

## **STATEMENT OF WORK (SOW)**

### **Blood & Blood Byproducts**

#### **1. BACKGROUND**

The Department of Veterans Affairs (VA) Veterans Health Administration (VHA) has a requirement for human blood products and related services. The Contractor shall be a blood bank, and shall provide supplies and services that conform to the contract.

#### **2. QUALIFICATIONS**

2.1 The Contractor shall ensure that all blood products shall be collected, processed, labeled, tested, packaged, and shipped in accordance with all regulations of the FDA, Center for Biological Evaluation and Review (CBER), as described in the Code of Federal Regulations (CFR) Title 21, Parts 600, 601, 606, 607, 610, 640, and 660, the Clinical Laboratory Improvement Amendments (CLIA), and the California Department of Public Health (CDPH).

2.2 The Contractor shall adhere to 29 CFR Part 1910.1030 Occupational Safety and Health Administration (OSHA) standards for the *Occupational Exposure to Blood Borne Pathogens Needlestick and Other Sharps Injuries*, and shall be accredited by the Joint Commission (JC) and American Association of Blood Banks (AABB), and licensed with the United States (US) Food and Drug Administration (FDA). The Contractor must have a current US registration or license which is issued by the FDA Director of the Bureau of Biologics under Section 351 of the Public Health Service Act as amended, 42 United States Code (USC) Section 262, as a source of supply for leukoreduced red blood cells. Should there be any interstate shipment of blood product(s), then approval must be authorized under Section 251 of the Public Health Service Act, as amended, 42 Section 262.

2.3 The Contractor shall provide current documentation of above qualifications, certifications, registrations, licensure, and accreditations to the CO upon any expiration or organizational change. The Contractor shall notify the CO within fifteen (15) minutes of learning about any threatened or actual revocation, suspension, or termination, or material modification of an accreditation, certification, licensure, or permit of the Contractor's blood bank. Donor testing laboratories utilized by the Contractor must be registered or licensed with the FDA, be CLIA certified, and shall have a current clinical laboratory license or permit from a state's department of public health that is applicable to the location of the Contractor's blood bank and VA facility. The Contractor shall include the business name, a POC, the address, and telephone number of donor testing laboratories utilized by the Contractor whenever there is a change in a donor testing laboratory utilized.

#### **3. SPECIFICATIONS REQUIRED**

1 - All cellular blood products (platelets and RBCs) shall be leukoreduced.

2 - Pre-storage leuko reduced RBC units must be provided.

3 - All blood components needed for transfusion(s) must be provided as listed in the price cost schedule of supplies and services.

4 - Allogeneic blood products must be typed for ABO and Rho(D) in accordance with licensed methodologies, and must be tested for all transfusion transmitted disease markers currently required by both the FDA and AABB.

5 - All blood products must be screened and processed utilizing the most current methods and in accordance with all federal, state, and local laws, rules, regulations, and guidelines; including but not limited to, the AABB, FDA, and the US Department of Health and Human Services' (HHS') current Good Manufacturing Practices.

6 - All blood shall be collected by closed system under aseptic conditions and shall be stored in currently approved, appropriate solutions and the container shall be correctly labeled. The label shall also bear the expiration date of the contents which shall not exceed forty-two (42) days from date of collection of source blood when collected and stored with anti-coagulant citrate phosphate, dextrose adenine solution (AS) or thirty-five (35) days from the date of collection of source blood when collected and stored with anticoagulant citrate phosphate dextrose adenine solution.

7 - All blood supplied must be grossly free of visible hemolysis, excessive chyle, and clots.

8 - Autologous blood products must be typed for ABO and Rho(D) in accordance with licensed methodologies, and must be tested for all transfusion transmitted disease markers currently required by the FDA.

9 - All blood must be tested as required by the FDA, AABB, HHS *CGMP*, and State of California's laws, rules, and regulations.

10 - In the event of a recall, the Contractor shall immediately send copies of the recall request to the COR, transfusion service, and transfusion service medical director at the VA.

Unless otherwise specified, all references to "days" are calendar and not business days.

11 - Autologous blood donors that have units drawn at the Contractor's collection site(s) shall not be required to pay any charges. Contractor shall bill the VA facility for the blood and apply a handling fee for an overall charge.

12 - Autologous donors that have units of blood drawn at facilities other than the Contractor's collection site(s) may have their blood delivered to the Contractor for shipment to the VA facility.

