

# **Statement of Work (SOW)**

## **Preventive Maintenance and Repair on**

### **Innovian Anesthesia and Innovian Anesthesia Analytics Reporting Tool Department of Veterans Affairs (VA) Veterans Health Administration (VHA)**

The Contractor shall provide all software and hardware upgrades, maintenance and technical support services for the Draeger Inc. Innovian Anesthesia and Innovian Anesthesia Analytics Reporting Tool systems, in both the Test and Production environments, within the Eastern Oklahoma VA Health Care System (EOVAHCS). This maintenance and support shall include all scheduled preventive maintenance, unscheduled repairs/corrective maintenance, server and work station upgrades and replacements, technical support, database administration support and training services described in this SOW. The Contractor shall ensure that the Innovian Anesthesia operates in a safe, effective, and efficient manner.

#### **PERFORMANCE PERIOD**

The base period of performance shall be October 1, 2019 to September 30, 2020. The Contractor shall provide support 24 hours per day, 7 days per week, and 365 days per year. Normal hours of work are defined as Monday through Friday from 7:00 a.m. to 5:30 p.m. Eastern Time, excluding Federal holidays or as otherwise arranged with the Contracting Officer's Representative (COR).

#### **PLACE OF PERFORMANCE**

Tasks under this SOW shall be performed at the EOVAHCS or may be performed remotely at Contractor facilities.

#### **TRAVEL**

All Contractor transportation, lodging, and subsistence expenses incurred by the Contractor shall be incorporated into the Contractor's fees and are the sole responsibility of the Contractor. Travel will be scheduled at the most cost-effective rate and fare, and by the most cost effective mode of travel in accordance with the General Services Administration.

#### **UPGRADES, MAINTENANCE AND TECHNICAL SUPPORT**

The Contractor shall perform all weekly proactive maintenance, remote and/or on-site maintenance, scheduled upgrades, preventive maintenance, unscheduled repairs, corrective maintenance, and technical support of all software and all hardware comprising the Draeger Innovian ARK System and components listed in Attachment 1, including all software version changes, upgrades, updates, patches, enhancements, corrections and new releases during the

performance period. VA anticipates quarterly software update releases of terminology. In turn, the contractor releases of terminology shall be per Draeger Update/Upgrade Development Process and Definitions in the section System Testing, in both the test and production environments at each Facility. The Contractor shall coordinate maintenance and support with the COR and VAMC Points of Contact (POCs).

Note: The Draeger Inc. Inventory and associated Draeger Inc. Inventory List in Attachment 1 is subject to change in order to meet VISN needs. In the event that the Inventory List of covered equipment is increased, Draeger reserves the right to adjust the charges proportional to the increase of covered equipment. Similarly, Draeger agrees to a reduction in charges if the Inventory List is reduced or to use a decrease at one facility to offset a corresponding increase at another facility if the *total* inventory does not change. The Contracting Officer may, at any time, make changes within the general scope of this contract in the Inventory items to be serviced (i.e., additions or reductions in the number of inventory items, relocation of items, etc.).

The service under this task includes all labor, tools, test equipment, diagnostic software, supplies, parts, shipping, and Contractor staff supervision necessary to perform remote and/or on-site services defined herein. The Contractor shall provide overnight, next day delivery of parts when needed to maintain full performance of the system. The Contractor shall provide shipping to return any defective parts from the VA Facility to the Contractor. There shall be no additional cost to the Government for shipping.

The Contractor shall not perform any additional services beyond those authorized at any time during the duration of the contract without the expressed written approval of the CO in accordance with the terms and conditions of this Contract. Any additional work performed without this approval, will be performed by the Contractor at no additional cost to the VA.

## **TELEPHONE AND ON-LINE SUPPORT AND TECHNICAL CONSULTATION**

The Contractor shall provide the VA with toll free corporate office telephone numbers, mobile telephone numbers, and email addresses for the Contractor's key staff for both normal hours and after hours. The Contractor shall provide telephone and online remote support 24 hours per day, 7 days per week, and 365 days per year for both maintenance and technical support. The Contractor shall allow an unlimited number of requests.

