(September 2021)

PERFORMANCE CRITERIA
FOR

SECTION 11 76 00

OPERATING ROOM EQUIPMENT
09/21

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GENERAL
This Performance Criteria specifies the requirements for operating room equipment.

[This section includes healthcare equipment in primarily surgical settings. Refer to section 11 72 00 EXAMINATION AND TREATMENT EQUIPMENT for healthcare equipment in primarily outpatient settings. Refer to section 11 73 00 PATIENT CARE EQUIPMENT for healthcare equipment in primarily inpatient settings.]

1.1 REFERENCE

1.1.1 Unified Facilities Criteria (UFC)
Contractor shall comply with the following:
- **A.** UFC 1-200-01 General Building Requirements
- **B.** UFC 1-200-02 High Performance and Sustainable Building Requirements
- **C.** UFC 3-120-10 Interior Design
- **D.** UFC 4-510-01 Military Medical Facilities

1.1.2 Military Standard
- **A.** MIL-STD 1691 Construction and Material Schedule for Medical, Dental, Veterinary and Medical Research Laboratories

1.1.3 National Fire Protection Association (NFPA)
- **A.** NFPA 99 Healthcare Facilities Code
- **B.** NFPA 101 Life Safety Code

1.1.4 Military Health System Standards
- **A.** Reserved for future

1.1.5 American National Standard (ANSI)
- **A.** ANSI Z136.1 American National Standard for Safe Use of Lasers

1.1.6 Underwriters Laboratories (UL)

A. UL 60601-1 Medical and Electrical Equipment, Part 1: General Requirements for Safety

1.1.7 International Electrotechnical Commission (IEC)

A. IEC 60601 Medical Electrical Equipment and Systems

1.1.8 Food and Drug Administration

A. CFR Title 21, Chapter I

1.1.9 International Organization for Standardization (ISO)

A. ISO 4135 Anesthetic and Respiratory Equipment - Vocabulary
B. ISO 5366 Anesthetic and Respiratory Equipment - Tracheostomy Tubes
C. ISO 5358 Anesthetic Machines for use with Humans
D. ISO 9001 Quality Management Systems
E. ISO 13485 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

1.1.10 Other Standards

A. Reserved for future

2.1 DESCRIPTION & MATERIALS

All requirements within the MIL-STD 1691 JSN descriptions must be met as well as the performance guidelines listed in the following descriptions.

2.1.1 All JSN'S

A. Paints, fabrics, and finishes must be selected from the manufacturer's standard options for the specified model unless noted otherwise.
B. All product finishes must be capable of maintaining sheen and color through warranty period when using industry standard cleaning and disinfection solutions.
C. All display panel surfaces must maintain clarity through warranty period when using industry standard cleaning and disinfection solutions.
D. All equipment that have components that are meant for reuse must be autoclavable or able to withstand industry standard cleaning and disinfection processes.
E. Electrified equipment must be 115 Volt 15 amp maximum unless noted otherwise.
F. Casters provided must be designed for use on the installed floor finish.
G. All products that have interoperability capable hardware (i.e. internal storage, data transmission via wireless, Ethernet, LAN, or USB to PC or server connectivity) must meet Cybersecurity requirements in accordance with DoDI 8510.01 Risk Management Framework.
H. DoDI 8510.01 applies to all DoD IT (medical devices included) that receive, process, store, display, or transmit DoD information. These technologies are broadly grouped as DoD IS, platform IT (PIT), IT services, and IT products. This includes IT supporting research, development, test and evaluation (T&E), and DoD-controlled IT operated by a contractor or other entity on behalf of the DoD solutions.

2.1.2 Anesthesia (Diagnostic)

M0630 – Anesthesia Apparatus, 3-Gas

A. Display must be LCD high contrast with continuous display of measured parameters. Display text will be readable in any ambient light level.
B. Alarm notifications must have options using visual or auditory or both for all monitored parameters.
C. Gases will have easy to read gauges for the operator.
D. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External parts must allow for thorough cleaning and disinfection. All components that come into contact with fluids or gases must be disposable or easily disinfected if being reused.
E. Unit must be suitable to accommodate patients of all ages and body weights.
F. Unit must be portable, mounted on wheeled base with at least two braking casters
G. Provide automatic battery backup in case of power loss.
H. Integrated monitor or standalone physiological monitor must be included. If no monitor, device compatible with connectivity to existing patient monitoring system.

