PERFORMANCE CRITERIA FOR

SECTION 11 79 00

THERAPY EQUIPMENT

09/21

TABLE OF CONTENTS

GENERAL

1.1 REFERENCE

2.1 DESCRIPTION & MATERIALS

- 3.1 SUBMITTALS
- **3.2 QUALITY ASSURANCE**
- 3.3 STANDARDS DEVIATIONS
- 3.4 DELIVERY, STORAGE AND PROTECTION
- 3.5 INSTALLATION, VERIFCATION AND ACCEPTANCE TESTING
- **3.6 WARRANTY**
- 3.7 OPERATIONS AND MAINTENANCE (O & M)

GENERAL

This Performance Criteria specifies the requirements for therapy equipment.

1.1 REFERENCE

1.1.1 Unified Facilities Criteria (UFC)

Contractor must 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 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
- C. NFPA 260 Standard Methods of Tests and Classification System for Cigarette Ignition Resistance of Components of Upholstered Furniture
- D. NFPA 701 Standard Methods of Fire Tests for Flame Propagation of Textiles and Films

1.1.4 Military Health System Standards

A. Reserved for future

1.1.5 American Society for Testing and Materials (ASTM)

A. ASTM E84 Standard Test Method for Surface Burning Characteristics of Building Materials

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 Other Standards

- A. CAL-117 (California Technical Bulletin 117-2013)
- B. 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 20 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 Cardiology (Diagnostic)

M8185 - System, Stress Exercise w/Treadmill

- A. Treadmills must have a user weight capacity of 500 lbs [227 kg].
- **B.** Treadmills must have an incline range of 0 25%.
- C. Systems must be configurable to test.
 - 1. Spirometry
 - 2. 12 Lead ECG
 - 3. O₂ and CO₂ Exercise Testing
- D. Surfaces must be non-porous, impervious to fluids and allow for thorough cleaning and disinfection.
- **E.** Hardware will include internal storage of patient records with expandable external storage available. Capable to connect and send patient data to DICOM/HL7 compliant EHR or PACS.
- **F.** Printer must be available as separate standalone or integrated within unit.
- **G.** Hardware will include wireless, Ethernet, or USB to PC connectivity for data transmission.

2.1.3 Ergometer (Diagnostic)

M8125 - Ergometer, Bicycle, Stationary

M8130 - Ergometer, Bicycle, Mobile

M8133 - Ergometer, Upper Body

M8135 - Ergometer, Bicycle, Testing/Evaluation

- A. Ergometers must have a minimum user weight capacity of 300 lbs [136 kg].
- B. Display must be LED/LCD high contrast with text readable in any ambient light level.
- C. Seats and/or handlebars must adjust to accommodate users of varying heights and abilities.
- **D.** Ergometers must have adjustable resistance levels.

D. Patient surfaces must be non-porous, impervious to fluids, and allow for thorough cleaning and disinfection.

2.1.4 Therapy (Feedback)

M8175 - Therapy Feedback Unit

M8180 - Biofeedback Analysis System

- A. Computerized machine with sensors to provide biofeedback on the following:
 - 1. GSR (Skin Conductance)
 - 2. Skin Temperature
 - 3. Pulse and/or Heart Rate Variability (HRV)
 - 4. Respiration
 - **5.** Electroencephalography Brain wave activity (EEG)
 - **6.** Electromyography Muscle Tension (EMG)
- B. Graphical Display:
 - 1. Hight contrast LED or LCD display
 - 2. Display of patient parameters Simultaneous and Singular
 - 3. Plotting graph to display patient progress on each parameter
 - **4.** Storage of patient data for review and transfer to EHR.
- C. Diversity of audiovisual forms of biofeedback music and images
- **D.** Multiple precision and sensitivity levels

2.1.5 Furniture (Support)

M8210 - Cart, Weight, Physical Therapy w/Weights

M9040 - Workstation, Splinting, Mobile

T0970 - Table, Work, Adult, Stand-In

T0975 - Table, Hand Therapy

T0976 - Table, Therapy, Horseshoe

- A. Patient surfaces must be non-porous and impervious to fluids and allow for thorough cleaning and disinfection.
- **B.** Mobile furniture bases must include swiveling casters with brakes.
- C. Furniture edges must be integral wood or PVC edge material.