13 - The Contractor may charge a processing and handling fee in accordance with the price cost schedule of supplies and services in the contract.

14 - The Contractor shall provide blood products and related services as available when ordered.

15 - The Contractor shall provide the most current version of the *Circular of Information for the Use of Human Blood and Blood Components* to the laboratory at the Martinez VA Medical Center.

16 - FFP products and/or Cryo products shall be direct sale products.

#### **4. DONOR REQUIREMENTS**

4.1 One-hundred (100) percent of blood supplied by the Contractor shall be donor blood as defined in CFR Title 21, Chapter I, Subchapter F, Part 606, Subpart G, Section §606.121(c)(8)(v)(B) where a volunteer donor is a person who does not receive monetary payment for blood donation. Benefits, such as time off work, membership in blood assurance programs and non-replacement fees that are not readily converted to cash, do not constitute any monetary payment. All blood must be collected from donors in accordance with the requirements of the AABB and FDA.

#### **5. DONOR SELECTION CRITERIA**

5.1 The Contractor shall maintain a blood donor list with unique identifier numbers. The list shall indicate the date the blood of a particular donor was furnished to the VA.

5.2 All donor selections shall be in accordance with criteria established by the AABB and FDA.

5.3 Blood samples that test positive during unit screening shall not be used for transfusion if the results are outside the established limits set by the FDA and AABB. When the FDA or AABB requires a new transfusion transmitted disease marker, it shall be performed by the Contractor.

#### **6. REFERENCE LAB SERVICES**

6.1 Reference laboratory services must be available twenty-four (24) hours per day, seven (7) days per week, and three-hundred and sixty-five (365) days per year.

6.2 Preliminary results of lab services must be provided within four (4) hours for STAT and as soon as possible (ASAP) orders, and within twenty-four (24) hours for routine orders.

6.3 Preliminary results must be provided within four (4) hours for urgent care situations, and within twenty-four (24) hours in non-urgent care situations, when red cell antibody identification reference lab services are ordered.

6.4 Screening for negative blood per antigen includes testing donor units for RBC antigens and select units negative for a given antigen.

6.5 Cross-matched, or HLA-matched platelet pheresis, shall include a compatibility test between recipient serum and donor platelets. Crossmatched or HLA matched platelet donor recruitment shall include a donor known from previous testing to be compatible with the recipient.

**6.6** The Contractor shall provide educational programs at no charge to the VA that are consistent with the programs offered at no charge to other non-VA contracted customers.

## **7.0 COLLECTION, PROCESSING, AND TYPING OF BLOOD**

**7.1** Blood shall be typed for ABO and Rh antigens and labeled in accordance with the methods recommended in the current *Standard for Blood Banks and Transfusion Services and Technical Methods and Procedures* that is published by the AABB.

**7.2** If there is an error by the Contractor in the blood typing, the Contractor shall pick up the errant blood immediately and a credit for the errant blood shall be given to the VA.

**7.3** All blood shall be collected by a closed system under aseptic conditions and shall be processed in appropriate solutions and the container labeled. The label shall bear the expiration date of the contents which shall not exceed the following:

**7.3.1** Twenty-one (21) days from the date of collection of source blood, or thirty-five (35) days from the date of collection of source blood, if when collected, it is stored with anticoagulant citrate phosphate dextrose adenine solution.

**7.3.2** Forty-two (42) days from date of collection for blood collected in Adsol.

**7.4** Irradiated units includes treating units with gamma irradiation to prevent lymphocyte proliferation and transfusion-associated graft vs. host disease.

**7.5** Pathogen-reduced products that have been approved by the FDA are acceptable in place of irradiated units only when approved by the FDA.

**7.6** CMV negative blood products shall be screened by the Contractor to ensure the absence of antibodies to CMV.

## **8. SHELF LIFE**

**8.1** All blood products must be labeled, stored, and shipped in accordance with the current regulations of both the FDA and the AABB. In the event that these regulations change during the course of the contract, the Contractor shall implement the necessary changes as directed/recommended by the regulatory and accrediting agencies.

**8.2** For routine orders, allogeneic blood products must be supplied with appropriate remaining shelf life, as detailed below.