I. Compatible with intra-operative anesthesia recording device that transfers patient data to electronic health record.

J. Basic unit will have three drawers one shallow, one medium, and one deep, seven long scale eleven-inch flowmeters, five cylinder yokes, and telescoping absorber post. Include two-canister model carbon dioxide absorber with inhalation and exhalation check valves, switch valve, switch valve elbow, sidearm Vernitrol, flow calculator, mouting kit, ventilator calculator, ventilator and oxygen popping inlet. Unit will include nitrous oxide fail save valve kit, aspiratior kit, gas evacuator with vacuum and flow meter safety cover.

2.1.3 Endoscopy (Diagnostic)

A. Endoscopy Equipment

M8516 – Heat Probe Unit, Endoscopic
M8550 – Light Source, Fiber Optic, Endoscopy
M8551 – Light Source, Fiber Optic, Headlamp
M8552 – Camera, Video W/Headlamp, Light Source
M8555 – Insufflator Automatic Controls
M8556 – Electrosurgical Unit, Endoscopy
M8557 – Suction Unit, Endoscopy

1. Display must be LCD high contrast with continuous display of measured parameters. Display text will be readable in any ambient light level.
2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External parts must allow for thorough cleaning and disinfection. All components that come into contact with fluids or gases will be disposable or easily disinfected if being reused.

B. Endoscopy Cart

M8605 – Endoscopy Cart, Fiber Optic, Basic
M8606 – Endoscopy Cart, Fiber Optic, w/Video Accessories
M8607 – Endoscopy Cart, Fiber Optic, w/Video, Info. Mgmt.
M8610 – Endoscopy Cart, Video (CCD) Scope
M8611 – Endoscopy Cart, Video (CCD) Scope, with Info. Mgmt

1. Display must be LCD high contrast with continuous display of measured parameters. Display text will be readable in any ambient light level.
2. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External parts must allow for thorough cleaning and disinfection. All components that come into contact with fluids or gases will be disposable or easily disinfected if being reused.
3. Unit must be portable, mounted on swivel caster base with at least two braking casters and bumpers on all four sides.
4. Provide integrated electrical cord management.
5. Carts will have accessory options available for shelves, drawers, flat panel monitor arms, keyboard trays, IV poles, and scope holders.
6. Cart system includes cart, light source, insufflator, suction unit, heat probe unit, an electrosurgical apparatus, video controller, monitors, video recorder and a color printer.
7. Hardware will include wireless, Ethernet, or USB to PC connectivity for data transmission.

2.1.4 Surgical Icemakers (Support)

R4785 – Ice Maker, Surgical Slush

A. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External parts must allow for thorough cleaning and disinfection. All components that come into contact with fluids or gases will be disposable or easily disinfected if being reused.

B. Provide quiet system that does not disturb the operating room environment.

C. Unit must be portable on locking casters.

2.1.5 Blood Warmers (Treatment)

M8950 – Warmer, Blood
M8970 – Warner, Blood, High Volume

A. Display must be LCD high contrast with continuous display of measured parameters. Display text will be readable in any ambient light level.

B. Alarm notifications must have options using visual or auditory or both.

C. Achieve a temperature of 38^{O}C at a flow rate of 2 – 150ml/min. Allows for adjustment of temperature in 1 degree

increments.

D. Unit will be light weight and portable.

E. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External parts must allow for thorough cleaning and disinfection. All components that come into contact with fluids or gases will be disposable or easily disinfected if being reused.

F. Unit must be capable of mounting on an IV stand or cart/trolley. Mobile stand is must be supplied by the manufacturer.