## **SCHEDULED MAINTENANCE**

The Contractor shall perform scheduled (preventive) maintenance in accordance with manufacturer's recommendations of all Draeger Innovian Anesthesia and Innovian Anesthesia Analytics Reporting Tool software and hardware. The Contractor shall initiate corrective maintenance whenever equipment defects are discovered as a result of the Contractor performing scheduled/preventive maintenance services.

The Contractor shall provide scheduled maintenance and software updates during normal working hours or at a mutually agreed upon time by the COR and the Contractor. The Contractor shall contact the COR and POCs to schedule mutually agreeable times for the performance of any scheduled activities. The Contractor shall recommend to the COR when equipment should be made available for scheduled maintenance. Upon COR approval, the Contractor shall finalize that schedule.

## **UNSCHEDULED MAINTENANCE**

The Contractor shall provide the EOVAHCS with an unlimited number of unscheduled maintenance and technical support incidents during the performance period. Support includes both remote and on-site support. Support includes weekly remote proactive maintenance of the system. The Contractor shall perform all unscheduled corrective maintenance during the performance period. The Contractor shall troubleshoot, repair and/or resolve, on request by the COR or POCs, all Innovian Anesthesia and Innovian Anesthesia Analytics Reporting Tool (where implemented) equipment, software and hardware. All software and hardware repaired by the Contractor shall be restored to manufacturer's specifications.

Equipment replacement due to maintenance remediation shall be the Contractor's responsibility. In the event that the Contractor is unable to repair or resolve an equipment problem, including all Innovian Anesthesia and Innovian Anesthesia Analytics Reporting Tool servers and associated peripheral devices and components such as, hard drives, mice, keyboards, mounting hardware, cables, etc.), the Contractor shall promptly replace the equipment at no additional cost. For technical problems, functional incidents or for questions during business hours, the Contractor shall provide communication options for EOVAHCS as described below.

For each request, the Contractor shall communicate the following via email or telephone to EOVAHCS in response to each event communicated by VA to the Contractor:

- a. Brief description of the problem
- b. What version or software is affected
- c. What equipment or component is affected
- d. If this issue affects patient safety
- e. Workaround (if any) and expected release date of patch, upgrade or update (if any)
- f. Status and estimated completion date/time

The Contractor shall communicate all known software and hardware issues to the COR weekly via email or by telephone. The Contractor shall respond to a request for unscheduled corrective maintenance for software or hardware issues, malfunctions or failures, by a fully qualified representative, in accordance with response time requirements defined in Table 1.

## **SYSTEM ENHANCEMENT SERVICES**

The Contractor shall provide all software upgrades, project management, implementation services, training and all labor associated with upgrades (on and off site), updates, and new versions including any replacement version or name revisions of the existing perpetual unlimited, non-exclusive software licenses. Onsite labor for upgrades is not included in this contract, but will be provided separately at labor rates listed in Draeger's FSS Schedule.

The Contractor shall follow the VA-nationally approved Draeger Inc. User Group standard operating procedures by which software and/or hardware enhancement requests submitted by the VA are evaluated, prioritized, and implemented into the application updates at no additional cost to VA during the duration of the contract period. The timeframe and method of delivery must be agreed upon by the COR and Contractor and must be approved by the Contracting Officer.

Upon approval, the Contractor shall coordinate and distribute enhancement and maintenance updates and releases by using an appropriate electronic media, printed media or its website in accordance with VA requirements for electronic, printed or web based media.

The Contractor shall test the system after any changes to ensure that the system continues to function in accordance with manufacturer's specifications.

## **SOFTWARE UPDATES AND UPGRADES**

Included in maintenance is the furnishing and installation of all currently licensed software updates, version changes and/or updates to the system. The Contractor shall provide continual currently licensed updates and patches, scheduled in advance, in order to keep the currently licensed components at the most current software releases and to include software feature requests. The Contractor shall provide any currently licensed updates, version changes, and updates.

All new software versions shall be covered in this effort including all subsequent versions designed to replace the version originally installed under this agreement.

As part of scheduled and/or unscheduled maintenance, the Contractor shall furnish, install and maintain all software updates, version changes and/or updates to the system. The Contractor shall offer and make available product enhancements covered under the maintenance agreement to maintain the system at the most current software releases. The Contractor shall provide any successor versions of Innovian© ARKs including, software updates, version changes, and upgrades covered under the maintenance services, with the exception of upgrade labor, which shall be made available at Draeger's then current FSS schedule labor rates.

