Leavenworth-CMOP Tablet/Capsule Automation (TCA) System Statement of Work

Introduction

The Leavenworth Consolidated Mail Outpatient Pharmacy (L-CMOP) is a 70,000 square foot facility located at 5000 South 13th Street, Leavenworth, Kansas, 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 tablet/capsule automation (TCA) system. L-CMOP requires a contractor to serve as a systems integrator who shall design, install and integrate a working full functional replacement TCA system.The system shall consist of an on-line production system, an off-line replenishment system, and the ancillary support equipment. These systems will share the same database but process independently of each other. The contractor shall be required to remove, cleanup, store and dispose of the identified existing L-CMOP automated production systems. The replacement TCA system shall occupy the identified facility footprint, integrate with current operations software, and minimize changes/additions to the current hardware and support equipment.

The timing for removal of the existing L-CMOP automated systems and delivery of replacement TCA system shall be coordinated with L-CMOP. Delivery shall not begin until removal process provides adequate floor space for storage of the new TCA system components.

PART I – SYSTEM DESIGN AND PERFORMANCE

1. The CMOP Tablet/Capsule Automation (TCA) system shall consist of an on-line dispensing system and an off-line canister replenishment system that provides a minimum throughput of 4,800 prescriptions 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. Current average is 1.8 prescriptions per order.

   The replenishment and dispensing systems shall share the same database but process independently of each other. The systems shall:

   a. Be installed with minimal impact on current TCA system throughput.

   b. Have no single point of failure (example: one capper) which would cause significant downtime.

   c. Replacement TCA system shall be designed to allow for disassembly and reassembly as a fully functional system to accommodate future production floor modifications

   d. Fit within identified square footage approximately 5,000 net square footage (nsf) with an additional 2,000 nsf available for offline replenishment.

   e. Fully integrate with Leavenworth CMOP's existing Operating System and current 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.

f. Signal an alert, visual and/or audible, when any operational programs malfunction or disengage.

g. Provide fiber optic network cabling with at least a gigabyte backbone that seamlessly integrates into the existing CMOP network.

h. 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.

i. Include a mechanism for capturing the image and determining the weight of the completed prescription to include the tare weight of the puck (or other like mechanism) and empty bottle prior to filling and the weight of the completed prescription. The drug image and weight shall be presented to the pharmacist at verification and stored in the CMOP database.

j. Convey the bottles after filled, verified by a pharmacist and capped, as follows:

i. If order consists solely of a single prescription TCA item and is ready for packaging; sort and convey verified bottle to packaging workstations.

ii. If order requires items from other sub-systems, sort TCA bottles if indicated and assign to Bar coded tote.

2. The CMOP TCA off-line canister replenishment system shall:

a. Provide a 100% failsafe mechanism, which must include forcing functions, when transferring bulk drug product into replenishment canisters prior to dispenser loading.

b. Provide a 100% failsafe mechanism to allow eligible product designated as “return to stock” to be added to an appropriate replenishment canister and update inventory accordingly. The inventory information required is quantity, NDC, lot code(s) and associated cost data.

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

a. Provide a 100% failsafe matching mechanism for canister loading and dispenser replenishment to ensure product accuracy, to include strength and dosage form (correct NDC) without interrupting production.

b. Ensure100% detection and double failure of bottle/puck (or like mechanism) mismatches to eliminate the possibility of wrong product dispensing. Double failure is defined as rendering orders associated with both the mismatched bottle and pick to a status that will not allow further processing.

c. Identify misrouted pucks (or other like mechanism) prior to dispensing, recirculate to correct dispenser and provide visible alert at verification to eliminate the possibility of wrong product dispensing.

d. Ensure CMOP patients consistently receive the correct quantity of ordered product by:

i. Demonstrating that proposed technology achieves and sustains 98% bottle count accuracy (not tablet count) on the first fill attempt.
ii. Providing redundant physical validation of count at dispense point.
iii, Providing 100% detection and correction of miscounts
iv. Satisfying this requirement through manual physical count validation at the bottle level during the “stress test”. The CMOP shall perform counts for NDC’s in current active inventory at time of testing.