<b>Allogeneic Blood/Blood Components</b>	<b>Appropriate Remaining Shelf Life</b>
RBCs	Shelf life of more than twenty-one (21) days, regardless of anti-coagulant
FFP	Shelf life of more than one hundred eighty (180) days

Plateletpheresis	Shelf life of more than forty-eight (48) hours, if not ordered/collected for a specific patient
Cryoprecipitate	Shelf life of more than one hundred eighty (180) days

**8.3** For STAT orders, the Contractor shall provide units with the appropriate remaining shelf life whenever possible, however, the VA understands that the urgency of the situation and the availability of the blood product(s) may preclude this possibility.

**8.4** The VA has in place the suitable temperature-monitored freezer, refrigerator, and platelet incubator/agitator for appropriate storage of blood products.

## **9.0 NOTIFICATIONS**

**9.1** With respect to Contractor supplied blood, if a blood donor originally tests negative at the time of donation, but then during a later donation, tests repeatedly reactive for the human immunodeficiency virus (HIV) antibody and/or other diseases as required by the FDA and/or AABB, then the Contractor shall provide the VA with the results of follow-up testing required or recommended by the FDA. The Contractor shall complete the follow-up testing within thirty (30) days after the donor's repeatedly reactive screening test. Under no circumstances shall the Contractor ever reveal the identity of the blood donor.

**9.2** The Contractor shall promptly notify the VA when additional information indicates that blood provided may adversely affect a transfusion recipient, provided that the Contractor shall not reveal the identity of the blood donor.

**9.3** Upon discovery, the VA shall report to the Contractor any blood lost or missing due to shipping error, and/or possible infectious disease or other serious complication associated with transfusion which may resulted from the blood, including without limitation, suspected post transfusion hepatitis, transfusion associated HIV or human T-cell lymphotropic virus (HTLV) infection, and/or any other transfusion related infections such as malaria, babesiosis, bacterial contamination or infection, and death due to adverse event (AE). VA shall cooperate with Contractor's investigation of any AE and provide de-identified information regarding the recipient of the blood upon forms provided by the Contractor, to the extent permissible under the applicable regulations of patient confidentiality.

**9.4** VA will make available to the Contractor information concerning transfusions to include product names, lot identifications and quantities, any therapeutic AE, complaints, or other pertinent information relating to blood products.

**9.5** VA shall keep complete and accurate records of patients supplied with blood, including product name, lot identifications and quantities, any therapeutic AEs, complaints, and any pertinent information relating to the blood.

**9.6** All notices given or required in the contract shall be provided to each of the parties in writing and delivered by certified or registered US first class mail, return receipt requested, or by commercial overnight courier service which provides proof of delivery to the name(s) and address(es) set forth in the signature block.

**9.7** The VA transfusion service shall report by telephone within twenty-four (24) hours to the Contractor any life-threatening AEs, and if appropriate, make arrangements to have a specimen of patient's blood, and the remaining portion of the blood component in question, sent to the Contractor for testing at no additional charge to the Government.

## **10. BUSINESS ASSOCIATE AGREEMENT (BAA) REQUIREMENT**

**10.1** Contractors that are not covered entities under the Health Insurance Portability and Accountability Act (HIPAA) shall be required to sign a BAA before the VA places any orders for apheresis or reference lab services, and before the VA provides any VA patient's protected health information (PHI) to the Contractor in any case where PHI is requested

**10.2** "Business Associate" shall have the same meaning as described at 45 C.F.R. § 160.103. "Covered Entity" shall have the same meaning as the term is defined at 45 C.F.R. § 160.103. "Protected Health Information" or "PHI" shall have the same meaning as described at 45 C.F.R. § 160.103.

## **11. PACKAGING AND MARKING**

**11.1** Each shipment shall be properly packaged, labeled, and accompanied by an itemized shipping list in accordance with the contract. An authorized individual will sign for receipt of blood products.

**11.2** Blood products shall be labeled in accordance with all FDA requirements, including kind of component, blood group and type (ABO/Rh), expiration date, unique donor unit identification, and storage and handling.

**11.3** All blood products must be labeled according to the most current International Standard for Blood and Transplant (ISBT 128) standard. The ISBT 128 standard shall be used for all deliverables.

**11.4** All blood shall be packaged to maintain FDA required temperature ranges during shipping. Red cell components shall be maintained at 1° to 10 ° Celsius (° C), frozen plasma components shall be maintained at below – 18 ° C, and platelet components shall be maintained at 20° to 24 ° C.