The updates can be 1) initiated by the Contractor to improve functionality of the Innovian© Anesthesia and Innovian© Anesthesia Analytics, 2) in response to changes in VA/VISN enterprise needs, 3) to maintain the Innovian© Anesthesia and Innovian Anesthesia Analytics as compliant with VA data standards, and/or regulatory requirements, 4) to maintain compatibility with other systems, including the VA Standardized Terminology 5) to maintain VA standards in regard to security updates and patching.

It is estimated that there will be quarterly updates per year required related to maintaining standardized terminology and compatibility among systems. Regardless of the reason for the update or upgrade, the Contractor shall plan and schedule these upgrades through coordination with the COR. Software updates shall be scheduled at least thirty (30) days in advance.

Updates or corrections related to patient safety, regulatory requirements or interface to Vista will have urgent priority. The Contractor shall implement an update (fix) within 180 days if the conditions are feasible and within the Contractor's control such as, but not limited to, the need for FDA clearances or other regulatory certifications. All supporting software and release notes, user and technical literature shall be updated and provided to the EOVAHCS within 30 days of the software's release.

As VA ARK systems evolve, new functionality that is not currently known or available and beyond the scope of quarterly updates for fixes, standard terminology compliance, etc., will be desired by the Government to enhance patient safety, quality and to improve patient care. Furthermore, other Vista applications are likely to be developed in the future; therefore, the Innovian Anesthesia and Innovian Anesthesia Analytics Reporting Tool system to be installed must have the flexibility within the application to adapt to the changing needs of VA. These types of improvements are upgrades or updates defined as hardware, software and/or firmware changes that provide additional application features and functionality to an existing system. An example of an update is changing from Version 6.0 to Version 6.1. An example of an upgrade is changing from Version 6.1 to Version 7.0. All Software Updates and Upgrades shall be included as part of maintenance at no additional cost. If an upgrade requires a major hardware upgrade in order to provide the additional functions it will be made available for purchase and is not included in the maintenance contract. Upgrades to Innovian Anesthesia and Innovian Anesthesia Analytics Reporting Tool applications include changes to the database that include additions of new branches or nodes to the MindMap, reorganization of existing terms and resultant term serial numbers. The Contractor is responsible for acquiring any certifications from a regulatory agency such as the Food and Drug Administration at no additional cost.

### **Draeger Update/Upgrade Development Process and Definitions**

When a new version of a standard term database is released and provided to Draeger, Draeger will react as follows:

- Upon receipt of the Final released and approved database version from the VA User Group, Draeger R&D Engineering will review the changes from the previous database and assess the work required to incorporate the new terms.
  - o An evaluation of the changes from the previous database will be conducted with the intent of determining the extent of the work needed to revise the current version of the Innovian Anesthesia application. This evaluation should take approximately two (2) weeks from receipt of new database. This time frame may be longer if there is a need to obtain clarification on any of the new terms from the VA User Group.
- In general, changes to the database that include addition or deactivation of terms from an existing clinical concept shall be considered as an "Update" to the application. In cases where such changes to the Innovian Anesthesia application require VA feedback or

approval, these proposed changes will be reviewed during VA User Group meetings. Once the VA User Group has approved the changes, Draeger will complete the work to achieve the update. Release of an Update from Draeger R&D to the Draeger Service organization should take approximately 90 days following User Group approval of the proposed changes.

- o An Update is typically identified in the version number as an increase to the digits after the main version number. For example, 4.2 is an update from 4.1.

Changes to the database that include additions of new branches or nodes to the MindMap, reorganization of existing terms and resultant serial numbers, etc. will require more extensive development work and result in an “Upgrade” to the application. Note that Upgrades frequently require more extensive deployment efforts, including but not limited to database migrations, end-user training, etc. Release of an Upgrade from Draeger R&D to the Draeger Service Organization will depend upon the complexity of the changes and will be determined on a case by case basis.

- An “Upgrade” is typically identified in the version number as an increase to the main version number. For example, version 5.0 is an upgrade from version 4.0.

