUA replenishment processes are apparent including system calibration, equipment needed, and work area for replenishment
  - e. The replenishment system provides failsafe mechanisms to prevent incorrect product selection for replenishment of placement of wrong product into dispensing devices.
  - f. Return to stock recycling procedures provide for drug accountability and prevention of error.
  - g. The operation and functionality the UUA including how rejects or system malfunctions are handled meets system requirements
  - h. Dispensing zones are arranged and dispensing areas can be recalibrated to accommodate various product sizes and shapes
  - i. Pharmacy Technician and Labeling workflow and support equipment integrates into overall system design and performance.
  - j. Pharmacy Technician and Labeling work stations assure system performance and throughput.
5. Operations and Maintenance. The contractor shall validate, verify, and demonstrate that each operation and maintenance element conforms to requirements within the Statement of Work. The contractor shall provide:
- a. A detailed operation and maintenance plan that includes details about infrastructure safety and security, construction requirements, and other needs to assure UUA performance.
  - b. System repair and maintenance procedures including the availability of replacement parts and the provision of emergency repair services is provided in a detailed plan.
  - c. "State of the art" technology is assured prior to system acceptance.
  - d. All deliverable documentation including parts, electrical schematics, detailed drawings, and all items necessary to describe all system components and subcomponents is provided.
  - e. A detailed preventive maintenance plan with technical requirements for user service is provided.
  - f. A training plan is provided for system operators and maintenance personnel.
6. Phased Acceptance Testing

a. First Phase – Functional Testing

- i. The contractor shall determine that the UUA physical installation and connectivity and wiring specifications meets requirements; that basic functional operation of subsystem is sound and meets required specifications; and subsystem quality assurance functionality is sound.
- ii. The contractor shall complete basic operational testing with VA provided pharmaceuticals. The contractor may simultaneously perform functional testing on subsystems and sub-components may be undertaken simultaneously.
- iii. The VA will acknowledge successful sub-component and sub-system testing using a pass/fail methodology. If a sub-system or sub-component fails testing, the contractor shall modify or replace components as needed to repeat testing until successful.
- iv. The VA shall acknowledge all subsystem and sub-component functional testing prior to the contractor proceeding to Integration Testing.

b. Second Phase – Integration Testing

- i. The contractor shall test each subsystem to ensure that it is integrated and functioning with the UUA system as a whole. The contractor shall also demonstrate internal controlling devices, programmable logic controls, and other inter-system communication and connectivity is in working order.
- ii. The contractor shall perform operational testing using discrete packets of simulated VA patient prescription orders through the automated production system software package. The contractor shall test all subsystem and sub-components individually, together, and simultaneously. The VA will acknowledge successful testing using a pass/fail methodology.
- iii. If at any time a subsystem, sub-component, or any connectivity between subsystems or sub-components fails, even after initial government acknowledgement of successful testing, the VA will revoke the successful testing acknowledgement.
- iv. The contractor shall repair, or replace and retest components. The VA will acknowledge successful re-testing using a pass/fail methodology.
- v. The VA shall acknowledge all sub-system and sub-component connectively and integration testing prior to the contractor proceeding to Certification and Accreditation Testing.

c. Third Phase – Certification and Accreditation Testing

- i. The VA shall certify and accredit (C&A) all installed systems and subsystems accordance with Federal Information Systems Management Act (FISMA) requirements.
- ii. The contractor shall repair, replace, and test all subsystem, subcomponent, or connectivity between subsystems or sub-components that fail C&A. the VA will acknowledge successful testing
- iii. The VA shall acknowledge all subsystem and sub-component connectivity and integration testing prior to the contractor proceeding Limited Stress Testing.

