

## B.3 STATEMENT OF WORK

### RICHMOND VA MEDICAL CENTER (VAMC) CUSTOM STERILE PROCEDURE PACKS

#### I. ABBREVIATIONS/DEFINITIONS

<b>AAMI:</b>	Association for Advancement of Medical Instrumentation
<b>AORN:</b>	Association of Operating Room Nurses
<b>ASTM:</b>	American Society for Testing and Materials
<b>CEN:</b>	European Committee for Standardization
<b>CFR:</b>	Code of Federal Regulations
<b>CO:</b>	Contract Officer
<b>COR:</b>	Contracting Officer Representative(s)
<b>EN 46001:</b>	European Nations Quality Standards
<b>ETO:</b>	Ethylene Oxide
<b>FAR:</b>	Federal Acquisition Regulation
<b>FDA:</b>	Food and Drug Administration
<b>GS1:</b>	Global Standards 1
<b>HF:</b>	High Frequency
<b>ISO:</b>	International Organization for Standardization
<b>MBO</b>	Manufacturers Back Order
<b>MSDS</b>	Material Safety Data Sheet
<b>NAFTA:</b>	North American Free Trade Agreement
<b>PO:</b>	Purchase Order
<b>PHT/DEHP</b>	Phthalates and Di(2-ethylhexyl)phthalate
<b>RFID:</b>	Radio Frequency Identification
<b>SMDA</b>	Safe Medical Device Act
<b>TAA:</b>	Trade Agreements Act
<b>UHF:</b>	Ultra High Frequency
<b>VA:</b>	Department of Veterans of Affairs

<b>Component</b>	A component is an item or set of items in a pack, used in a procedure for the benefit of the patient or clinician. Components are not defined as material required, while maintaining the integrity of the package.
<b>Contractual Exceptions</b>	Packs not shipped due to manufacturer's backorder, manufacturer's recall, manufacture's discontinued items. Packs for which delivery is excusable as set forth in FAR 52.212-4(f).
<b>Custom Sterile Procedure Pack Program</b>	Custom pack programs are designed to develop individualized procedure packs to save on operating room start-up times, cut down on the time between patients, and generally create standard practices that result in hospital effectiveness, efficiency and charge/cost capture.
<b>Fill Rate</b>	Rate in which ordered products are delivered within contracted delivery time. The calculation for fill rate will be (Items Delivered/Items Ordered). The fill rate is applicable to all

	approved full production custom sterile procedure packs.
<b>First Article Pack</b>	As defined by the FAR, a First Article means a preproduction model, initial production sample, test sample, first lot, pilot lot, or pilot models. First article packs shall be at no cost to the Government.
<b>Manufacturer Back Order (MBO)</b>	A physical order placed by the Custom Sterile Procedure Pack contractor to a product supplier and which is not shipped to the Custom Sterile Procedure Pack Contractor from the product supplier within thirty days.
<b>MSPV - MED/SURG Prime Vendor</b>	MSPV is the VAs primary means of medical and surgical supply distribution. VA facilities realize a number of benefits from utilizing a single ordering and distribution prime vendor, including reduced administrative burden, inventory cost, and ordering efficiency. The current MSPV vendor for the Richmond VA Medical Center is Cardinal Health.
<b>New Pack</b>	A brand new pack that is required of the facility that is newly configured.
<b>Pack Conversion</b>	A reconfiguration of an existing pack.
<b>Piggyback</b>	Component part that is affixed to the outside of the custom sterile procedure pack due to the inability to include it inside the pack (i.e. unique sterilization requirements).
<b>Radio-frequency identification (RFID)</b>	The wireless use of <a href="#">electromagnetic fields</a> to transfer data, for the purposes of automatically identifying and tracking tags attached to objects. The tags contain electronically stored information. Some tags are powered by <a href="#">electromagnetic induction</a> from magnetic fields produced near the reader. Some types collect energy from the interrogating radio waves and act as a passive transponder. Two primary frequencies are used within the VA. They are 13.56 MHz High Frequency (HF) and 433 MHz Ultra High Frequency (UHF).
<b>Short Dated Product</b>	Any product delivered with an expiration date less than twelve months from date of delivery.
<b>Packs Totally Filled</b>	Includes an order for which all packs ordered were delivered
<b>Packs Partially Filled</b>	Includes any packs where the quantity delivered is less than quantity ordered.