2.1.6 Therapy (Support)

A. Splint Warming

M8100 - Bath, Warming, Splint

- 1. Warming bath machine for the softening of splinting sheets
- 2. Constructed of heavy duty stainless steel with double wall insulation
- 3. Must have a drain, timer and thermometer.
- **4.** Must accommodate 24" x 18" splinting sheets
- 5. Must have a thermostatic controlled operating temperature between 150° and 190°

B. Storage

M8260 - Hooks, Mat, Gym

M8270 - Rack, Pack, Hot/Cold, Wall Mounted

1. Surfaces must be non-porous, impervious to fluids, and allow for thorough cleaning and disinfection.

2.1.7 Exam & Treatment Tables/Mats (Treatment)

A. Exercise Platform

M8245 - Platform, Exercise w/Mat

M8305 - Platform, Exercise w/Mat, Powered

- 1. Must have a minimum tested weight capacity of 300 lbs [136 kg].
- 2. Table frame material must be aluminum, steel, hardwood, or wood laminate.
- 3. Mat must be latex free and must include vinyl, nylon, or polyfoam materials.
- 4. Include adjustment to accommodate users of varying heights and abilities.
- 5. Patient surfaces must be non-porous, impervious to fluids, and allow for thorough cleaning and disinfection.
- **6.** Provide upholstered top in seamless nylon-reinforced vinyl with 2" high-density urethane foam padding, rounded corners
- B. Exercise Mat

M8250 - Mat, Exercise

1. Mat must be latex free and include vinyl, nylon, or polyfoam materials

2. Handles must be provided for hanging or transporting

C. Exercise Mat

M8300 - Table, Examination/Treatment, Wood

M8310 - Table, Tilt

M8315 – Table, Traction, Physical Therapy

- 1. Must have a minimum tested weight capacity of 300 lbs [136 kg].
- 2. Table frame material must be aluminum, steel, hardwood, or wood laminate.
- 3. Mat must be latex free and must include vinyl, nylon, or polyfoam materials.
- 4. If required, include option for head and foot sections to incline 90°.
- 5. Provide adjustment range between 21" and 41".
- 6. Patient surfaces must be non-porous, impervious to fluids, and allow for thorough cleaning and disinfection.
- 7. Provide upholstered top in seamless nylon-reinforced vinyl with 2" high-density urethane foam padding, rounded corners

2.1.8 Exerciser (Treatment)

A. Upper Extremity

M8140 - Exerciser, Ladder

M8275 - Pulley, Triplex

- 1. Frame material will be metal, hardwood or wood laminate finish.
- 2. Patient surfaces must be non-porous, impervious to fluids, and allow for thorough cleaning and disinfection

B. Walking and Climbing

M8145 - Exerciser, Staircase, Convertible

- **1.** Double therapy staircase, converts to straight line to corner configuration.
- 2. Wood construction, rails and rail supports are finished hardwood, stairs and landing are laminate over wood
- 3. Anti-slip safety treads on all steps and platform
- 4. One stair run must be 6" high steps, the other stair run must be 4" high steps
- 5. Weight capacity of 350 pounds
- 4. Patient surfaces must be non-porous, impervious to fluids, and allow for thorough cleaning and disinfection

C. Walking and Balance

M8150 - Exerciser, Ramp and Curbs

- 1. Frame material will be hardwood or wood laminate finish
- 2. Patient surfaces must be non-porous, impervious to fluids, and allow for thorough cleaning and disinfection
- 3. Ramp rises gradually from ½" to 8" high
- 4. Must include three wide, deep curbs which are 2", 4" and 6" high

2.1.9 Hydrotherapy (Treatment)

A. Whirlpools

M8030 - Whirlpool, Mobile, Extremity, Medium

M8045 - Whirlpool, Mobile, Extremity, Large

M8060 – Whirlpool, Full Body, Mobile

- 1. Hydrotherapy unit for the treatment and prevention of sports injuries allowing coverage of the extremities, hips and back area
- **2.** Tank material is seam-less welded construction, fabricated from heavy gauge type 304 stainless with finished seams.
- 3. Unit has a turbine (1/2 HP jet) assembly with raising and lowering device which functions both as agitator and emptying device
- **4.** Mobile bases must include heavy duty swiveling casters with brakes.
- **5.** Must have a thermometer to monitor temperature of water.