Note that any additions to the standard term database that require changes to Innovian Anesthesia requiring additional certifications from a regulatory agency such as the FDA will likely require a lengthy development, testing and certification cycle.

## **INTERFACE SUPPORT**

As part of the unscheduled and scheduled maintenance, the Contractor shall ensure that all Innovian Anesthesia and Innovian Anesthesia Analytics Reporting Tool side interfaces, including but not limited to, Vista, Vista Imaging/CPRS, Medical Devices, analytics, Anesthesia Record Keeper (ARK), etc.) and data transfer links are maintained consistently throughout the period of performance.

The Contractor shall coordinate with other Vendors and/or Contractors when necessary to accomplish this. The VA shall also be responsible for assisting Draeger in the effort to coordinate with other Vendors and/or Contractors by encouraging them to cooperate with Draeger’s effort to support the interfaces with their systems and participating in any required discussions.

### **Vista INTERFACE Support**

The integration of Draeger Inc. Innovian Anesthesia with Vista shall be maintained by the Contractor to ensure that the Innovian Anesthesia side of the interface provides for transfer of clinical and administrative data between the Innovian Anesthesia and the Vista system at EOVAHCS. EOVAHCS shall implement the Vista side of the interfaces under a separate contract using the Document Storage Systems (DSS) DataBridge interface.

The Contractor shall certify to the Contracting Officer and COR that its Innovian Anesthesia interface with VistA meets VHA National standards. The Contractor must perform ongoing certification as DataBridge updates are/or Draeger Inc. updates are released quarterly in order to verify that the Innovian Anesthesia retains full functionality and integration through the DSS DataBridge to VistA.

The Contractor shall coordinate with other Vendors and/or Contractors when necessary to accomplish this task.

### **MEDICAL DEVICE INTERFACES Support**

The Draeger Inc. Innovian Anesthesia side of the medical device interface shall be maintained and supported by the Contractor. Interfaces include physiological monitors, ventilators, anesthesia machines and other medical devices.

The Contractor shall coordinate with other Vendors and/or Contractors when necessary to accomplish this task.

### **ADDITIONAL MEDICAL DEVICES AND INTERFACE CABLES**

The Contractor will provide EOVAHCS with an unlimited number of new/additional SW interfaces during the performance period and shall perform all work associated with new medical device interfaces requested during the performance period at no additional cost.

In addition, the Contractor shall provide all associated additional and replacement interface cables required for any interfaces (existing or new) at the pricing in Draeger's current FSS contract.

### **ANALYTICS INTERFACE SUPPORT**

The Contractor shall support integration of Draeger Inc. Innovian Anesthesia with VistA systems on this contract and ensure the capability to extract clinical data from the Innovian Anesthesia for input to analytics databases which may include, but not be limited to, Draeger Inc. Data Repositories, VHA or VISN data warehouses, or commercial analytics systems.

The Contractor shall implement and maintain data integrations with the analytics databases and with the VistA systems in EOVAHCS through the DSS DataBridge interface or other means.

The Contractor shall ensure, as far as it depends upon the Contractor that data is inclusive of all administrative and clinical data contained within the Innovian Anesthesia. The Contractor shall ensure that Innovian Anesthesia provides the data extracts to the analytics database(s) in the

proper format. The Contractor shall coordinate with analytics Contractor(s), VA data warehouse staff, VAMC staff and the COR to validate the data.

The Contractor shall coordinate with other Vendors and/or Contractors when necessary to accomplish this task.

## **REPORT TEMPLATE SHARING**

All Draeger Inc. Innovian Anesthesia and Innovian Anesthesia Analytics Reporting Tool (where implemented) “reports” produced using data aggregation, analytics, stored procedures, extractions, reporting services, business intelligence tools, or any other method, for information gathering and expressing (in any format) including but not limited to such as statistical analysis, compliance measures, performance measures, audits, quality improvement, usage trends, etc., that are developed by the Contractor for any VA facility or a VISN, must be made available to all other VA facilities having the same Contractor at no additional cost to VA.