## II. PURPOSE

Provide for a Custom Sterile Procedure Pack Program for the production and delivery of individualized custom procedure packs to be utilized by the Richmond Veterans Affairs Medical Center (Richmond VAMC). The Custom Sterile Procedure Pack Program will include pack assembly/manufacture, sterilization, quality assurance, and packaging, contractor electronic communication ordering reporting, and delivery. Orders will be made for the custom trays as identified in Contract/Solicitation Attachment A – Pack Contents. All aspects of pack assembly, packaging and sterilization must adhere to the quality control standards set by the FDA.

## III. SCOPE

The Contractor shall provide all labor, materials, transportation, equipment and supervision, in compliance with federal, state and local regulations, to provide a Custom Sterile Procedure Pack program for the Richmond VAMC. The packs shall be available for distribution by the Medical Surgical Prime Vendor (MSPV) or by direct purchase, at the discretion of the local facility.

#### IV. CONTRACT TRANSITION

The Contractor shall have a clear implementation and transition plan that addresses the unique requirements of the Richmond VAMC. The plan shall include a project management plan with specific goals and a schedule of significant milestones.

##### A. Implementation Plan.

The contractor shall submit a plan to the Contracting Officer (CO) and Contracting Officer's Representative (COR) outlining how it intends to implement the Custom Sterile Procedure Pack program within 30 calendar days after receipt of award notification. If the initial plan is disapproved, the contractor shall provide corrected plans, using the same time period above, until approved by the Contracting Officer.

- (1) During the implementation period, the contractor shall validate pack configuration to ensure compliance with facility specifications.

Validation shall consist of, but not be limited to the following tasks:

- Configuration of components from Contract/Solicitation Attachment A – Pack Contents.
- Production of First Article Packs shall be required at the request of the COR. The disposal of the first article pack shall be the responsibility of the contractor.
- Delivery of first articles for testing and approval. Production of approved packs upon confirmation from the COR and CO.

##### B. Transition Plan.

The Government intends to make awards at least 60 calendar days prior to the expiration date of any existing orders/contracts, or options thereof, which the new contract award(s) will replace. Full contract conversion means that all packs requested are available for delivery by the contractor. To ensure **full contract conversion time has been allowed for continuity of supplies at required quality levels as well as anticipated inventory levels.** Contract(s) shall begin no later than 60 calendar days from the date of award. The Richmond VAMC may have current inventory that will have to be exhausted prior to placement of orders, therefore orders for some packs may occur outside of the 60 day timeframe but the contractor shall be prepared upon request of new orders no later than 60 calendar days from award. **The Contractor shall provide copies of the standard operating procedures governing batch control, product tracing, component manufacturing lot numbering, and written policies and/or procedures on component recalls within 30 days of contract award and within two weeks of any pack conversion.**

#### V. ORDERING

Upon validation of pack configuration of components and after approval of any required first article testing, a delivery order will be issued to initiate pack manufacture and delivery. A separate delivery order for the initial transition custom pack orders and for each subsequent order will be provided to the contractor.

ORDERING PROCEDURES:

(1) Delivery Orders shall be issued by facsimile or electronic commerce methods, and only by the Contracting Officer or his/her authorized VA representative for the CLIN Series outlined in the schedule of items identified in the awarded contract.