B. Whirlpool Chair

M8065 - Chair, Whirlpool, Adjustable

- 1. The chair must have a reinforcing brace, arm rests, padded seat and back rest.
- 2. Attached step is covered with non-slip material
- 3. Constructed of heavy gauge tubular steel
- **4.** Adjustable height from 33" to 46"

2.1.10 Stimulator (Treatment)

- M8165 Stimulator, Neuromuscular
- M8170 Stimulator, Neuromuscular, Portable
- M8171 Stimulator, Neuromuscular, Interferential
- M8172 Stimulator, Transcutaneous Electric Nerve
- M8173 Stimulator, Neuromuscular, Multi-Channel
- M8174 Ultrasound/Neuromuscular Stimulation Combo Unit
- A. Multi-Modality Capability
 - 1. Patterned Electrical Neuromuscular (PENS) waveform for neuromuscular re-education
 - 2. Interferential Current (IFC) Stimulation with varied and full-field frequency protocol capability for management of pain and nerve blocking
 - 3. Medium Frequency Alternating Current (MFAC) for muscle strengthening, disuse atrophy treatment and spasm reduction
 - 4. Low Voltage Pulse Current (LVPC) for muscle re-education
 - 5. Transcutaneous Electric Nerve Stimulation (TENS) for nerve stimulation for pain management
- **B.** Provide capability to treat the following patient conditions:
 - 1. RSD/CRPS
 - 2. Incontinence
 - 3. Muscle Disuse Atrophy
 - 4. Torticollis
 - **5.** Spasticity
 - **6.** Spinal cord injury
 - 7. Lower Back Spasms
 - 8. Post-Stroke Rehabilitation
 - 9. Post-Surgical Joint Rehabilitation
 - **10.** Patello-Femoral Dysfunction
 - 11. Neuromuscular Diseases
- C. Provide pre-programmed condition specific protocols that can be utilized
- D. Multiple precision and sensitivity levels
- E. Exterior surfaces must be non-porous, impervious to fluids, and allow for thorough cleaning and disinfection.

2.1.11 Treadmills (Treatment)

A. Powered

M8330 - Treadmill, Electric

- 1. Must have a minimum tested weight capacity of 400 lbs [181 kg].
- 2. Display must be LED/LCD high contrast with text readable in any ambient light level.
- 3. Exterior surfaces must be non-porous, impervious to fluids, and allow for thorough cleaning and disinfection.
- 4. Minimum adjustable incline of 0% 15%
- 5. Start and stop speed of 0.0 mph
- 6. Patient attached safety lanyard to plug into control
- 7. Parallel medical handrails
- 8. [Hardware will include wireless, Ethernet, or USB to PC connectivity for data transmission.]

B. Gait Training

M8332 - Treadmill, Instrumented

- 1. Must have a minimum tested weight capacity of 400 lbs [181 kg].
- 2. Display must be LED/LCD high contrast with text readable in any ambient light level.
- 3. Exterior surfaces must be non-porous, impervious to fluids, and allow for thorough cleaning and disinfection.
- 4. Start and stop speed of 0.0 mph
- 5. Patient attached safety lanyard to plug into control
- **6.** Parallel medical handrails
- 7. Must have a split belt which can be controlled independently (speed and uphill and downhill adjustments)
- 8. [Hardware will include wireless, Ethernet, or USB to PC connectivity for data transmission.]

C. Weight Reduction

M8331 - Treadmill, Weight Bearing System

M8333 - Treadmill, Anti-Gravity

- 1. Must have a minimum tested weight capacity of 400 lbs [181 kg].
- 2. Display must be LED/LCD high contrast with text readable in any ambient light level.