**11.5** Packaging shall be of a protective quality to ensure that the product is undamaged during handling.

## **12. DELIVERIES, RETURNS, AND SPECIMEN PICK-UP**

**12.1** The Contractor shall make every effort to deliver routine orders during the time of day suitable to, and as requested by, the VA. The Contractor shall have sole responsibility for the proper care and

handling of all blood products until delivery and acceptance has taken place at the designated room at the applicable VA. All deliveries shall be delivered to the VA's transfusion service(s) at the following address(es):

VA Martinez Outpatient Clinic, Transfusion Service, 150 Muir Rd, Martinez, CA 94453

**12.2** All shipments under the contract shall be accompanied by delivery tickets or sales slips that shall contain the following minimum information: name of supplier/Contractor, contract number, date of purchase, purchase order number, itemized list of supplies or services furnished, quantity, unit price, extended price of each item, less applicable discounts, and the date of delivery or shipment. Orders will be categorized into three (3) types: routine, stock, and STAT orders. These categories are as follows:

**12.3** Routine orders – Shipments of blood products that are ordered on an “as needed” basis. The Contractor shall make every effort to make routine deliveries during the time of day suitable to, and as requested by, the VA transfusion service.

**12.4** Stock orders – Shipments of blood products to maintain minimum inventory levels or blood products ordered to fulfill a standing request. One (1) scheduled delivery shall be made on Mondays, Wednesdays, and Fridays. Stock deliveries will not be made on holidays, and alternate delivery days and times will be coordinated between the Contractor and VA transfusion service to make up for any missed deliveries due to a holiday. All stock orders shall be delivered before 1 p.m. PST.

**12.5** STAT orders – An emergent, unscheduled need for blood products so acute that a patient's life could be jeopardized if the request for blood products is unfulfilled. STAT orders must be delivered within one (1) hour. The VA shall make reasonable efforts to minimize the frequency of STAT orders.

**12.6** The Contractor shall make every effort to ensure that delivery of autologous blood components are made prior to the applicable scheduled surgeries. Deglycerolized cells shall be delivered to the VA within four (4) hours of preparation to assure adequate dating.

**12.7** The Contractor shall provide deliveries of blood products twenty-four (24) hours per day, seven (7) days per week, three-hundred and sixty-five (365) days per year.

**12.8** Within ten (10) days after any delivery order award, the Contractor shall submit a proposal that includes the route (including VA facility room number) and time(s) of delivery it proposes in order to facilitate coordination of deliveries with the VA. Agreed upon schedules may be adjusted periodically.

**12.9** Once units are accepted by the VA, those units become the property of the VA, and payment will be made appropriately, based on contract terms and proper invoicing. Deliverables are not to be treated as though they are on consignment. However, for inventory control purposes, efforts will be made by the VA transfusion service to assist the Contractor and other facilities in meeting patient transfusion needs.

**12.10** The Contractor shall own, control, and solely be responsible for any loss, destruction, or damage to the blood product(s) until delivered or received and accepted. After such delivery or receipt and acceptance, the VA shall own the blood. The VA also agrees and acknowledges that no blood product(s) supplied by the Contractor, including part and or derivatives thereof, shall be sold, bartered, traded, or exchanged by the VA without prior authorization from the Contractor. Upon delivery of the blood product(s), the VA transfusion service shall inspect the blood. Upon acceptance of the blood product(s), the VA shall maintain proper refrigeration or other proper storage facilities for the blood product(s) in compliance with all regulations, as well as, the standards of the AABB, as applicable.

### **13. RETURNS**

**13.1** When the VA returns units prior to expiration in accordance with the Contractor's return policy, the Contractor shall credit the VA for units which are returned. The Contractor shall be responsible for the packaging of blood products for shipment for return(s) or redistribution(s).

**13.2** The VA will comply with all requirements and regulations associated with the recall and withdrawal of blood products from its inventory. Credit for returned, unacceptable, transferred, recalled, withdrawn, or rotated blood products shall be included on the billing statements/invoices, along with, the date of return, within thirty (30) days of the return, unaccepted item(s), transfer, recall, withdrawal, or rotation of blood product(s). Full credit shall be given by the Contractor, if for a technical reason, the blood component cannot be used, regardless of the expiration date, provided the Government notifies the Contractor within twenty-four (24) hours of discovery and the VA transfusion service completes the appropriate documentation. Full credit shall be given by the Contractor for any blood product(s) returned or exchanged before the expiration date.