(2) Delivery Orders shall contain at a minimum the following information:

- (a) Date of order;
- (b) Contract Number and Order Number;
- (c) CLIN, Description, Quantity, Unit Price, and Total Amount;
- (d) Delivery or performance Schedule; and
- (e) Place of Delivery or Performance (Including Consignee)

(3) Upon receiving a delivery order, the Contractor shall deliver within three (3) calendar days for standard deliveries and within twenty-four (24) hours for emergency deliveries, unless otherwise stated in the delivery order.

(4) The Contractor shall have full-time representation to receive orders. The Government shall place delivery orders to the following: **(Offeror to complete)**

- (a) Contact Person: \_\_\_\_\_
- (b) Telephone Number: \_\_\_\_\_
- (c) Fax Number: \_\_\_\_\_
- (d) Department: \_\_\_\_\_
- (e) Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

(5) In accordance with contract clause FAR 52.216-19, Order Limitations, if the Contractor does not wish to provide deliveries requested on a delivery order, which are below the minimum order amount or above the maximum order amount as specified herein they shall submit in writing within twenty-four (24) hours of receipt of the delivery order, an explanation of non-intent.

(6) Under this contract, facility needs may require flexibilities to place daily, weekly, monthly, quarterly, annual, or other interval orders upon facility conversion to be delivered at specified dates. Once placed, the ordering frequency may need to change at any time for orders to be delivered within the contractually required timeframes. The Government requires a supplier that can be flexible in meeting the changing needs of the Government. The scenarios are not all inclusive of the Government's needs, but are representative of the flexibilities necessary.

**VI. PRODUCTION AND SUPPLY**

- A. The Government requires the Contractor to undertake production of such quantities of the product as are necessary to reasonably assure the Government of an uninterrupted supply of the product based upon an anticipated monthly usage. The Government may not obligate funds for product in inventory or production whenever the contract is terminated. The Contractor shall complete component pack changes within thirty (30) days. Due to the possible need for changes, the Government shall be obligated to only a thirty (30) day supply of packs manufactured at the time of the change acceptance and not exceeding the current fiscal obligation time period. In the event the Government terminates the contract, the Government will not be held responsible to procure the additional inventory. In the event of component changes in any pack, the Government agrees to purchase up to a maximum thirty (30) day usage of the current pack composition before the new pack composition is shipped.

**B. Changes to Composition/Components of Procedure Trays.**

(1.) The Richmond VAMC may change individual component parts of the tray/pack after thirty (30) days of usage. Pricing and recommended requested changes will be forwarded to the Contractor by the facility COR. The Contractor shall be requested to consider all component part changes and provide a price estimate of each item to be changed. The price proposal will include price plus an estimate for credit for deleted items. In accordance with FAR clause 52.212-4(d), changes may be made only by written agreement of the parties. Only the Contracting Officer has the authority to make changes to the contract. Changes will be made by contract modification/supplemental agreement.

- a.) A Pack Change Worksheet shall be utilized for all pack changes. The change form shall include all of the components, quantity and manufacturer detail for the affected pack. The format of this form is at the discretion of the contractor, to be approved after award.
- b.) The sales representative (or equivalent) shall supply the COR with the completed change form. With the agreement of the two parties, each shall sign the change form.
- c.) The signed change form shall be forwarded to the Contracting Officer for approval.
- d.) Once approved by the Contracting Officer, the Contracting Officer shall issue a contract modification/supplemental agreement; the change shall be submitted to the Contractor for the next production run of that pack.
- e.) The Contractor shall provide the facility with an electronic inventory report each week which details: the number of packs on order, the current forecast, the three month average usage, the six month average usage, the number of packs per case, and the cost of the pack. Trends must be communicated between the sales representative and the COR with a mutual determination to adjust inventory levels.
- f.) The arrangement of the component parts in the tray/pack shall be coordinated by both the designees and Contracting Officer's Technical Representative (COR). This coordination shall be prior to production by the Contractor.
- g.) Substitutions of items shall not be made without prior approval, in writing to the facility POC and approved by the Contracting Officer via contract modification.**

- C. The Contractor's Quality Assurance shall verify changes and ensure the product meets the Government specification. When additions or deletions occur, the Contractor shall provide the Contracting Officer with the costs of each individual component added or

deleted at the time of the change or before written authorization by the Contracting Officer.