- 3. Exterior surfaces must be non-porous, impervious to fluids, and allow for thorough cleaning and disinfection.
- 4. Minimum adjustable incline of 0% 15%
- 5. Start and stop speed of 0.0 mph
- 6. Patient attached safety lanyard to plug into control
- 7. Parallel medical handrails
- 8. Utilizes differential air pressure or incremented weight system for safe partial weight bearing therapy
- **9.** [Hardware will include wireless, Ethernet, or USB to PC connectivity for data transmission.]

D. Hydrotherapy

M8334 - Treadmill, Underwater Chamber System

- 1. Must have a minimum tested weight capacity of 400 lbs [181 kg].
- 2. Display must be LED/LCD high contrast with text readable in any ambient light level.
- 3. Exterior surfaces must be non-porous, impervious to fluids, and allow for thorough cleaning and disinfection.
- **4.** Consists of a therapy pool with a forward and reverse direction treadmill
- 5. [Hardware will include wireless, Ethernet, or USB to PC connectivity for data transmission.]

2.1.12 Ultrasound (Treatment)

M8200 - Ultrasonic Treatment Unit

M8201 - Ultrasonic Unit, Treatment

M8202 - Ultrasonic Unit. Patient Treatment

- A. Electrotherapy unit for the delivery of therapeutic electricity
- B. Provide six therapeutic modalities: ultrasound; electrotherapy; ultrasound/electrotherapy combination; laser; sEMG and sEMG +stim
- C. Display must be LED/LCD high contrast with text readable in any ambient light level.
- **D.** Programmed clinical protocols and indications or user defined protocols
- E. Equipment must be non-porous, shockproof, waterproof, impervious to fluids, and allow for thorough cleaning and disinfection

2.1.13 Wound Therapy (Treatment)

M4300 - Wound Therapy System, Negative Pressure

- **A.** Mechanically powered negative pressure wound therapy systems indicated for the application of suction (negative pressure) to promote wound healing and for the removal of fluids such as wound exudate, irrigation fluids, bodily fluids or infectious materials
- B. Must have a battery life of 12 hours or more
- C. Must have a minimum 250ml interchangeable canister
- **D.** LCD display with interface to ease of use
- E. Equipment must be non-porous, shockproof, waterproof, impervious to fluids, and allow for thorough cleaning
- F. Have an alarm to ensure patient safety and assist staff in providing care

2.1.14 Therapy (Treatment)

A. Heat/Cold Therapy

M8105 - Bath, Paraffin, Hand/Foot

- 1. Mobile tank for heating paraffin used in hand, arm, elbow, leg calf and foot therapy
- 2. Double walled 22-gauge stainless steel tank for heating of paraffin
- 3. Thermostatic controlled operating temperature between 126° and 130°
- 4. Must have a drain, timer and thermometer.
- 5. Must have a stand with casters.

M8110 - Fluidotherapy Unit, Double Extremity

M8111 - Fluidotherapy Unit, Single Extremity

- 1. Therapy heating unit for use with natural cellulose dry heat media to provide therapy on extremities
- 2. Can be configured in single or double extremity
- 3. Variable adjustments for time, temperature and air speed.
- 4. Thermostatic controlled operating temperature between 88° and 125°
- 5. Must have a stand with casters.

M8115 – Conditioner, Cold Treatment Pack

- 1. Refrigeration unit with heavy duty compressor for cold therapy packs
- 2. Stainless steel welded construction
- 3. Drain valve for easy cleaning and defrosting

- 4. Thermostatic controlled operating temperature
- 5. Swivel-type rubber casters for silent, friction-free movement

M8120 - Therapy Unit, Hydroculator

- 1. Therapy heating unit for use with moist heat hot packs
- 2. Tank constructed of stainless steel with insulated wall
- 3. 3-gallon water capacity with low water sensor
- 4. Thermostatic controlled operating temperature between 120° and 160°
- 5. Swivel-type rubber casters for silent, friction-free movement

B. Static and Dynamic Balance System

M8182 - Balance System, Reactive

- 1. Computer controlled, multidirectional platform used to challenge balance and reaction ability of key muscle groups of a patient
- **2.** Provides assessment, measurement and training of neurologic, orthopedic or vestibular conditions affecting stability, posture, strength or mobility
- 3. Must have patient handrails and safety harness