e. Provide a mechanism for correction when required (i.e. Exceptions station(s)).

f. Be designed with single zone dispensing to prevent the potential for cross-contamination of pharmaceutical products or product dust.

g. Provide a minimum of 650 unique dispensers which accommodate various tablet and capsule unit sizes, textures, and shapes and allow for multiple canisters of identical medications for highly used items in order to meet throughput requirements.

h. Provide positive dispenser to bottle contact to guarantee spill-free dispense.

i. Achieve minimum throughput of 77,184 bottles (labeled, filled, verified, capped) per 12 hour day. A single prescription may consist of multiple bottles -- currently average 1.34 bottles per prescription.

4. The TCA packaging conveyor system shall:

a. Accommodate eligible single patient orders completed within the TCA dispensing system.

b. Convey completed prescription orders directly from the TCA automation to the packager, and also allow for manual induction into the packaging system.

c. Provide an automated mechanism to remove TCA completed prescription(s) from transporting puck(s) (or other mechanism) onto packaging conveyor or next destination, and recirculate puck(s) (or other like mechanism) back into the TCA system.

d. Handle a variety of bottles ranging from120cc-130cc (small) or 240cc-260cc (large) individually.

e. Provide an adjustable parameter for the number of bottles allowed in the queue and provide a mechanism to divert incoming bottles when the system becomes overloaded.

f. Stop processing and signal an alert, visual and/or audible, when any systems malfunction or disengage.

g. Conveyor shall include a minimum of four ergonomic packaging workstations each workstation shall have a fiber network connection,quad 120ccvac outlet and task lighting to support the packaging process.

h. Conveyor shall include an ergonomic automated mechanism to transport and load completed prescription order packages into a standard BMC used at L-CMOP.

i. Provide real time event logging and data capture and allow for retrieval using TSQL Server.

5. Puck (or other like mechanism) Features and Controls:

a. Puck (or other like mechanism)s shall be made of appropriate material such that static electrical discharge related to staff handling is prevented and noise is minimized.

b. Puck (or other like mechanism)s are tracked through each stage of production and can be located from a master control area.

c. The system shall provide 100% automatic puck (or other like mechanism) recycling.

6. System shall be adjustable to allow for use of:

   a. Commercially available bottles

   b. Commercially available bottle caps, including convertible caps.

   c. Commercially available label stock

   d. Other consumable items used by the CMOP system in the processing of prescriptions

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. Dust control system shall minimize personnel exposure and interference with count accuracy and dispenser operation and shall meet or exceed OSHA requirements.

   e. 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 puck (or other like mechanism)s to proper area with bump-free/anti-splash conveyance.

   b. Provide all required components, including but not limited to, transmitters and readers, necessary to route all puck (or other like mechanism)s using Radio Frequency Identification (RFID) technology.

   c. Provide all required components for accumulation and sorting to integrate with current mainline conveyor and 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. Bottling system shall:

   a. Provide mechanism to orient bottle, apply prescription label, and assign to puck (or other like mechanism).

b. Provide ergonomically sound bulk bottle loading.

c. Accommodate two commercial bottle sizes. Size range for the small bottle shall be 120cc – 130cc and the large bottle shall be 240cc – 260cc. (As estimated 80-84% are 120cc bottles and 16-20% are 250cc bottles)

3. Puck (or other like mechanism)s provided by contractor shall:

a. Include RFID transmitters.

b. Be of sufficient quantity as to achieve throughput requirements.

c. Accommodate two commercial bottle sizes. Size range for the small bottle shall be 120cc – 130cc and the large bottle shall be 240cc – 260cc. (As estimated 80-84% are 120cc bottles and 20% are 250cc bottles)

4. Dispensers shall be designed and installed to:

a. Accurately count and dispense pharmaceutical products into labeled prescription bottles.

b. Provide redundant physical validation of count at dispense point.

c. Provide ergonomically safe operation and replenishment.

d. Provide easy access for regular and corrective maintenance and repair.

e. Limit lifting requirements to 40 pounds and provide a lift-assist.

f. Provide minimum capacity of 3 liters.

g. Allow for straightforward physical removal of cell and set-up/calibration.