## **SYSTEM TESTING**

The Contractor shall participate in testing of the Innovian Anesthesia software and interfaces in accordance with the current version of the Government-approved Innovian Anesthesia Test Script, including connectivity tests with VistA, medical devices, VA networks, servers, work stations, data marts and data extractions for VA and/or commercial analytics systems. Upon completion of any Innovian Anesthesia and Innovian Anesthesia Analytics Reporting Tool software repairs, updates, upgrades and installations, the Contractor shall test the system to ensure it is fully functional in accordance with the manufacturer specifications. The Contractor shall also be responsible for validating compliance with VA data standards and terminology for the clinical data in the Innovian Anesthesia.

Testing shall be coordinated and scheduled with the COR and facility POCs. The Contractor shall in conjunction with VA create for approval Test Plan for installation of updates and upgrades including comprehensive test scripts that shall include a comprehensive actual-patient, parallel test. The Test Plan shall encompass a phased approach in which the integration with Interfaces is demonstrated in Phase I to ensure that no changes that were made to the system following the initial validation caused unintended effects that degraded the integration of the Innovian Anesthesia with the Interfaces.

Phase II shall demonstrate the validation of existing Innovian Anesthesia and Innovian Anesthesia Analytics Reporting Tool Reports to ensure they function properly after the update or upgrade and data extraction capability of the Innovian Anesthesia to the analytics database(s) to similarly show no degradation to the capability during the system development and integration. It is anticipated that continued refinement of the test scripts will occur throughout the life of the contract at no additional costs to VA and will be reviewed as needed by VA. The third phase shall demonstrate the full end-to-end functionality of the Innovian Anesthesia and Innovian

Anesthesia Analytics Reporting Tool prior to final acceptance of an update or upgrade in a patient environment.

In addition to testing for the immediate functionality of the Innovian Anesthesia in accordance with the System Specification, this test plan shall specifically incorporate user management, session management with VistA; data exchange with VistA; and extraction of data for completeness and for compliance with data standards and VA terminology. The Contractor must provide initial detailed scenarios for testing that demonstrate full functionality of the application. These scenarios may be modified by the VA to include specific elements of the interface as defined in System Specifications.

The Contractor shall participate with VA in the system testing in accordance with the VA-approved Test Plan, including connectivity with medical devices and for readiness for operation at the VA facilities and on the VA networks and servers. The Contractor shall also be responsible for validating compliance with VA data standards and terminology for the clinical data in the Innovian Anesthesia; and for testing the integrations of the Innovian Anesthesia with VistA/Interfaces and with any data extraction or transfer.

#### **MANDATORY CHECK IN/OUT AND REMOVABLE MEDIA SCANNING**

For any services performed on-site the Contractor shall, upon arrival at EOVAHCS, report to the Facility POC to check in before proceeding to the any department and before performing any services. Prior to leaving the medical center, the Contractor shall check out with the POC. This check in and check out is mandatory.

Upon check in with the Facility POC and before performing any services, the Contractor shall ensure that any removable media is scanned by the Biomedical Engineering Section prior to connecting to any EOVAHCS network, device or system. The Contractor shall provide any removable media to Biomedical Engineering staff. Biomedical Engineering staff will perform a malware/virus scan of the Contractor's removable media. If "nothing found" is displayed, the Contractor may proceed and use the removable media. If "nothing found" is not displayed and/or the number of detections is greater than zero (0), the removable media shall be presumed infected with malware and shall not be allowed to be used. The media shall be returned to the Contractor for virus removal. The Government will not perform any virus or malware removal on the Contractor's removable media. Biomedical Engineering will report any detection to the Facility Information Security Officer (ISO). Failure by the Contractor to check in, check out, provide removable media for scanning, or use of any infected media is a breach of security and shall be acted upon in accordance with the terms and conditions of this contract.

#### **RESPONSE TIME**

The Contractor shall provide the upgrades, maintenance and technical support within a specified time published in the response time requirements below in Table 1. If the problem cannot be resolved over the phone or remotely, then an authorized representative of the company will

commence work within the designated time identified, and will proceed progressively to rectify the problem without undue delay without any additional cost to the government. The Contractor shall be responsible to coordinate the method of response with the COR.

1. **Urgent priority** is defined as any issue that affects patient safety, regulatory compliance, and/or Innovian Anesthesia interfaces which affect life and/or property. Urgent priority applies when malfunction or failure can result in patient injury or death or significant damage to equipment. This includes any issue that adversely impacts patient care. Examples include partial or complete system outages, interruptions making a critical functionality inaccessible, interruptions causing a severe impact on application availability, or data corruption resulting in missing or incorrect patient information, duplicate records, loss of data, etc. Urgent priority requires immediate action by the Contractor.