C. Shortwave Heat Therapy

M8195 – Diathermy Treatment Unit

- 1. Unit that is used for deep tissue heating for rehabilitation treatments utilizing shortwave diathermy
- 2. Flexible arm with multiple articulation points for positioning to various parts of the body
- 3. Pulse width must be 20 400 µsec in 20 µsec increments
- 4. Pulse frequencies 10 800 Hz in 10 Hz increments
- **5.** Easy to use touch screen interface.
- **6.** Programmable treatment duration 1 30 minutes in 1 minute increments

D. Rehabilitation Light Board

M8230 - Board, Light, Interactive Touch, Physical Therapy

- 1. Powered interactive light board for testing visual motor, neuro-cognitive, balance and functional mobility skills
- **2.** Light box of heavy duty, impact resistant, cleanable material in meter frame on adjustable height stand with locking casters.
- 3. 64 raised targets which light up for the patient to push and record results
- 4. Lighted target area is a minimum of 48" x 48"
- **5.** Lighted targets must be adjustable by location, color, frequency and duration
- 6. Integrated control unit

E. Exercise Bars

M8240 - Parallel Bars, Physical Therapy

- **1.** 7' to 15' foot in length that can have manual or electric powered adjustments (powered models will have manual crank override.
- 2. Walking aisle must have a finish in natural wood or covered with vinyl matting
- 3. Exterior surfaces must be non-porous, impervious to fluids, and allow for thorough cleaning and disinfection.
- 4. Powder coated steel uprights
- **5.** Tapered anti-slip ends on platform
- 6. Height adjustable from 25" to 40"
- 7. Bar width adjustable from 15" to 25"

F. Potters Wheel

M8265 - Wheel, Potters

- 1. Potter's wheel used in hospitals for rehabilitation therapy
- 2. All steel construction and solid table
- 3. Motor is ½ HP or greater and can center up to 100lbs of clay
- **4.** Variable speeds from 0 240 rpm that can be controlled by hand lever or foot pedal
- 5. Adjustable height to accommodate wheel chair

G. Hand Impairment Evaluator

M8280 – Evaluator, Hand Impairment

- 1. System includes a dynamometer, pinch meter and goniometer
- **2.** LCD display reads grip force ranging from 0-200 lbs for dynamometer and 0-40 lbs for pinch meter
- 3. Includes carrying case

H. Rehabilitation Equipment

M8285 - Simulator, Driving, Work Therapy

1. Partial cab based upon actual vehicle

- 2. Standard automotive driver controls including accelerator and brake pedals, steering, gear select, ignition, turn signals and headlights
- 3. Adjustable car seat to accommodate patients of varying height and weight
- 4. Custom scenarios specifically designed for OT assessment and evaluation
- 5. High-resolution visual displays with a minimum 110° field of view
- 6. Computer desktop workstation with high performance graphics card
- I. Functional Evaluation/Rehabilitation System

M8290 - Treatment System, Occup/Phys Ther, Computer Assist

- 1. Computer assisted treatment system used for work hardening programs in OT or PT rehabilitation programs
- 2. Provide multiple resistance modes: Isotonic, Isometric, Isokinetic and CPM
- 3. Provide multiple attachments for simulating different activity-specific work simulation exercises
- **4.** Provide easy to use touchscreen
- J. Traction System

M8325 - Traction Unit, Portable

M8326 - Traction Unit, Hydraulic, Low Back

- 1. Decompression therapy unit that relieves pressure on the spine. Use to treat herniated discs, sciatica, degenerative disc disease, pinched nerves and other back conditions
- 2. Provide unit that is [hydraulic] [electric] with traction tension parameters from 0 200 lbs
- **3.** Provide intermittent, static and cyclic traction
- 4. Digital touchscreen interface with user defined protocols
- 5. Compatible with a treatment table, chair or hospital bed
- K. Movement Therapy Machine

M8335 - Exerciser, Continuous Passive Motion (CPM)

- 1. Powered machine designed for therapy with legs and/or arms using pedals, accessible for patients confined in a bed
- 2. Height and horizontal extension adjustments
- 3. Provide adjustments for limiting the range of motion
- 4. Motor power adjustments with therapy setting for passive, motor-assist and active modes

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 --