5. Canisters provided by contractor shall:

a. Be constructed of clear material compliant with FDA light-resistance standards.

b. Have a minimum capacity of 3 liters.

c. Allow attachment of tamper-evident seals upon fill verification.

d. Be provided in sufficient quantity to allow single shift off-line canister replenishment to meet dispense requirements for a minimum of two shifts.

6. Pharmacist verification system provided by contractor shall:

a. Provide sufficient throughput capacity to sustain system requirements.

b. Be designed to allow visual verification of bottle contents in an ergonomic configuration to minimize repetitive motion.

7. Capping system provided by contractor shall:

a. Utilize one cap size for all bottles.

b. Apply tamper-evident inner seal.

c. Provide sufficient throughput capacity to sustain system requirements.

d. Provide ergonomic mechanism for cap replenishment

8. Contractor shall provide all equipment and controls associated with the on-line production and off-line replenishment systems, including but not limited to:

a. Ergonomic workstations

b. Docking stations

c. Scanning devices (wired or wireless depending on function)

d. CPUs, monitors and PDAs

e. Direct Thermal Printers

f. Shelving for canister exchange

g. Task lighting

h. Label applicators

i. Audible and visual notification devices

j. Supplies and consumables not currently furnished by the VA required for testing

9. 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 bottle/puck (or other like mechanism) match at marriage point.

b. Direct validated bottle/puck (or other like mechanism) match to correct dispense zone.

c. Provide a status change or hard stop to prohibit dispensing action for both orders associated with mismatched bottle/puck (or other like mechanism) and direct both to exceptions prior to dispense activity

d. Detect misrouted puck (or other like mechanism)s prior to dispense, redirect for fill, and provide alert flag at verification.

e. Retain a short-counted bottle/puck (or other like mechanism) within a dispense zone for auto-correction when possible to avoid unnecessary generation of return to stocks.

f. Recirculate, as determined by an adjustable parameter, any short-picked bottle/puck (or other like mechanism) that cannot be auto-corrected then route the bottle/puck (or other like mechanism) to exceptions for resolution prior to verification.

g. Provide an adjustable parameter to establish minimum and maximum tolerances for count variation specific to each pharmaceutical product.

h. Direct bottles containing dispensed quantities outside established tolerances to an exceptions station prior to pharmacist verification.

i. 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.

j. Confirm bottle/puck (or other like mechanism) match after dispense, automatically provide a status change or hard stop prohibiting verification for both orders associated with mismatched bottle/puck (or other like mechanism), and direct to exceptions prior to verification.

k. Direct filled and confirmed bottle/puck (or other like mechanism) matches to an ergonomically sound pharmacist verification station.

l. Detect, release from zone, and route to exceptions, any empty puck (or other like mechanism) prior to dispense.

m. Provide sorting mechanism, sufficient to meet production requirements, which will direct eligible single patient orders completed within the TCA dispensing system to the packaging equipment

   i) Orders not eligible shall marry to bar coded tote and convey via mainline conveyor to packing
   ii) Orders not exclusively within the automation shall marry to bar coded tote and convey via mainline conveyor for further processing.

n. Maintain system throughput independent of order profile (i.e. throughput should be maintained regardless if it process single order prescription orders or multiple prescription orders).

o. Provide mechanism to meter release of back orders that will not impact or overload product dispensing.

p. Display a visual image of the correct product during the verification, replenishment, and return to stock processes.

q. Provide electronic initiation, operator alert, validation, and tracking of all events related to dispenser loading and refilling (on-line dispenser replenishment).