d. Fourth Phase – Limited Stress Testing

- i. The VA shall evaluate the integration of all UUA subsystems in a progressively expanding manner, while operating under an interim authority waiting the granting of a C&A, using discrete packets of live patient order data from the automated production system software package with correct pharmaceutical product.
  - ii. During the stress testing phase the UUA system will not be relied upon for CMOP to meet ongoing workload demands. However, due to the need to test the UUA system with actual patient data and actual product, discrete packets of live orders will be used for testing purposes.
  - iii. The VA will use distinct packets of live patient order data with successively larger prescription loads to test the full integration and functionality of all subsystems, sub-components, and connectivity between all UUA units, automated production system database structure, data servers, and other components necessary for the complete functionality of the UUA system.
  - iv. Due to the expense of actual pharmaceuticals used for testing, the VA will provide licensed pharmacists to verify that live patient orders are correctly filled so they can be dispensed to patients.
  - v. If at any time a subsystem, sub-component, or any connectivity between subsystems or sub-components fails, even after initial VA acknowledgement of successful testing, the VA shall deem the subsystem, sub-component, or connectivity between subsystems or sub-components as not operating to specifications. The VA will revoke successful testing acknowledgement.
  - vi. The contractor shall repair, replace and retest the subsystem, subcomponent, or connectivity between subsystems or sub-components. The VA will acknowledge successful retesting. The VA shall acknowledge all subsystem and sub-component connectivity integration testing prior to the contractor proceeding to Large Scale Stress Testing.
- e. Fifth Phase – Large Scale Stress Testing
- i. The VA shall expand stress testing to a point for UUA throughput rate testing, while operating under an interim authority waiting the granting of a C&A, large discrete batches of live patient prescription order data will be provided in a quantity sufficient to fully test all UUA subsystems for sustained operation at current maximum achievable throughput.
  - ii. As with Fourth Phase – Limited Stress Testing, live product will be dispensed to patients. While each discrete test uses live data with product dispensed to individual patients, each stress test, regardless of the number of prescriptions filled, is not part of day-to-day operational activities of the CMOP and dispensing of product does not indicate conditional acceptance of the UUA system.
  - iii. If at any time a subsystem, sub-component, or any connectivity between subsystems or sub-components fails, even after initial VA acknowledgement of successful testing, the VA shall deem the subsystem, sub-component, or connectivity between subsystems or sub-components as not operating to specifications. The VA will revoke the systems successful testing acknowledgement.
  - iv. The contractor shall repair, replace and retest the subsystem, subcomponent, or connectivity between subsystems or sub-components. The VA will acknowledge all subsystem and sub-component, and connectivity between subsystems and sub-component integration testing prior to UUA system acceptance by the VA.

- v. Fifth Phase – Stress Testing will be completed when there are five (5) sustained consecutive five (5) day runs that demonstrate that the required UUA system minimum throughput rate as defined in the Statement of Work over the time frame specified.

## **PART VII - CONFIDENTIALITY AND NONDISCLOSURE**

It is agreed that:

1. The preliminary and final deliverables and all associated working papers, application source code, and other material deemed relevant by the VA which has been generated by the contractor in the performance of this contract are the exclusive property of the U.S. Government and shall be submitted to the CO at acceptance.
2. The CO will be the sole authorized official to release verbally or in writing, any data, the draft deliverables, the final deliverables, or any other written or printed materials pertaining to this contract. No information shall be released by the contractor. Any request for information relating to this contract presented to the contractor shall be submitted to the CO for response.
3. Press releases, marketing material or any other printed or electronic documentation related to this project, shall not be publicized without the written approval of the CO.

## **PART VIII - Information System Security**

1. The contractor shall ensure adequate LAN/Internet, data, information, and system security in accordance with VA standard operating procedures and standard contract language, conditions laws, and regulations. The contractor's firewall and web server shall meet or exceed the government minimum requirements for security. All government data shall be protected behind an approved firewall. Any security violations or attempted violations shall be reported to the VA project manager and VA Information Security Officer as soon as possible. The contractor shall follow all applicable VA policies and procedures governing information security, especially those that pertain to certification accreditation.

### **a. Security Training**

All contractor employees and subcontractors under this contract or order are required to complete the VA's on-line Security Awareness Training Course and the Privacy Awareness Training Course. The Privacy Awareness Training requirement may be fulfilled under additional privacy awareness training options, based on the prerogative of the Contracting Officer. Contractors must provide signed certifications of completion to the CO prior to on-site installation. Signed certifications of completions are also required for contractor employees that have remote electronic access to the system.

This requirement is in addition to any other training that may be required of the contractor and subcontractor(s).