2. **High priority** is defined as having a potential to affect patient care such as degradation in performance or functionality, work flow interruptions or delays, etc. High priority warrants special attention and takes precedence over normal and low priorities. Examples include interruption to critical functionality, access denied to data and systems, sustained degraded or unusable capabilities, not life threatening but having a potential for impact on services availability if not resolved. High priority also requires immediate action by the Contractor in order to minimize risk of becoming an urgent priority event.

3. **Normal priority** is defined as a defect or fault event but the system is operable with no impact to patient care. Normal priority requires same day initial action but resolution may take more time. Examples include impairment of non-critical functions or procedures, capabilities that have become unusable or hard to use but with no direct impact on patient care services or system availability. Normal priorities will typically have a workaround available. Normal priorities take precedence over low priorities.

4. **Low priority** is defined as preventive maintenance or issues that do not require immediate action or attention.

Table 1. Listed response times by priority types as defined by VA. The Contractor shall meet the response time requirements associated with each priority:

	<b>Call Back Response</b>	<b>Remote-Log In Response</b>	<b>Turn Around Time (to restore to full performance)</b>
<b>Urgent</b>	<b>1 hour</b>	<b>1 hour</b>	<b>8 hours</b>
<b>High</b>	<b>2 hours</b>	<b>2 hours</b>	<b>16 hours</b>
<b>Normal</b>	<b>2 hours</b>	<b>8 hours</b>	<b>40 hours</b>
<b>Low</b>	<b>4 hours</b>	<b>10 hours</b>	<b>48 hours</b>

If Full Performance cannot be restored within the above timelines an on-site response may be required as agreed upon by VA and Contractor. Full performance means that all defective software, hardware and/or parts have been replaced with equivalent to or better than the original

manufacturer's parts and that replacements meet or exceed the manufacturer's original performance specifications.

## **SYSTEM UPTIME**

The system uptime shall be operable and available for use at least 98.9% of the time, 24/7. Downtime will be computed from notification of problem. Scheduled maintenance will be excluded from downtime during normal working hours as detailed herein. Operational Uptime will be computed during a month long time period. Repeated failure to meet this requirement can subject the Contractor to Termination for Cause action.

## **SERVICE REPORTS**

The Contractor shall provide a Service Report to the Facility VA Point of Contact (POC) designated by the COR at the completion of a service call prior to departing the EOVAHCS or at the conclusion of remote service.

The Service Report shall document the services rendered and shall include equipment description, model, equipment entry (barcode) number, serial number, date and time of service, description of services, the latest version of software patch or upgrade, results of services, name of individual who performed the services, and travel, labor and parts information.

## **Monthly ELECTRONIC SERVICE LOG**

The Contractor shall provide and maintain an Electronic Service Log for tracking of all services performed under this contract. This Electronic Service Log shall be VA-accessible. The content of the log shall include all service calls, repairs, updates, upgrades, version changes, or changes required to the system and special service requests generated throughout the duration of the contract. For each service item, the Electronic Service Log shall include a unique reference number, date and location of service, problem, staff assigned, actions taken, follow up actions required, estimated completion time, completion time, date complete. This log will be provided to the Government monthly in Excel format. The Contractor shall provide a sample of the above log for approval by the COR before implementing the Electronic Service Log.

## **MANUALS, RELEASE NOTES, AND SERVICE BULLETINS**

The Contractor shall provide an electronic copy of the user manuals, system administrator manuals, operating/maintenance and/or technical manuals, release notes, service bulletins, etc. necessary for the operation and support of the software and hardware to the COR.