r. Fully integrate with current consolidated exceptions functionality (TCA, UUA, multi system and ancillary) 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 by 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 bottle (using a unique label instance) through the dispensing process and associated statuses for the purpose of system or software troubleshooting and error investigation.
ii. Tracking of canister replenishment activity from initiation through final canister verification for the purpose of system or software troubleshooting and error investigation.

c. Include in the existing operation events table, events relative to:

i. Off-line canister cleaning, replenishment and verification.
ii. On-line dispenser loading and refilling
iii. Puck (or other like mechanism)/bottle marriage and match validation
iv. Bottle level dispensing
v. Bottle level verification
vi. Exceptions processing
vii. Return to stock generation and utilization through off-line 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, bottle number, label instance number and puck (or other like mechanism) 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, TCA bottles verified, TCA prescriptions packed.

3. Conveyor system shall provide single zone dispensing to prevent the potential for cross-contamination of pharmaceutical products or product dust.

4. Bottling system shall eliminate any source of “out of sequence” prescriptions.

5. Dispensers shall:

a. Accurately count and dispense various tablet and capsule unit sizes, textures, and shapes.

b. Provide redundant physical validation of count.

c. Accommodate bottle quantities which range from 1 to maximum bottle volume

d. Require minimal set-up/calibration time and technical skill.

6. The off-line canister replenishment system shall:

a. Require replenishment activities to be conducted in a separate area, away from dispensing.

b. Provide an error-free mechanism to accommodate product (NDC) changes in a specific location to prevent inaccurate dispenser loading.

c. Sequence replenishment activities to prevent interruption of dispensing.

d. Provide a unique physical identifier on each canister.

e. Provide the ability to electronically flag each canister for dedicated or flexible dispenser assignment.

f. Provide mechanism to assign and track status for each canister in real time (for example: assigned, verified/staged, loaded, released, ready).

g. Require replenishment operator log-on to initiate process.

h. Track all replenishment actions to every canister and dispenser to include prescription bottles that are restocked.

i. Electronically assign a canister to a single dispense location and its associated NDC at replenishment dock. Ensure that only one NDC can be assigned to a canister at time.

j. Require a valid bar code scan for every stock bottle or return to stock bottle used to replenish or restock a canister and provide hard stop for an unexpected scan.

k. Require electronic verification of filled canister by a pharmacist to include the generation of a unique canister/seal identifier bearing dispenser location and fill date. Electronically transfer inventory, to include NDC and lot information, from bulk storage to canister storage location and update existing inventory management system accordingly.

l. Provide a failsafe mechanism to identify, track, and utilize any product designated for return to stock. Electronically transfer inventory, to include NDC and lot information, associated with return to stock product to bulk, canister, or dispenser location as indicated and update existing inventory management system accordingly.

m. Require electronic confirmation of canister cleaning prior to reuse.

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.

c. Allow only filled, verified, sealed canisters to be loaded on assigned dispenser location prior to release of product to dispenser (i.e. prohibit on-line replenishment). Electronically validate the physical pairing of canister/dispenser when loading.

d. Electronically transfer inventory from canister storage location to dispensing location and update existing inventory management system accordingly.

PART IV – QUALITY ASSURANCE

To ensure prescription accuracy and patient safety, the TCA system shall be required to:

1. Have no single point of failure (example:one capper) which would cause significant downtime.

2. Provide and track in real time internal electronic validation of canister to dispenser match with failsafe mechanism that prevents dispensing if mismatched.

3. Provide physical tamper-proof lock of canister to dispenser.

4. Provide and track redundant physical validation of count at dispense point, routing bottles/puck (or other like mechanism)s directly to an exceptions station if variation is outside of tolerance set within an adjustable parameter.

5. Prevent the potential for cross-contamination of pharmaceutical products or product dust.

6. Track all replenishment actions to every canister and dispenser in real time to include product that is restocked.

7. Provide positive dispenser to bottle contact to guarantee spill-free dispense.

8. 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 or off-line replenishment processes.

9. 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 during replenishment.