2.1.6 Cardiology (Treatment)

M4808 – Thrombectomy Device, Rheolytic
M4810 – Heart/Lung Machine, Bypass, Modular
M4811 – Pump, Intra-Aortic, Balloon

A. Display must be LCD high contrast with continuous display of measured parameters. Display text will be readable in any ambient light level.

B. Alarm notifications must have options using visual or auditory or both.

C. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External parts must allow for thorough cleaning and disinfection. All components that come into contact with fluids or gases will be disposable or easily disinfected if being reused.

D. Unit must be portable, mounted on swivel caster base with at least two braking casters.

E. Hardware will include wireless, Ethernet, or USB to PC connectivity for data transmission options.

2.1.7 Drills (Treatment)

M4830 – Drill, Surgical, Air Drive
M4831 – Drill, Surgical, Electric Drive

A. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External parts must allow for thorough cleaning and disinfection. All components that come into contact with fluids or gases will be disposable or easily disinfected if being reused.

B. If system is rechargeable, a charging station with batteries must be provided from the same manufacturer.

2.1.8 ESU/Ablation (Treatment)

A. Electrosurgical Equipment

M3108 – Electrosurgical Unit, Mobile, Unblended
M3109 – Electrical/Coagulator, Argon Plasma
M3170 – Electrosurgical Loop Excision System
M3175 – Electrosurgical Unit, Dual Output
M3177 – Ultrasonic Tissue Ablation System
M3185 – Electrosurgical Unit, Monopolar, Wall Mounted
M3190 – Generator, RF Cardiac Ablation
M3195 – Coagulator, Infrared
M8528 – Laser Tissue Ablation

1. System must consist of a cart, generator and smoke evacuator in one compact station
2. Display must be LCD high contrast with continuous display of measured parameters. Display text will be readable in any ambient light level.
3. Multifunction generator with both monopoloar and bipolar modes, self-diagnostics, and recall of stored power settings.
4. Power level must be adjustable by user. [Control will be provided by foot pedal with 6 foot connection cable.]
5. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External parts must allow for thorough cleaning and disinfection. All components that come into contact with fluids or gases will be disposable or easily disinfected if being reused.
6. Unit must be portable, mounted on swivel caster base with at least two braking casters.
7. Equipment must have protections against defibrillator discharges.
8. Unit will have the capability to regulate output while simultaneously monitoring system for safety hazards.
9. Unit must provide audible safety features for operating settings with an automatic self-test mechanism.

B. Smoke Evacuation

M5512 – Laser, Smoke Evacuator

M8523 – Evacuation System, Smoke, Surgical

1. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External parts must allow for thorough cleaning and disinfection. All components that come into contact with fluids or gases will be disposable or easily disinfected if being reused.
2. Disposable filter system will be included.
3. Smoke evacuation system must utilize 4-stage ULPA filtration to remove 99.99% of smoke contaminants from the surgical site.
4. Must accommodate a variety of tubing sizes.
5. Multiple flow settings must meet the needs of several different procedure types.

2.1.9 Laser (Treatment)

M8525 – Laser, Surgical, CO2
M8526 – Laser, Pulsed Dye
M8527 – Laser, Surgical, KTP

A. Display must be LCD high contrast with continuous display of measured parameters. Display text will be readable in any ambient light level.

B. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External parts must allow for thorough cleaning and disinfection. All components that come into contact with fluids or gases will be disposable or easily disinfected if being reused.

C. All manufacturer safeguard options must be included with the equipment to protect the operator from harm during normal operation. All external surfaces must remain at safe temperatures during use.

D. Electrified mobile lasers must be 115 Volt 20 amp maximum all other lasers must be 240v 30 amp maximum unless noted otherwise.

2.1.10 Operating Table (Treatment)

M9060 – Table, Minor Surgery, Pedestal, 4 Section, Mobile
M9075 - Table, Operating, Fracture, Orthopedic
M9080 - Table, Operating, Pedestal, 5 Section
M9095 - Table, Operating, Remote Control
M9100 - Table, Procedure, Urological
M9110 - Table, Operating, 5 or 6 Section, Trauma
M9115 - Table, Operating, Spinal

A. All exposed metal parts, including the table base, must be constructed of stainless steel. Construction must be free of sharp edges, non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Non-metal parts must be anti-static, antimicrobial, non-porous, and impervious to fluids.