## **SECURITY REQUIREMENTS**

This Draeger Inc. Innovian Anesthesia and Innovian Anesthesia Analytics Reporting Tool upgrades, Maintenance and Technical Support contract involves the Contractor's access, use of VA secure networks and equipment and exposure to VA sensitive personal information while implementing contract services defined herein. This contract does not intentionally involve the use or disclosure of sensitive information as the object of this contract. Any access to sensitive information by the Contractor personnel in completion of their services is considered incidental. Access and exposure to VA sensitive personal information occurs as a by-product of Contractor personnel duties and cannot be reasonably prevented. As such, in accordance with Department of Veterans Affairs Memorandum, "VA Maintenance/Installation (Warranty) Contracts (VAIQ 7058822), dated March 24, 2011, such disclosures are incidental and permitted by the HIPAA Privacy Rule (see 45 CFR 164.502 (a)(1). Furthermore, this contract includes the following five requirements per 38 U.S.C.§§ 5723 and 5725:

a. Prohibition on unauthorized disclosure: "Information made available to the contractor or subcontractor by VA for the performance or administration of this contract or information developed by the contracting in performance or administration of this contract shall be used only for those purposes and shall not be used in any other way without the prior written agreement of the VA. See Handbook 6500.6, Appendix C, paragraph 3.a.

b. Data breach notification: Upon discovery of any known or suspected security/privacy incidents, or any unauthorized disclosure of sensitive information, including the contained in system(s) to which the contractor/subcontractor has access, the contractor/subcontractor shall immediately and simultaneously notify the COR, the Designated ISO and Privacy Officer for the contract. The term "security incident" means an event that has or could have resulted in the unauthorized access to, loss or damage to VA assets, or sensitive information, or an action that breaches VA security procedures. See VA Handbook 6500.6, Appendix C, paragraph 6.a.

c. Requirement for pay liquidated damages in the event of a data breach: In the event of a data breach or privacy incident involving sensitive personal information the contractor processes or maintains under this contract, the contractor shall be liable to VA for liquidated damages of \$37.50 per affected individual to cover the cost of providing credit protection services to those individuals. See VA Handbook 6500.6, Appendix C, paragraph 7.a, 7.d.

d. Requirement for annual security/privacy awareness training: Before being granted access to VA information or information systems, all contractor employees and subcontractor employees requiring such access shall complete on an annual basis either: (i) the VA security/privacy awareness training (contains VA's security/privacy requirements) within 1 week of the initiation of the contract, or (ii) security awareness training provided or arranged by the contractor that conforms to VA's security/privacy requirements as delineated in the hard copy of the VA security awareness training provided to the contractor. If the contractor provides their own training that conforms to VA's requirements, the Contractor shall provide the COR or CO, a yearly report (due annually on the date of the contract initiation) stating that all applicable employees involved in VA's contract have received their annual security/privacy training that meets VA's requirements and the total number of employees trained. See VA Handbook 6500.6, Appendix C, paragraph 9.

e. Requirement to sign VA's Rules of Behavior: Before being granted access to VA information or information systems, all contractor employees and subcontractor employees requiring such access shall sign on an annual basis an acknowledgement that they have read, understand, and agree to abide by VA's Contractor Rules of Behavior which is attached to this contract or by completing the VA Talent Management System (TMS) "VA Privacy and Information Security Awareness and Rules of Behavior" course. See VA Handbook 6500.6, Appendix C, paragraph 9, Appendix D. Note: If a medical device vendor anticipates that the service under the contract will be performed by 10 or more individuals, the Contractor Rules of Behavior may be signed by the vendor's designated representative. The contract must reflect by signing the Rules of Behavior on behalf of the vendor that the designated representative agrees to ensure that all such individuals review and understand the Contractor Rules of Behavior when accessing the VA's information and information systems

## **ACCESS TO VA INFORMATION AND VA INFORMATION SYSTEMS**

The contractor/subcontractor shall request logical (technical) and/or physical access to VA information and VA information systems for their employees, subcontractors, and affiliates only to the extent necessary to perform the services specified in the contract, agreement, or task order. The contractor or subcontractor must notify the Contracting Officer immediately when an employee working on a VA system or with access to VA information is reassigned or leaves the contractor or subcontractor's employ. The Contracting Officer must also be notified immediately by the contractor or subcontractor prior to an unfriendly termination.

Contractor employees shall complete a VA Systems Access Agreement if they are provided access privileges as an authorized user of the computer system of VA.

The Contractor will notify the COR immediately when their employee(s) no longer require access to VA computer systems.