- D.** It is reasonable to expect usage and/or requirements may change during the contract period. The Government reserves the right to negotiate with the Contractor to add and/or delete item(s) to pack components.
- E.** If for any reason the Contractor is unable to deliver the agreed upon packs, the contractor will provide (12) hour notice to the COR. The contractor will find an alternative source and initiate a backup plan.
- F.** Contractor shall list in the spaces below the name(s) and address(s) of customer service departments with whom the Government or Government's Prime Vendor will place orders:

Company Name:

Address:

Phone No.:

Fax No.:

Contact Name:

Email:

Company Name:

Address:

Phone No.:

Fax No.:

Contact Name:

Email:

## **VII. DELIVERY REQUIREMENTS**

- A.** All deliveries are FOB Destination to the MSPV and the Richmond VAMC. Supplies shall be delivered to the destination warehouse unloading platform, or receiving dock, at the expense of the Contractor, except in the case of certain emergency orders. The Government shall not be liable for any delivery, storage, demurrage, accessorial, or other charges involved before the actual delivery (or "constructive placement" as defined in carrier tariffs) of the supplies to the destination. If motor carrier (including "piggyback") is used, supplies shall be delivered to truck tailgate at the unloading platform of the consignee, except when the supplies delivered meet the requirements of Item 568 of the National Motor Freight Classification for "heavy or bulky freight." When supplies meeting the requirements of the referenced Item 568 are delivered, unloading (including movement to the tailgate) shall be performed by the consignee, with assistance from the truck driver, if requested. If the contractor uses freight forwarded for less than carload shipments, the contractor shall ensure that the carrier will furnish tailgate delivery, when required, if transfer to truck is required to complete delivery to consignee.

MSPV address is as follows:

Cardinal Health 200, Inc.  
Baltimore Distribution Center  
7611 Brandon Woods Blvd.  
Baltimore, MD 21226

- B. Pack deliveries shall be made within 72 hours.
- C. When shipping through MSPV, the contractor shall provide pack contents listing to the MSPV such that is necessary for the MSPV to meet all regulatory storage and shipping requirements. In accordance with DOT requirements, if a pack contains chemicals, a Material Safety Data Sheets (MSDS) shall be provided to both the MSPV and customer in either paper or electronic form at the discretion of the customer.
- D. The contractor shall maintain, at a minimum, a 97% fill rate for all orders. Fill rates are calculated as described below. The contractor shall furnish fill rate reports quarterly to the contracting officer and the contracting officer shall independently verify the contractor's fill rate based on utilization data.
  - (1) Fill-Rate Calculation. The contractor shall individually calculate the fill rate on a quarterly basis for each medical center, based only on those packs, ordered by the medical center, for which the contractor has been authorized to deliver. The Fill-Rate Level will be calculated as follows:

**Fill Rate = Packs accepted by the Government / (Total Packs ordered – Contractual Exceptions)**

## **VIII. PACKAGING**

- A. Unless otherwise specified in the statement of work, the product shall be packed in substantial containers of the type, size and kind commonly used within the industry for this purpose. The container(s) will be constructed as to ensure acceptance and safe delivery by common carriers to the point of delivery designated by each facility. Items must be packaged adequately to prevent deterioration and damage during shipping, handling and storage. All packs must be clearly labeled on the outside covering if they contain latex products. **However, all products should be totally latex free, except where authorized by the COR.**
  - (1) Each pack shall have a label specifying the manufactured date and sterilization date of the pack and the expiration date of any dated products. This label, located inside of each pack, shall also contain an itemized listing of all components, as well as any missing items that were approved to be left out by the VA. Pack contents list must contain item, quantity, and country of origin information. Color coded packs, or some sort of visual cue to distinguish between pack types must be available upon request by the COR at no additional charge. Expiration dating of all custom sterile procedure packs delivered under this program shall have a minimal shelf life of 12 months