### **b. Equipment**

Contractor supplied equipment; PCs of all types, equipment with hard drives, etc. for contract services must meet all security requirements that apply to Government Furnished Equipment (GFE) and Government Owned Equipment (GOE) as identified in VA Policy. If non-VA owned equipment must be utilized, a waiver must be in place. VA Approved Encryption Software must be installed on all laptops or mobile devices before placed into operation, b) Bluetooth equipped devices are prohibited within the VA; Bluetooth must be permanently disabled or removed from the device, c) Equipment must meet all sanitization requirements and procedures before disposed of, d) All remote systems (VAGFE and OE) must be equipped with, and use, VA

Approved Antivirus Software and a personal (host-based or enclave based) firewall that is configured with a VA Approved Configuration. The COR, CO, the Project Manager, and the ISO must be notified and verify all security requirements have been adhered to.

## 2. Contractor Personnel Security

All contractor employees who require access to the Department of Veterans Affairs' computer systems shall be the subject of a background investigation and must receive a favorable adjudication from the VA Security and Investigations Center (07C). This requirement is applicable to all subcontractor personnel requiring the same access. If the security clearance investigation is not completed prior to the start date of the contract, the employee may work on the contract while the security clearance is being processed, but the contractor will be responsible for the actions of those individuals they provide to perform work for the VA.

### a. Background Investigation

The position sensitivity for this effort has been designated as high risk system and the level of background investigation is a high level agency investigation.

## **BACKGROUND INVESTIGATION PROCEDURES**

(a) In accordance with VA Handbook 6500.6 Contract Security, VA Handbook 0710 VA Personnel Suitability and Security Program, and VA Directive 0710, the Department of Veterans Affairs has implemented new procedures to obtain background security investigations for all contracted personnel.

(b) All contractor employees are subject to the same level of investigation as VA employees who have access to VA Sensitive Information. The position sensitivity for this effort has been designated as High Risk and the level of background investigation is a Background Investigation (BI). This requirement is applicable to all subcontractor personnel requiring the same access.

The risk level designations for public trust positions and the corresponding background investigation levels, as defined in VA Directive 0710, are:

### Public Trust Risk Level Designation

High Risk

Moderate Risk

Low Risk

### Background Investigation Level

Background Investigation (high public trust: e.g., access to mission critical data or patients) (BI).

Minimum Background Investigation (moderate levels of public trust: e.g., access to facilities or sensitive data) (MBI)

National Agency Check with Written Inquiries (NACI)

1. **STEP ONE: Complete Background Investigation Request Worksheet:** Within five business days of contract award, the contractor shall submit a completed **Background Investigation Request Worksheet (Form #1)** that lists **all** contractor employees who will be working on the subject contract to the Contracting Officers Representative (COR) or Contracting Officer via password protected or encrypted e-mail. **Please note:** due to the personal information contained in the Background Investigation Request Worksheet, the information must be sent in a secure manner. Please **do NOT** e-mail a document containing social security numbers unless the e-mail is encrypted.



If a contractor employee has a background investigation from another federal agency, it may be reciprocated as long as the background investigation meets the appropriate level designated in the current statement of work and has occurred within the last five years with a favorable adjudication and no break in service. Please be aware that any public trust case that is older than two years and does **not** have a favorable adjudication cannot be reciprocated unless it was a no issue case.

The Contracting Officer will coordinate with the VA Security and Investigations Center (SIC) staff to verify reciprocity. If the contractor employee receives the automated e-mail from the VA SIC CRD and believes he/she may be eligible for reciprocity, please contact the VA SIC using the contact information in the e-mail. Reciprocity is **NOT** automatic. If a background investigation can be reciprocated, the VA SIC will send an e-mail notification to the contractor.