B. Upholstery must be removable from table for easy cleaning. Mattress pad must match layout of table across sections and accessories.

C. Designed to protect patient from excess manipulation, trauma, and abrasion.

D. Tables must support patient's weight (500 lbs. minimum) and body during surgical procedures, stabilizing patient's position and providing optimal exposure of the surgical field.

E. Table control must be provided by foot pedal or remote control.

F. Base must be non-mobile, fixed, mobile on swivel caster with brakes. Base will not obstruct operator access to patient.

G. Table must have battery back-up to operate, in case of lost power.

H. Table movements will be motorized and able to be controlled individually or grouped. Functions allow for separate movement of head, torso, and legs as well as overall height adjustment for ease of user access.

I. Table must have the following accessories:

1. Lateral bars for accessories.
2. Armrests.
3. Arm Guards.
4. Side restraints.
5. Leg slings.
6. Leg supports.
7. Foot supports and extension.
8. Hand supports.
9. Head supports or Rests.

10. Shoulder support.
11. Wrist support.
12. Sterilizable basin.
13. Table Pads.
14. Anesthesia frames.
15. Lateral Supports.

2.1.11 Patient Temperature Management (Treatment)

A. Patient Warming/Cooling

M4815 – Hypo/Hyperthermia Unit, Automatic/Manual, Mobile

1. Units designed to warm or cool a patient by circulating liquid.

2. Units consist of a central device including a cooling system, a heating element, and pumps for circulating liquid with a specially designed reusable or disposable blanket with appropriate channels for liquid circulation.

3. Display must be LCD high contrast with continuous display of measured parameters. Display text will be readable in any ambient light level.

4. Alarm notifications must have options using visual or auditory or both.

5. Various preset temperature settings must be available.

6. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External parts must allow for thorough cleaning and disinfection. All components that come into contact with fluids or gases will be disposable or easily disinfected if being reused.

7. Unit must be capable of mounting on a mobile stand or rail. If mobile include mobile cart or trolley supplied by the manufacturer.

B. Patient Warming

M4816 – Warming Unit, Patient, Automatic/Manual Air

1. Unit designed to warm the patient by blowing warm air across the patient.

2. These units consist of a warming device with a thermostatically controlled fan heater (blower) heating and forcing the air circulation, a specially designed reusable or disposable blanket for the patient, and a flexible hose that attaches to an inlet in the warming blanket.

3. Display must be LCD high contrast with continuous display of measured parameters. Display text will be readable in any ambient light level.

2. Alarm notifications must have options using visual or auditory or both.

3. Various preset temperature settings must be available.

4. Provide construction that is non-porous, impervious to fluids, non-ferrous, and corrosion resistant. External parts must allow for thorough cleaning and disinfection. All components that come into contact with fluids or gases will be disposable or easily disinfected if being reused.

5. Unit must be capable of mounting on a mobile stand or rail. If mobile include mobile cart or trolley supplied by the manufacturer.

2.1.12 Surgical Microscopes (Treatment)

M8530 Microscope, Operating, Ceiling Mounted
M8534 Microscope, Operating, Portable, General Use
M8535 Microscope, Operating, Portable
M8540 Microscope, Operating, Wall Mounted

A. Used to magnify minute structures (e.g., nerves, vessels) in the performance of delicate surgical procedures which require high magnification and adjustable focusing

B. Surgical microscopes typically consist of a stereo microscope (standard or modified) and a mobile floor stand or wall or ceiling mount.

C. Microscopes must be held by an adjustable arm attached to a support mechanism.

D. Include variable magnification lens selection and fine focus adjustments on eyepiece.

E. LED or halogen light sources msut be provided with variable light intensity controller.

F. Construction must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant.

G. Unit must be capable of various mounting options including mobile, wall, table and ceiling mounts.

H. Hardware will include port for input and output data transmission using the manufacturers standard software interface.