**13.3** The Contractor shall assist with, and facilitate the transfer of all blood components, when a transfer is conducted to ensure its use. This includes irradiated and other transferrable blood components.

**13.4** The Contractor shall remove rejected blood products within forty-eight (48) hours of notice of rejection.

### **14. SPECIMEN PICK-UP**

**14.1** The Contractor shall pick-up specimens for testing from the VA's transfusion service at the following address:

VA Martinez Outpatient Clinic, Transfusion Service, 150 Muir Rd, Martinez, CA 94453

**14.2** Specimens for reference lab testing will be picked-up within the time specified as follows:

**14.2.1** STAT orders: Specimens will be picked-up within one (1) hour of order.

**14.2.2** ASAP orders: Specimens will be picked-up within two (2) hours of order.



**14.2.3** Routine orders: Specimens will be picked-up within twenty-four (24) hours of order

## **15. CONTRACT ADMINISTRATION DATA**

### **15.1 AUTHORIZED REPRESENTATIVES**

The primary CO/CS for this contract is:

Shannon Archer, Contract Specialist  
Department of Veterans Affairs  
Network Contracting Office 21  
Southern Nevada Healthcare System  
6900 N. Pecos Road, Admin Building #6, Rm #2H210G  
North Las Vegas, NV 89086

**15.2** Each VA facility may have its own COR. The primary COR(s) for projects under this contract is/are:

TBD

**15.3** Each VA facility may have its own secondary/alternate COR(s) The secondary/alternate COR(s) for projects under this contract is: TBD

**15.4** Each of the VA facility's primary and/or secondary/alternate COR(s) will be responsible for technical monitoring of the Contractor's performance and deliveries. The CO and the COR and/or secondary/alternate COR shall work together to ensure that all contractual requirements are being met.

**15.5** The COR(s) will interpret specifications or technical portions of the work. The COR(s) is/are not authorized to perform, formally or informally, any of the following actions:

**15.5.1** Promise, award, agree to award, or execute any contract, contract modification, or notice of intent that changes or may change the contract;

**15.5.2** Waive or agree to modification of the schedule;

**15.5.3** Make any final decision on any contract matter subject to the disputes clause;

**15.5.4** Terminate, for any reason, the Contractor's right to proceed;

**15.5.5** Obligate in any way, the payment of money by the Government. Only a warranted CO is authorized to obligate funds on this or any other contract action.

**15.5.6** The Contractor shall immediately notify the CO in writing if the COR(s) or secondary/alternate COR(s) has/have taken an action (or fails to take action) or issues directions (written or oral) that the Contractor considers exceeding the above limitations.

**15.5.7** The Contractor shall provide the CO information copies of all correspondence provided to the COR(s).

## **16. ORDERS**

**16.1** The Contractor shall use reasonable efforts to supply the blood product(s) and related service(s) when the blood product(s) and/or related service(s) is/are ordered. In the event that the Contractor is unable to fill an order, the Contractor shall notify the VA transfusion service immediately upon determination that it is not able to fill an order, in which event, the VA shall complete the order elsewhere. Ordering shall be conducted in accordance with applicable laws and the contract.

**16.2** Orders may be placed via email, facsimile, electronic data interchange (EDI), telephone, in hard copy format, or in any other manner consistent with accepted commercial business practices.

**16.3** The CO may designate representatives and alternate representatives to place orders against the contract. Authority limitations for COR(s) and Alternate COR(s) shall be established through individual appointment letters signed by the CO. **The CO/CS, COR(s), and Alternate COR(s) are the only individuals authorized to place orders against the contract.**

**16.4** The representative(s) of the VA transfusion service may place orders against a valid contract on an as needed basis within the terms of the contract. Each individual order shall describe the tasks, services, and/or deliverables required.

**16.5** The Contractor shall notify the VA transfusion service if any order(s) are modified. Modified orders for product(s) or service(s) shall be approved by the applicable VA transfusion service either verbally, by email, or by facsimile, prior to the shipment of any such products. The applicable VA transfusion service reserves the right to refuse any modified product(s) offered by the Contractor.

**16.6** The Contractor shall have the ability to receive orders via email and fax transmission, and shall provide the applicable email address and fax number below. The Contractor shall also provide a telephone number and name and title as a POC for orders.