- remaining upon delivery to the Government. Prior written approval by the facility COR is required before delivery of short dated products.
- (2) Each pack shall also have a separate label on the outside of the pack that includes the ordering station number and station specified pack name.
  - (3) All outer shipping packages shall contain the complete contract number and delivery order number in addition to the shipping address.
  - (4) Package content quality is the responsibility of the prime contractor, including items affixed to the outside of the pack (piggyback) and distributed as a part of the pack. Any pack determined to be defective (e.g. contains expired components, sterility has been compromised, etc.), through no fault of the Government, shall be returned to the Contractor at the Contractor's expense. Full credit or replacement shall be made to the Government.
  - (5) The Veterans Health Administration is currently implementing Real Time Location Services (RTLS) throughout its Medical Centers nationwide. One component of the RTLS project includes cardiac catheterization lab supplies using RFID smart cabinets. The purpose is to track those high cost items for increased supply chain visibility and track invasive supplies using a unique device identifier to associate those supplies to a patient through a direct link with our Cart-CL documentation software. The application and use of RFID may expand beyond the CATH lab in future years. Cabinets currently in use include those manufactured by WaveMark, Solstice, and Terso. Where **RFID** Tags are specified, tags shall be Global Standards 1 (GS1) compliant and must be available in both UHF and HF technologies, as specified by the Richmond VAMC. Tags will be placed either on specified components or the packs, at the discretion of the ordering facility.

## IX. MANUFACTURING

### A. ASSEMBLY AND STERILIZATION

The contractor shall ensure an individual lot number for each custom sterile procedure pack is assigned for clear tracking of all packs. The packing list shall include the manufacturer and lot number of each component item to ensure traceability. The contractor shall meet the following assembly and sterilization requirements:

- (1) The contractor shall validate the sterilization process, with the Association for Advancement of Medical Instrumentation (**AAMI**) at a minimum annually. The Contractor shall send **the validation to the Contracting Officer within 30 days of annual inspection completion.**
- (2) All Component debris, sterility tests, and residual tests are to be performed by contract laboratories at contractor's expense.
- (3) The contractor shall guarantee prior to sterilization, the products shall be assembled in secure air controlled rooms, which are accessible only to authorized personnel with proper attire. International Association of Healthcare Central Service Material Management (IAHCSMM) (<https://www.iahcsmm.org>) and Association for the Advancement of Medical Instrumentation (AAMI) (<http://www.aami.org>) provide guidelines for proper attire.
- (4) The Contractor shall follow current **ISO** (International Organization for Standardization) for Sterilization of health care product.



- (5) The contractor shall guarantee all aspects of the assembly, packaging and sterilization must adhere to the quality control standards set by the **FDA**. The Contractor (all entities in the production process) shall be registered with the FDA.
- (6) In accordance with the Executive Order 13514 dated October 5, 2009. The Contractor should consider earth friendly solutions, and provide a program that supports green purchasing. Contractor should provide a recycling program for re-useable items that are salvageable and recommend green product components when available.
- (7) The Contractor shall not provide re-sterilization of any single use product for resale to the VA.
- (8) The Contractor shall have in-house sterilization capability or have, the ability to provide sterilization services at all times. The in-house or contract sterilization partners shall be ISO9001:2000 (International Organization for Standardization) certified and undergo routine FDA inspections.
- (9) The contractor shall inspect all component products and also check for damage and short dates.
- (10) The Contractor shall have continual maintenance performed on all sterilizing equipment.
- (11) The contractor shall provide quality assurance staff which shall include personnel familiar with operating room procedures, infection control practices, aseptic techniques and sterilization methods.
- (12) The contractor shall ensure that all individual components within the pack are **TAA** compliant unless otherwise authorized by the CO to place orders from a non-TAA compliant country.