I. Include output connections to display and record images/video to an external monitor.

2.1.13 Warming Cabinets (Treatment)

M3105 Cabinet, Warming, F/S, 1 Heated Compartment, Elect

M3110 Cabinet, Warming, F/S, 2 Heated Compartment, Elect

A. Intended for warming of IV fluids, irrigation solutions, linens and blankets.

B. Adjustable shelving for flexible organization and storage.

C. "Look-In" glass doors to provide visual inventory control without need for opening doors

D. Display must be LED/LCD high contrast with continuous display of measured parameters. Display text will be readable in any ambient light level.

E. Construction must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant.

2.1.14 Warming System (Treatment)

M3120 Warming System, Irrigation Fluid, Mobile

A. Unit designed to warm irrigation fluids at optimum flow rates. Keeps patient temperature warm during high volume irrigating procedures.

B. Display must be LCD high contrast with continuous display of measured parameters. Display text will be readable in any ambient light level.

C. Construction must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components that come into contact with will be disposable or easily disinfected if being reused.

M4287 Irrigation System, Surgical (Recommend change to Irrigation System, Arthroscopic)

A. Unit used during endoscopic orthopedic procedures to keep the cavity of a joint (typically the knee, but also shoulder, elbow, hips and other joints) filled with pressurized distention solution.

B. Display must be LCD high contrast with continuous display of measured parameters. Display text will be readable in any ambient light level.

C. Construction must be non-porous, impervious to fluids, non-ferrous, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components that come into contact with will be disposable or easily disinfected if being reused.

2.1.15 Monitor, Display, Medical Grade (Treatment)

M7801 Monitor, Display,Medical Grade 26-42"

M7802 Monitor, Display,Medical Grade 55-65"

A. High-definition video monitors designed to display electronic images with a definition that is high enough for examination and diagnosis of most medical images (e.g., radiographic, ultrasonic, MRI).

B. Display resolution must be equal to or better than high-definition (1080 pixels of vertical resolution, i.e., 1920 x 1080 pixels).

2.1.16 Navigation System, Electrophysiology (Treatment)

M7862 Navigation System, Electrophysiology Mapping

A. Stereotactic image-guided computer-aided system designed to provide the capability to map the three-dimensional (3-D) anatomy of the heart.

B. Designed to determine the electrophysiologic data at any given mapped-out point, design the ablation strategy, and then return accurately to the desired site to aid in the performance the ablation procedure.

C. System typically consist of a cardiac catheter with electrodes and miniaturized coils at the tip, a magnetic-field generator located underneath the patient, a computerized unit to process the currents induced in the coils when the catheter is moved, and a graphical display on which images are a real-time representation of the 3-D geometry of a cardiac chamber, color-coded with relevant electrophysiologic information.

2.1.17 Surgical System, Robotic (Treatment)

M8560 Surgical System, Robotic

A. Telemanipulation system designed for planning, training, and/or performing minimally invasive surgical procedures using robotic arms outfitted with surgical instruments.

B. System usually consists of robotic arms that replicate the surgeon's hand movements, an endoscopic guiding system, and a workstation that includes a computerized processor, displays showing a three-dimensional graphic simulation, and control unit operated by the surgeon.

C. System must have dual console capability to support training and collaboration for minimal invasive surgical procedures.

D. Console provides high definition 3D image, ergonomic controls, a surgeon touchpad, fingertip controls, fingertip

clutching of robotic arms, and footswitch pedals to operate the energy sources and instruments.

2.1.18 Surgical Waste Management (Support)

S9755 – Suction System, Surgical, Mobile Rover Unit

S9756 – Suction System, Surgical, Rover Docking Station

A. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.

B. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

C. System must produce a sound level of 5 sones or less when vacuum pump is running.

D. Provide ability to adjust suction strength.

E. [System must have integrated or portable smoke evacuation capability.]

3.1 SUBMITTALS

3.1.1 Submittals required for government review

A. Submittal requirements are outlined in [Division 01] [PWS SOW] [___]

B. [Product Information must include manufacturer's installation instructions, sizing (including required clearance for access and maintenance), utility requirements, isometric drawings, tagged floorplans showing placement for count accountability and accessories/options/consumables lists.]