## **17. INDIVIDUALS AUTHORIZED TO PLACE ORDERS**

17.1 VA authorizes the following entities to place orders: CO/CS, COR, and Alternate COR

## **18. INVOICES**

**18.1** An itemized invoice shall be submitted monthly or upon expiration of this contract, whichever occurs first, for all deliveries made during a billing period and for which payment has not been received.

**18.2** Fees that are included on an invoice shall be itemized as processing services or blood services.

## **19. MANAGEMENT CONTROL**

**19.1** The contract holder shall provide to the CO a list of all teaming partners or sub-contractors within thirty (30) calendar days after order award. As sub-contractors and/or teaming partners are added, and/or deleted, an updated listing shall be provided to the CO within thirty (30) calendar days of such change. All contract holder personnel shall display identification badges at all times while charging hours to an order or while at a Government or Government Contractor location. Authorized Government personnel shall accompany all visits to VA program offices, unless other specific arrangements have been made.

## **20. POST AWARD PERFORMANCE CONFERENCE**

**20.1** A post award conference shall be scheduled with the Contractor if deemed necessary for contract orientation purposes.

## **21. REPORTS**

**21.1** Reference laboratory reports shall be provided by telephone and facsimile to the VA transfusion service as soon as testing is completed. A written report shall be issued within seven (7) business days following the telephone report.

**21.2** Complicated reference cases may take longer to report and shall be handled on a case by case basis. Mutually agreeable reporting requirements shall be determined between the VA transfusion service and Contractor for more complicated reference cases.

## **22. PRICING DATA**

**22.1** In the event that there is an expansion of blood testing requirements mandated by the FDA during the contract period, specific price adjustments may be requested by the Contractor to address the cost of the additional testing. In the event that this should occur, a letter detailing the rationale for the price increase must be submitted to the CO at least thirty (30) days before the intended implementation date. The letter may be mailed or emailed to the CO, and a contract modification may be written. Informal price and cost data shall be included with any request for a price adjustment. The determination as to the sufficiency of the informal price and cost data shall be made by the CO. Cost and price data must be sufficient to be able to determine if a price increase is fair and reasonable.

**21.2** Any order already placed shall not be affected by any change to contract pricing.

## **23. SMOKING POLICY**

**23.1** Smoking is not permitted within or around VA facility grounds, except in designated areas.

## **24. PARKING**

**24.1** It is the responsibility of the Contractor's personnel or other delivery personnel to park in the appropriate designated parking areas. Parking information is available from the applicable VA police and security service(s). VA facility(ies) will not provide reimbursement for or invalidate parking violations of the Contractor's personnel or any other delivery personnel under any circumstance(s).

## **25. Records Management Language for Contracts Required**

**25.1** The following standard items relate to records generated in executing the contract and should be included in a typical Electronic Information Systems (EIS) procurement contract:

1. Citations to pertinent laws, codes and regulations such as 44 U.S.C chapters 21, 29, 31 and 33; Freedom of Information Act (5 U.S.C. 552); Privacy Act (5 U.S.C. 552a); 36 CFR Part 1222 and Part 1228.
2. Contractor shall treat all deliverables under the contract as the property of the U.S. Government for which the Government Agency shall have unlimited rights to use, dispose of, or disclose such data contained therein as it determines to be in the public interest.
3. Contractor shall not create or maintain any records that are not specifically tied to or authorized by the contract using Government IT equipment and/or Government records.
4. Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected by the Freedom of Information Act.
5. Contractor shall not create or maintain any records containing any Government Agency records that are not specifically tied to or authorized by the contract.
6. The Government Agency owns the rights to all data/records produced as part of this contract.
7. The Government Agency owns the rights to all electronic information (electronic data, electronic information systems, electronic databases, etc.) and all supporting documentation created as part of this contract. Contractor must deliver sufficient technical documentation with all data deliverables to permit the agency to use the data.
8. Contractor agrees to comply with Federal and Agency records management policies, including those policies associated with the safeguarding of records covered by the Privacy Act of 1974. These policies include the preservation of all records created or received regardless of format [paper, electronic, etc.] or mode of transmission [e-mail, fax, etc.] or state of completion [draft, final, etc.].
9. No disposition of documents will be allowed without the prior written consent of the

Contracting Officer. The Agency and its Contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. Records may not be removed from the legal custody of the Agency or destroyed without regard to the provisions of the agency records schedules.

10. Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (sub-Contractor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under, or relating to, this contract. The Contractor (and any sub-Contractor) is required to abide by Government and Agency guidance for protecting sensitive and proprietary information.