## **B. COMPONENT PARTS**

- (1) Components that are listed as **DO NOT SUBSTITUTE** are due to the requirements of the specific medical center staff or instruments currently being used in the operating room or other circumstances. The substitution or changing of these specific items after award would require the changing of instruments or equipment in order to utilize the substitute of an alternative item. Should an equal product be substituted in lieu of that specified, the product line must specify which item is equal and substituted for which item and be approved by the medical center prior to substitution. If no substitution of an equal product is offered, it will be presumed the offeror will provide the pack as specified.
- (2) Items that are subject to substitution -All substitutions shall be clearly identified with country of origin, and shall be **TAA** compliant.
- (3) All component items required for the tray/pack are to be provided by the Contractor. All component packaging will be removed from outer packaging to reduce steps in the operating/procedure room, unless otherwise required by the customer or the component manufacturer.
- (4) All packs are to use hard plastic base trays and components parts to reduce **ETO** (Ethylene Oxide) residue and eliminate possible particulate contamination from Styrofoam. Biodegradable trays that have the same affect are acceptable. ETO tape/indicator is to be affixed to the outer wrap and tray where applicable. All custom packs should be sterilized in an approved packaging material with a plastic dust cover. Custom packs material must

allow the sterilization of the contents, maintain sterility, and provide a way to remove the contents without contamination. Plastic dust covers should be sealed with a method of sealing which results in a complete seal that is tamper evident and allows for ease of aseptic presentation. Accessories used to secure custom packs should be chosen to allow penetration of the sterilization process, avoid constriction of the package and maintain package integrity.

- (5) Requirements for gowns and drapes shall meet the following criteria:
  - (a) Materials shall be of a soft, memory-free type that precludes shifting of drapes.
  - (b) Material shall be non-abrasive and free of toxic ingredients, non-fast dyes and noxious odors.
  - (c) Materials shall be non-glare and of a color that minimizes distortion from reflected light.
  - (d) Gowns shall fit and allow freedom of movement. Gowns shall have stockinet cuffs, raglan sleeves and welded or stitched seams.
  - (e) Gowns and drapes shall maintain an environment appropriate to body temperatures.

When substitutions are necessary and approved for surgical gowns and drapes, quantitative data must be available to show that the materials for surgical gowns and drapes provide an effective barrier to microbes. The materials must meet the American Society for Testing and Materials (ASTM) requirements for barrier protection, including blood borne pathogens, microbial challenge, as well as hydrostatic pressure with resistance to tears, abrasion and stains. All materials must be lint-free and meet or exceed the requirements of the National Fire Protection Regulations for flammability in Part 1610 of the Code of Federal Regulations.

- (6) The materials for cloth towels must be lint-free and meet or exceed the requirements of the National Fire Protection Regulations for flammability in Part 1610 of the Code of Federal Regulations. When substitutions are necessary and approved for cloth towels, x-ray detectable or not, they are to be absorbent, disposable or towels made of 100% cotton, and pre-washed.
- (7) All components must be **Latex Free** unless specified otherwise by the using facility. All packs must be clearly labeled on the outside covering if they contain latex products. All products containing latex must also be clearly labeled individually as containing latex.

### **C. UNAVAILABILITY OF COMPONENT PARTS**

Should a component part become unavailable which will temporarily or permanently delay the production of the pack(s), the Contractor shall immediately notify the (COR) and the Contracting Officer by telephone (with written notice to follow within five (5) calendar days) of the situation and the anticipated length of delay.

At a minimum, the unavailability notification shall include the following information:

- (1) Complete item description, (product and lot number) and/or identification
- (2) Contract and Delivery Order
- (3) Reason for unavailability
- (4) If a direct recall was issued, the contractor shall include the manufacturer disposition instructions and level of recall.