10. Electronically capture in real time all operation events which impact the integrity of the finished product.

11. 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 TCA.

12. Provide failsafe mechanism to detect bottle/puck (or other like mechanism) mismatch and automatically provide a status change or hard stop that disallows further processing for both orders associated with the mismatch, and prevent verification of all associated orders prior to correction.

13. Log in real time details of all unexpected events, including but not limited to failures at verification, incorrect NDC scan during replenishment, and puck (or other like mechanism)/bottle mismatch, into the existing Exception Items table.

14. 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.)

15. 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 TCA. 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 TCA 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 TCA 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 production 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 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

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 Technical Representative (COTR) 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 and supervisors.

    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 TCA 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. <u>General Requirements</u>

    a. The contractor shall provide a five-phase testing program that is designed to fully evaluate TCA 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 TCA 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 TCA 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 TCA 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 pharmacists, pharmacy technicians,shipper/packers, and other ancillary personnel needed.

3. Technical Quality. The contractor shall validate, verify, and test the TCA 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 TCA 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 TCA that identifies and appropriately handles broken or misshaped tablets or capsules

   e. A TCA ergonomically designed that includes workstations designed for functional area and workstations designed to minimize unnecessary operator reaching, twisting, or repetitive motion

   f. SCADA and HMI (control systems, status, displays, alerts, audible and visible alarms). The contractor shall generate activity reports and traceable logs

   g. Operator safety is achieved with system design including minimization of operator exposure to airborne and other contaminants

   h. A TCA that will allow the interchangeable use of consumable supplies including bottles and bottle caps.

4. Subsystem Requirements. The contractor shall validate, verify, and test the TCA and demonstrate that each sub-system element conforms to requirements within the Statement of Work. The contractor shall demonstrate:

   a. Printed materials are incorporated into system design and function

b. Cross checks and safety procedures ensure complete labels print and that printed labels are applied and delivered through the TCA fulfillment process undamaged.

c. The operation of the conveyance system is detailed including item tracking and item location during normal system operation.

d. The TCA meets dispensing needs including throughput, accuracy, and storage security.

e. The TCA accomplishes patient safety including prevention of cross contamination of product, wrong product selection, and wrong product dispensing.

f. Off-line TCA replenishment processes are apparent including system calibration, equipment needed, and work area for replenishment

g. The replenishment system provides failsafe mechanisms to prevent incorrect product selection for replenishment of placement of wrong product into dispensing devices.

h. Return to stock recycling procedures provide for drug accountability and prevention of error.

i. The operation and functionality the TCA including how rejects or system malfunctions are handled meets system requirements

j. Dispensing zones are arranged and dispensing areas can be recalibrated to accommodate various product sizes and shapes

k. Pharmacist verification (PV) workflow and support equipment integrates into overall system design and performance.

l. Packing/manifesting 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 TCA 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 TCA 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 TCA 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 TCA 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 TCA system will not be relied upon for CMOP to meet ongoing workload demands. However, due to the need to test the TCA 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 TCA units, automated production system database structure, data servers, and other components necessary for the complete functionality of the TCA 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 TCA 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 TCA 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 TCA 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 TCA 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 TCA 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. <u>If non-VA owned equipment must be utilized, a waiver must be in place</u>. 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 COTR, 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	Background Investigation Level
High Risk	Background Investigation (high public trust: e.g., access to mission critical data or patients) (BI).
Moderate Risk	Minimum Background Investigation (moderate levels of public trust: e.g., access to facilities or sensitive data) (MBI)
Low Risk	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 Technical Representative (COTR) 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 Technical Representative (COTR) 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 COTR:

    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

    Within five business days of receiving the Background Investigation Request Worksheet and required documents listed above, the COTR 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 COTR 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 COTR. In order to obtain access to the VA training via the VA's Learning Management System (LMS), please contact the COTR.

   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. 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
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
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

.

Form #2

DELIVERY INFORMATION

Equipment delivery shall begin within four months of contract award date. 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 contract award 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 HIPPA 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.