2. **STEP TWO: Complete Fingerprint Verification Memorandum:** ALL contractor employees are required to be fingerprinted within 14 calendar days of contract award, except for those who received an e-mail from the VA SIC confirming reciprocity. Courtesy electronic fingerprints can be obtained at some VA facilities. Please contact the Contracting Officer's Representative (COR) to schedule a fingerprinting appointment at a VA facility as soon as possible. Each contractor employee shall take a copy of the **Fingerprint Verification Memorandum (Form #2)** to the fingerprinting appointment and complete it. Completed forms shall be provided to the Contracting Officer with their submission of required documents in Step 3.
3. **STEP THREE: Complete and Submit Background Investigation Documents:** Upon receipt of the Background Investigation Request Worksheet (see Step One), each contractor employee must complete and submit the required documents to the Contracting Officer **within 15 business days**. The following documents are to be completed by each contractor employee and submitted to the COR:
  - 1) VA Form 710
  - 2) Fingerprint Verification (If a Contractor submits Electronic Fingerprints then they only forward a completed Fingerprint Verification memo. HOWEVER, if Contractors do not have access to an Electronic Fingerprint Facility, they must use the FD-258 Fingerprint Card, which is then "mailed" to the Security and Investigations Center.)

Forms may be obtained at [http://www.osp.va.gov/Security\\_and\\_Investigations\\_Center\\_FF.asp](http://www.osp.va.gov/Security_and_Investigations_Center_FF.asp)

Within five business days of receiving the Background Investigation Request Worksheet and required documents listed above, the COR or Contracting Officer will enter a background investigation request into the VA Security Investigation Center (SIC) Contractor Request Database (CRD) for each contractor employee. When the request is entered, an automated "initial" e-mail is sent to the contractor point of contact listed on the Background Investigation Request Worksheet. The automated e-mail identifies the background investigation level requested and provides a website link with further instructions. The contractor personnel are to follow the instructions to complete their background investigation. Once completed, the contractor personnel shall provide the COR with the following documents within 3 calendar days:

- 1) E-QIP Certification Page
- 2) E-QIP Release of Information

Please Note: As contract personnel are added to the contract or order, the Background Investigation Request Worksheet must be updated and submitted to the Contracting Officer so that a background investigation can be initiated. The additional contract employee cannot start work until all security requirements listed are completed.

The VA SIC reviews the documents within seven business days for completion and accuracy. If the documents do not contain any errors, the VA SIC forwards them to the Office of Personnel Management (OPM) to conduct the background investigation. If the documents contain errors, the VA SIC will return them to contractor with corrective instructions. The corrections must be made immediately and sent back to the VA SIC. Once the documents are completed correctly and VA SIC forwards them to OPM, an automated e-mail is sent to the contractor point of contact stating that the background investigation has been initiated.

On the 20th day, if the VA SIC has not received a completed package, the Contractor POC will receive an e-mail notification that the request is still pending and has not been initiated. On the 40th day, if the VA SIC has not received a completed package, the Contractor POC will receive an email stating that the request has been terminated and the contract employee must be replaced due to non-compliance with security requirements and a new background investigation request will need to be submitted.

4. **STEP FOUR: Complete Required Training and Sign Contractor Rules of Behavior:** All contractor employees shall complete the training indicated in the solicitation. The contractor shall **provide copies of training certificates and signed Contractor Rules of Behavior for each employee within five business days of reciprocation or receiving notice of initiated background investigation and favorable SAC adjudication contractor and annually thereafter** to the COR. In order to obtain access to the VA training via the VA's Learning Management System (LMS), please contact the COR.

All contractor employees and subcontractors under this contract or order are required to complete the VA's on-line Security Awareness Training Course and the Privacy Awareness Training Course annually:

[https://vaww.infoprotection.va.gov/portal/server.pt?open=512&objID=429&&PageID=294261&mode=2&in\\_hi\\_userid=2&cached=true](https://vaww.infoprotection.va.gov/portal/server.pt?open=512&objID=429&&PageID=294261&mode=2&in_hi_userid=2&cached=true). The Privacy Awareness Training requirement may be fulfilled under additional privacy awareness training options, based on the prerogative of the Contracting Officer, pending assigned VA duties of the contractor employees and subcontractors under this contract. Contractors must provide signed certifications of completion to the Contracting Officer during each year of the contract. This requirement is in addition to any other training that may be required of the Contractor and Subcontractor(s).