Recalls: In accordance with the **Safe Medical Device Act**, (SMDA) the Contractor shall have a documentation system for component product traceability and lot number recordings for product recalls. The Contracting Officer and Contracting Officer Representatives (COR) must be notified immediately by telephone (with written notice to follow within five (5) calendar days) if affected by a product recall. The contractor shall also provide a method of identifying affected packs on the shelf such as a brightly colored sticker or other visual identifier within 24 hours so that VA may mark the existing pack identifying the recalled component(s). Vendor existing inventory will be marked using the same method provided to VA staff. If the recalled component is unavailable for further production of the custom sterile procedure pack(s), no substitutions will be made by the Contractor without written authorization of the CO. Pack conversions in the result of a recall shall adhere to the same timelines for change out as all other pack conversions.

The contractor shall notify the COR and the Contracting Officer of any Manufacturer Backorder (MBO). The status clearly states the reason for any unavailability of component parts due to MBO and shall indicate the length of time for replenishment by product supplier. The government retains the right to investigate the backorder situation to determine the cause of the backorder and to provide assistance to the Custom Sterile Procedure Pack contractor and the participating customers during the MBO period.

No deletions or substitutions will be made without written authorization from the Contracting Officer or delegated representative. If the component will be out of stock for a prolonged period of time and the using service chooses to have the pack assembled without the product, written authorization must be given by the Contracting Officer or COR. The cost of the pack must be adjusted to reflect the change. In addition, the content listing will clearly identify any missing items approved to be left out by the VA.

**X. CONTRACTOR CUSTOMER SERVICE LIAISON AND CONTRACTOR ASSESMENTS**

The Contractor shall provide one customer service liaison who shall act in regard to pack conversions, backorder issues, additions/deletions for pack components, and site visits. The customer service liaison shall be available regardless of ordering or distribution method. No later than 30 days after contract start date, the VA shall be provided with a list of liaisons serving each site covered under this contract. The contact list shall include name, phone, email, (other contact info), etc.

- A. The name of this person shall be designated in writing to the Contracting Officer. The Contractor’s program manager shall have full authority to act for the Contractor on all matters relating to daily operations of this contract.

COMPANY NAME: _____			
Customer Service Liaison Name:	Phone Number:	Fax Number:	Email:

- B. Contractor site visits (assessments) shall occur no less than quarterly (or more frequently at the request of the COR) to review: program quality, contract performance and administration, and availability of value added services. Value added services, such as utilization review shall be provided by clinical experts to the VA as needed at no additional cost

## **XI. CONTRACTOR ELECTRONIC COMMUNICATION AND REPORTING REQUIREMENTS**

- A. At a minimum the contractor shall utilize a web based system that provides for electronic communication for inventory tracking to include: digital imagery, pack conversion management program, and reporting services for the purposes of projecting needs. The web based system will allow for electronic signature for pack conversions. New packs and pack changes will require a dual signature for both clinical and logistics signatures. Individuals authorized to sign on behalf of the facility will be provided at time of award. It will also include a database that can be loaded with VA mandatory contracts at no additional charge to the VA. It will provide non-editable access to the database for all personnel authorized by the COR for the purpose of identifying like packs across the region. It will provide for easy identification of component, product utilization, latex, sterilization requirements, country of origin information, and VA standardization information. This electronic communication and inventory tracking system shall be available regardless of the ordering or distribution method.
- B. Custom Sterile Procedure Pack Status Reports shall be provided to the VA, by the contractor monthly. Reports submitted shall be marked as "Contractor Reports". Reports need to be submitted to the COR by the 15<sup>th</sup> of every month. Reports shall be reflective of, and applicable to the distribution method used, either through VA MSPV, directly to VA ordering facility. Reports shall include, but not be limited to the following:
  - (1) Fill rates, to include calculation details and explanation of exclusions, if any
  - (2) Quality Delivery Reports, to include returns and exchange information, emergency deliveries, and drop shipments
  - (3) Customer feedback reports related to quality of service
  - (4) Pack Conversion information, including name of person approving pack conversion.
  - (5) Usage by pack and dollar value
  - (6) Usage by component, to include cost and standardization information
  - (7) Product utilization information calculated based on recommended and accepted pack conversions, as well as any other discounts applied
  - (8) Substitution information, including name of person authorizing the substitution
  - (9) Credit and rebill information, and outstanding invoice information, to include specifics that would allow the COR to follow up.
  - (10) Contractor Supply Problem Report that includes identification of any problems encountered with MBO situations, shipping or delivery problems and recalls.
- C. The Contractor in collaboration with the VA customers assists when requested upon for information in determining product utilization and obsolescence opportunities information may include the following:
  - (1) Alternative cost saving components
  - (2) Alternative standard packs to meet the needs of a requested custom sterile procedure pack when identical or similar components are involved