C. All submittals require Government approval prior to procurement. Submit all listed items herein, with information sufficient to show full compliance with the criteria. Submit all product selections for review and approval, including but not limited to: materials, finishes, colors, options, accessories, and complimentary products. Provide for review all warranties and service contracts and any available extended warranty or service options.

D. Samples: Furnish material samples and full range of color selection options for all items that offer material and color selections.

E. Submit and highlight all applicable options for Government review for all items which optional accessories are provided.

F. [Joint Interoperability Test Command (JTIC) Approval Documentation.]

3.2 QUALITY ASSURANCE

3.2.1 Materials and Equipment

A. Materials and equipment must be standard products of a manufacturer regularly engaged in the manufacture of products which are of a similar material, design, and workmanship and are offered for sale on the commercial market through advertisements, manufacturer's catalogs, or sales brochures. The products must have been in commercial or industrial use under similar circumstances and of similar size for 2 years prior to selection for approval/procurement. Products must be supportable for at least three years after government acceptance.

3.2.2 Alternative Service Record

A. Products having less than a 2-year field service record will be acceptable if a certified record of the manufacturer's factory or laboratory tests demonstrating performance compliance is provided to the Contracting Officer.

3.2.3 Service Support

A. Equipment items must be supported by service organizations located near the equipment installation, able to service the equipment on a regular basis and respond to emergency calls throughout the warranty period.

3.2.4 Manufacturer's Nameplate

A. Each item of equipment must have an attached nameplate that is securely affixed in a conspicuous space. A nameplate listing only the name of the distributing agent is not acceptable. The nameplate must contain the following fields in English:

1. Manufacturer's name and address
2. Model and Serial Number
3. Item's utility ranges and/or capacities
4. Voltage, amperage, and applicable Underwriters Laboratory (UL) or Conformitè Europëenne (CE) rating if

electrically powered
5. Date of manufacture

3.2.5 Factory Inspection

A. Arrange and perform all quality control and quality assurance inspections required by the technical sections of the criteria, unless otherwise specified. Report these inspections in the daily report to the Government inspector.

3.2.6 Product Qualifications

A. The products specified in the technical sections of this criteria establish standards for each item.

3.2.7 Design Parameters

A. It is not the intention of this Criteria to limit consideration to products of specific manufacturers. The product standards establish the characteristics for which submitted items of equipment will be reviewed and approved by the Government. Equipment furnished must meet each of the following parameters specified in the technical sections:

1. Size of equipment
2. Function of equipment
3. Standard and listed accessories and options
4. Equipment controls and performance of equipment
5. Construction of equipment
6. Finish

3.3 STANDARDS DEVIATIONS

3.3.1 Reporting and Submission for Approval

A. Submit for approval a record of deviations from the standards listed in section (3.2.7.A.) established for each specified product, before ordering equipment.

3.4 DELIVERY, STORAGE AND PROTECTION

3.4.1 Packaging and Transporting

A. Each unit of equipment must be placed in a substantial shipping container or crate for safe transportation to final destination. The shipping container or crate for heavy equipment must be on skid construction to facilitate handling by lift equipment.

3.4.2 Packing List

A. Clearly and legibly indicate on exterior of each container or crate the shipping address and a brief description of contents. Fasten to outside of container a packing list and complete instructions for uncrating equipment and setting it in place. Protect such information in a weatherproof envelope.

3.4.3 Protection

A. Properly protect all materials and equipment from injury and damage during storage, installation, and acceptance.

3.5 INSTALLATION, VERIFICATION AND ACCEPTANCE TESTING

3.5.1 Qualifications of Installers and Inspectors

A. If required by product warranty, use installers that are approved and licensed by the manufacturer. When required to complete installation, all electricians and plumbers used must be bonded and licensed in the project's jurisdiction.

B. [Company specializing in installing the products specified in this section must have a minimum 5 years of documented experience.]