## **GENERAL**

The Contractor, contractor personnel, subcontractors, and subcontractor personnel shall follow, and shall be subject to, the same Federal laws, regulations, standards, and VA Directives and Handbooks as VA and VA personnel regarding information and information system security, handling of privacy information and shall be subject to penalties associated with the release of such data. Failure to comply with the Contractor personnel security requirements may result in termination of the contract for default.

The Contractor shall ensure adequate LAN/Internet, data, information, and system security in accordance with VA standard operating procedures and this SOW, conditions, laws, and regulations. The Contractor's firewall and web server shall meet or exceed VA minimum requirements for security. All VA data shall be protected behind an approved firewall. Any

security violations or attempted violations shall be reported to the VA Program Manager, COR and VA Information Security Officer as soon as possible.

The Contractor shall not transmit, store or otherwise maintain sensitive data or products in the Contractor systems (or media) within, or outside, the VA firewall in accordance with VA Handbook 6500.6 dated March 12, 2010. All VA sensitive information shall be protected at all times.

### **NATIONAL CONTRACTOR ACCESS PROGRAM, INTERCONNECTION SECURITY AGREEMENT /MEMORANDUM OF UNDERSTANDING AND REMOTE ACCESS**

The Draeger Inc. Innovian Anesthesia and Innovian Anesthesia Analytics Reporting Tool Upgrades, Maintenance and Technical Support contract involves Contractor remote access to VA VISN 16 networks in accordance with the VA OIT National Contractor Access Program (NCAP). Inter-connection between the Contractor and VA shall be via an approved Site to Site Virtual Private Network (VPN) under an Interconnection Security Agreement/ Memorandum of Understanding/ (ISA/MOU) approved for the Site to Site VPN. VA will provide access to EOVAHCS Draeger Inc. Innovian Anesthesia and Innovian Anesthesia Analytics Reporting Tool systems as required for execution of the tasks via the remote access site to site VPN technology, which will provide Contractor access to EOVAHCS' Innovian Anesthesia specific hardware and software. This enables the Contractor to perform the required Upgrades, Maintenance and Technical Support.

The Draeger Inc. Innovian Anesthesia/VA utilizes a Memorandum of Understanding (MOU) to document the terms and conditions for sharing data and information resources in a secure manner. The supporting information within the MOU will define the purpose of the interconnection, identify relative authorities, specify the responsibilities of both organizations, and define the terms of the agreement. Additionally, the MOU provides details pertaining to apportionment of cost and timeline for terminating or reauthorizing the interconnection.

### **VA DIRECTIVE 6550 PRE-PROCUREMENT ASSESSMENT**

The Contractor shall complete the VA Directive 6550 Pre-Procurement Assessment and Manufacturer's Disclosure Statement worksheet as necessary for networked Innovian Anesthesia devices. These must be completed to assure that Innovian Anesthesia devices are integrated effectively and securely.

### **NON-DISCLOSURE AGREEMENT**

In performance of this effort, contract support personnel will be required to execute a Non-Disclosure Agreement and report any Organizational Conflict of Interest. The Contractor shall not disclose any information encountered during the conduct of this work.

The Contractor shall keep confidential, not disclose, or make use of VA information, at any time either during or subsequent to the contract performance period, any confidential information, knowledge, data or other information of the VA relating to processes, test data, customers,

business plans and strategies, budgetary information or other subject matter pertaining to any business of the VA. This agreement also pertains to any deliverable during the course of this contract. The Contractor shall not deliver, reproduce, or in any way allow any such confidential information, knowledge, data or other information or any documentation relating thereto, to be delivered to or used by any third parties, including the Contractor, without specific direction or consent of a duly authorized representative of the VA. The Contractor must maintain VA proprietary and otherwise confidential information. Knowledge and data in confidence shall only be relieved by written consent from VA. At the conclusion of this contract or in the event of termination of Contractor personnel with the Contractor, the Contractor personnel agree to promptly surrender and deliver to VA all records, materials, equipment, documents and data of any nature pertaining to the business of the VA. The Contractor personal will not take with them any confidential information knowledge, data or other information, or any documentation, which may be produced or obtained during the course of this contract.

#### **BUSINESS ASSOCIATE AGREEMENT**

The contractor shall have a Business Associate Agreement (BAA) and safeguard Personal Health Information (PHI) agreements.