- (3) Alternative supply chain processes or any other processes that might result in cost savings or avoidance
- (4) Component utilization reviews
- (5) Provide annual cost savings report to the contracting officer. Report needs to be submitted to the CO no later than 30 days after the government's fiscal year end.
- D.** Contractor shall provide copies of proof of Workers Compensation and Employee Public Liability Insurance within fifteen (15) calendar days after notification of contract award.
- E.** The Contracting Officer will schedule a post-award performance conference with the contractor for contract orientation purposes. The post-award performance conference may be scheduled within 30 days of contract award.

## **XII. QUALITY ASSURANCE**

- A.** The Custom Sterile Procedure Pack manufacturing facilities must be registered and in good standing with The FDA and ISO9001:2000 certified **ISO, CEN** (European Committee for Standardization), **AAMI** (Association of the Advancement of Medical Instrumentation), and **AORN** (Association of Operating Room Nurses) are other Industry standards that must be met. Per FAR 25.4, Trade Agreements, each end product is certified as a U.S.-made, designated country, Caribbean Basin country, or **NAFTA** country (Canada or Mexico) end product.
- B.** "Quality System Program" to prevent non-conformances at all product/service stages from design through distribution must be utilized. It is designed to comply with the requirements of **ISO9001:2000**, 21 CFR 820 (Code of Federal Regulations), **EN 46001**, and United States regulations regarding the sales and distribution of medical products. At a minimum ISO9001:2000 Certification must be available at time of proposal submission, and continuously maintained throughout the duration of the contract.
- C.** The Custom Sterile Procedure Pack program must provide certain measures in the manufacturing of the kits.
  - (1) Product specifications including video images, bills of material, biological evaluations, component specification, and identification of critical design and process parameters. These include how the parameter is to be met.
  - (2) Production process specifications, including the appropriate equipment specification, production methods, production procedures, compatibility of the design with current systems and equipment.
  - (3) Quality assurance procedures and specifications, i.e., quality plan, including quality assurance checks used and the quality testing apparatus, fixtures, resources, skills, subjective standards and documentation used.
  - (4) Packaging and labeling specifications, including methods and processes used.
  - (5) Sterilization requirements and methods.
  - (6) Testing requirements and methods.

The Government may, at its option and expense, request an unrelated third party to inspect the packs provided by the Contractor. The Contractor shall repair, at the Contractor's cost, any faults or omissions discovered by the inspection of the third party within fifteen (15) days when notified by the COR.

The Government may, at its option and expense, inspect the contractor's manufacturing and distribution centers at least annually, within five working days upon request by the COR.

**XIII. FURNISHED ITEMS AND SERVICES**

- A.** The Government shall not provide the facilities, equipment, materials, or any products under this contract.
- B.** The Contractor shall furnish and provide everything required to perform this contract in accordance with all of its terms.