C. [Company specializing in installing the products specified in this section must be within 200 miles or 4 hours travel time.]

3.5.2 Installation, Operation, Testing and Certification

A. Products must be delivered in manufacturer's original packaging with manufacturer's installation instructions. Include clearly marked project reference.

B. Prior to installation, thoroughly examine the equipment, materials, and components for both visual defects and conformance with criteria.
C. Install all equipment in compliance with manufacturer's written instructions and installation procedures.
D. After installation, the equipment must be inspected and tested under operating conditions. If the equipment fails an inspection or test, such defects/failures must be corrected. Upon correction of defects/failures, inspect and retest all affected functions related directly and indirectly to the defect or failure. Corrections, replacement, and retesting must be made at no additional expense to the Government.
E. Provide all items necessary to make equipment fully functional.
F. Provide appropriately trained personnel to energize, commission, inspect, electrical safety check, calibrate, certify, and provide all required technical testing for equipment and systems. Contractor must provide documentation, test reports and certification documentation attesting that the equipment is properly installed, functional, safe, calibrated, and ready for its intended use.
G. An equipment item will be considered defective if it cannot be made to meet all established criteria consistent with the activities listed in section (F).
H. Provide two sets of special tools, software, and any other item/s for each equipment [item] [item type] if required for maintenance and/or future reconfiguration of the item.
I. Contractor to supply all start-up supplies for medical equipment for a fully operational installation. Contractor must supply to the Government a listing of all needed supplies for ongoing equipment operation for each item of equipment requiring additional supplies for operation.
J. Engage a factory-authorized service representative to train Government's staff and maintenance personnel to adjust, operate, and maintain medical equipment.
K. [Confirm functionality of required interfaces to other systems and networks.]

3.6 WARRANTY

3.6.1 Minimum Requirements

A. Warranty requirements are outlined in [Division 01] [PWS SOW] [___].
B. [Provide manufacturer's written warranty for all items listed. Provide warranty for a minimum of (1) year against defects in materials and workmanship. Warranty must provide for material, labor and all associated replacement and/or repair costs required to provide for a fully operational equipment replacement or repair. Submit manufacturers and installers standard service contract beyond the warranty period for Government review. Warranty must be transferrable to the final owner without risk of being voided. All warranty certification and documentation must be provided to the final owner after date of acceptance.]
C. Provide routine warranty service in accordance with manufacturer's warranty requirements, for a period of [12 months (minimum)] [___] after the open for business date. Perform work during regular working hours. Perform service only by factory trained personnel. Maintain a maintenance log of all service orders performed during the warranty period.

3.7 OPERATIONS AND MAINTENANCE (O & M)

3.7.1 Provide the following to the final owner

A. Provide O & M data for all FFE-LVS as outlined in [Division 01] [PWS SOW] [___].
B. Upon completion of equipment installation, furnish [two (2)] copies of operators/service/maintenance manuals for each type of equipment which will require service or maintenance
C. Each manual must contain operating instructions and information required for performing periodic maintenance on the equipment. Each service manual must include an illustrated parts breakdown which identifies each part of the unit with manufacturer's part number, wiring diagrams, and a list of necessary service parts, tools, and equipment needed to support maintenance requirements.
D. Accessory Catalogs: Upon completion of the Project, furnish two copies of the manufacturer's catalogs containing optional accessory items available for all equipment relative to the procured equipment/system delivered herein.
E. Provide instruction video for cleaning and maintenance, when available.
F. Provide cleaning requirements for all items to prevent void of warranty.
G. [Provide contact information for Repair Technician or Emergency Repair Company]
H. Provide contact information to [Logistics, Pharmacy, Laboratory, and Biomedical Equipment Services.]
I. Train designated staff in the operation and maintenance of the provided equipment/system. Provide two training sessions for equipment/system users and two training sessions for maintenance personnel scheduled to

accommodate shift work. [Provide training certificates that can be executed up to eleven months after the system is installed, in order to provide a refresher course for each group of trainees.] Provide DVD copy of the training with the O & M data.

--End of Section--