Office of Personnel Management sends the results of the background investigation to the Contracting Officer who will inform the Contractor POC of the outcome. The contractor, when notified of an unfavorable determination by the Government, shall withdraw the employee from consideration from working under the contract. The contractor primarily utilizes personnel that have already been cleared for sensitive data access for onsite and remote (VPN) access to the VA systems. The contractor shall initiate the process of clearing all other individuals that require access to these systems (e.g. new employees that have not yet been cleared). Under no circumstances will any individual that has been denied this clearance be allowed to work on VA CMOP systems, whether on site or by VPN. Contracted staff members that will have access to the VA CMOP systems (directly or by VPN) will participate in the required online continuing education security awareness courses. U.S. law requires companies to employ only individuals who may legally work in the United States – either U.S. citizens, or foreign citizens who have the necessary authorization. This contract requires contractor personnel to read, write, speak, and understand the English language, unless otherwise specified in this contract or agreed to by the Government. Failure to comply with the contractor personnel security requirements may result in termination of the contract for default.



Department of Veterans Affairs  
NATIONAL ACQUISITION CENTER  
ATTN: Marie Harvey, Contract Specialist  
CMOP, Building 37 P.O. Box 76  
Hines, IL 60141  
[Marie.harvey@va.gov](mailto:Marie.harvey@va.gov)  
Phone 708-786-4984 Fax 708-786-4996

## Background Investigation Request Worksheet

The Contractor is responsible for updating the background investigation form as personnel are added to the order. The Contractor must submit the updated form to the Contracting Officer within five business days of the date to begin work.

### Contractor Information

Contracting Officer/Contracting Specialist:

Telephone:

Station/VISN Number:

SAO Region (East/Central/West):

Purchase Order Number:

Risk Level (Low/Medium/High):

Contractor Name (Sub in parentheses):

Prime Contractor POC Name & Phone:

Prime Contractor POC Email:

Prime Contractor Address:

### Contractor Employee Information

(Date and Place of Birth are required to cross check clearances issued by other departments/agencies.)

Employee Name	SSN	Employee Home Address	D.O.B.	Place of Birth	Previous Investigations Yes/No/Date

Form #1



Department of Veterans Affairs  
NATIONAL ACQUISITION CENTER  
ATTN: Marie Harvey, Contract Specialist  
CMOP, Building 37 P.O. Box 76  
Hines, IL 60141  
[Marie.harvey@va.gov](mailto:Marie.harvey@va.gov)  
Phone 708-786-4984 Fax 708-786-4996

## Fingerprint Verification Memorandum

**FINGERPRINTS MUST BE COMPLETED WITHIN FIVE (5) BUSINESS DAYS AFTER NOTICE OF AWARD**

### Employee Information (please print)

Name (First Middle Last):

Social Security Number:

Contractor (yes/no):

### VA Security Specialist Use Only

SON: 955C / SOI: VA08

Federal Agency Name:

VISN Number:

Station Number:

Date Fingerprinted:

Method of Fingerprinting:

Electronically

**After fingerprints are captured, submit this document with completed forms to the address at the top of this page or via e-mail to [Marie.harvey@va.gov](mailto:Marie.harvey@va.gov)**

**Form #2**

## **DELIVERY INFORMATION**

Equipment delivery of replacement UUA system shall be coordinated with L-CMOP. The start date for this projects installation shall not begin prior to completion and acceptance of the L-CMOP TCA upgrade. Installation (to include demolition and removal of existing equipment, and the five-phase testing program by the contractor and the CMOP must be completed before final acceptance) and final acceptance shall occur within 1 year of installation start date. Onsite training of CMOP staff shall be ongoing through all phases of installation and completed prior to stress testing.

A guarantee period of 1 year post-acceptance is required.

## **Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule**

The HIPAA Privacy Rule promulgates rules governing the security, use and disclosure of Protected Health Information (PHI) by covered entities, including Federal agencies such as the Department of Veterans Affairs (VA). A covered agency must obtain satisfactory written assurances from its business associates that they will appropriately safeguard PHI that is received from or created on behalf of the agency. If the VA contracting officer determines, or is notified by CMOP personnel, that HIPAA is applicable to an offer that is submitted under this solicitation, the offeror will be required to enter into a Business Associate Agreement (BAA) with the agency prior to the effective date of the contract; or, if a contract has already been awarded, at any time it is determined that a BAA is required. The BAA will describe the permitted and required uses of PHI by the contractor; provide that the contractor will not use or further disclose the PHI other than as permitted or required by the contract or by law; and require the contractor to use appropriate safeguards to prevent unauthorized disclosure of the PHI.