(September 2021)

PERFORMANCE CRITERIA

FOR

**SECTION 11 72 00**

**EXAMINATION AND TREATMENT EQUIPMENT**

09/21

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**GENERAL**

This Performance Criteriaspecifies the requirements for examination and treatment equipment.

[This section includes 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 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 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

**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 E667 Standard Specification for Mercury-in-Glass, Maximum Self Registering Clinical Thermometers

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

**C.** ASTM E1112 Standard Specification for Electric Thermometer for Intermittent Determination of Patient Temperature

**D.** ASTM F2132 Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps

**E.** ASTM 2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

**F.** ASTM E2623 Standard Practice for Reporting Thermometer Calibrations

**G.** ASTM F1453 Standard Guide for Training and Evaluation of First Responders Who Provide Emergency Medical Care

**1.1.6 American National Standards Institute (ANSI)**

**A.** ANSI/AAMI/ISO 81060-1 Non-invasive sphygmomanometers

**1.1.7 Underwriters Laboratories (UL)**

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

**1.1.8 International Electrotechnical Commission (IEC)**

**A.** IEC 60601 Medical Electrical Equipment and Systems

**1.1.9 Food and Drug Administration**

**A.** CFR Title 21, Chapter I

**1.1.10 Occupational Safety and Health (OSHA)**

**A.** OSHA 1910

**1.1.11 Business & Institutional Furniture Manufacturers Association (BIFMA)**

**A.** ANSI/BIFMA x5.6 - Panel Systems

**1.1.12 International Organization for Standardization (ISO)**

**A.** ISO 10942 Ophthalmic Instruments – Direct Ophthalmoscopes

**B.** ISO 13485 Quality Management system for Medical Devices

**C.** ISO 26782 Anesthetic and Respiratory Equipment - Spirometers

**D.** ISO 23747 Anesthetic and Respiratory Equipment – Peak flow meters

**1.1.13 Specialty Steel Industry of North America (SSINA)**

**A.** Specifications for Stainless Steel - Designer Handbook

**B.** The Care and Cleaning of Stainless Steel - Designer Handbook

**1.1.14 European Union (EU)**

**A.** MDD 93/42/EEC Medical Devices Directive

**1.1.15 American Thoracic and European Respiratory Societies**

**A.** ATS/ERS Standards

**1.1.16 American Academy of Sleep Medicine**

**A.** AASM PSG Guidelines

**1.1.17 Other Standards**

**A.** CAL-117 (California Technical Bulletin 117-2013)

**B.** Reserved for future

* 1. **DESCRIPTION & MATERIALS**

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

**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 UL listed and capable of 110-240 volts, 50/60 Hz, Autosensing, unless otherwise noted.

**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 Exam Lights (Diagnostic)**

**A.** General Exam Lights

**M7400 - Light, Exam, Table Mounted, Spotlight**

**M7401 - Light, Exam, Mobile, Spotlight, Mobile Stand**

**M7420 - Light, Exam, Mobile**

1. LED lights must have at a minimum, not less than, 3200K color temperature. Maximum intensity must equal or exceed 15,000 Lux at 12-16 inches [30-40 cm] working distance.

2. Controls must allow for minimum two levels of illumination and controls must be available on the light as well as via remote touchpad.

3. Light must allow for adjustability in the vertical, horizontal, and diagonal axes as well as tilt of the beam direction.

4. Lights must have mounting options for chair, post, ceiling, track, wall, or cabinets.

5. Provide construction that is free of sharp edges, resistant to corrosion, and splash proof. External parts will allow for thorough cleaning and disinfection.

**B.** Ultraviolet Exam Light

 **M7410 - Light, Exam, Ultraviolet (Woods)**

1. Must have at a minimum 2x magnification.

2. Provide options for mounting on wall, floor stand, desktop, or handheld.

3. Provide construction that is free of sharp edges, resistant to corrosion, and splash proof. External parts will allow for thorough cleaning and disinfection.

4. Provide mounting options for floor stand, ceiling, wall, table, or rail.

**2.1.3 General Screening Equipment (Diagnostic)**

**A.** Sphygmomanometer

 **M4100 - Sphygmomanometer, Aneroid, Wall Mounted**

1. Aneroid must be mercury-free. External parts will allow for disassembly for thorough cleaning and disinfection.

2. Provide options for mounting on wall, 5-leg mobile stand, or handheld.

3. Equipment must allow for reusable or disposable cuffs in all sizes, at a minimum adult, pediatric, neonatal, and thigh sizes. Cuffs must be antimicrobial treated and latex free.

**B.** Thermometer

 **M4110 - Thermometer, Temporal**

 **M7910 - Thermometer, Electronic**

1. Unit must have a 5 second reading response time, low battery indicator, temperature recall, Celsius or Fahrenheit reading options.

2. Unit must have an LCD high contrast display and anti-theft options.

3. Unit must be portable and mobile with available options for mounting on wall or mobile stand.

4. Construction must be impact resistant and splash proof. External parts will allow for disassembly for thorough cleaning and disinfection. All components contacting patient must be disposable or easily disinfected if being reused.

**C.** Otoscope/Ophthalmoscope

 **M4200 - Otoscope/Ophthalmoscope, Wall Mounted**

 **M4205 - Otoscope/Ophthalmoscope, Desk Charger Set**

1. Handles must turn on/off automatically when removing or replacing handle in main unit. Internal rechargeable batteries [or disposable alkaline] must be used. Unit must accept any instrument head from the same brand.

2. Magnification must be wide angle with the ability to adjust focus.

3. Light source must be LED [xenon] [halogen] with adjustable intensity on handle.

4. Specula must be interchangeable and accepted onto any head. Provide varying diameters from 2.0 to 5.0 mm. Disposable or reusable speculum are acceptable. Reusable specula must be designed for disinfection.

5. Provide options for mounting on wall, wallboard, and handheld/desktop.

6. Construction must be impact resistant and splash proof. External parts will allow for disassembly for thorough cleaning and disinfection. All components contacting patient must be disposable or easily disinfected if being reused.

**D.** Pulse Oximeter

 **M7905 - Oximeter, Pulse**

1. Display must be LCD high contrast with continuous display of patient parameters. Display text must be readable in any ambient light level. Must visually display signal strength or quality of readings.

2. Accuracy must be better than +-3% SpO2 and +-5 bpm Pulse Rate.

3. Measurement range must be 70 to 99% SpO2 and 30 to 240 bpm Pulse Rate.

4. Printouts must be available in real time or trend, integrated into unit or as a connected standalone printer.

5. Unit must have the ability to connect to nurse call outputs with data port. Allow for wireless, RS232, and USB to PC connectivity for data transmission options.

6. Unit must be able to accept reusable and disposable sensors.

7. Construction must be impact resistant and splash proof. External parts will allow for disassembly for thorough cleaning and disinfection. All components contacting patient must be disposable or easily disinfected if being reused.

**2.1.4 Ophthalmology (Diagnostic)**

 **M7590 - Light, Corneal Microscope, Circular**

 **A.** Unit must consist an illumination ring, center fixation bulb, power source and connecting fiberoptic cable.

**B.** Light source must be 150 watt variable intensity fiber optic light source.

**C.** Color temperature must be 3200 degrees kelvin.

**2.1.5 Patient Monitoring (Diagnostic)**

 **M4116 - Monitor, Vital Signs**

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

**B.** Alarm notification must have options using visual or auditory or both for all parameters.

**C.** Unit must be table-top with the option for wall mount. [Unit must be mobile and mounted on an included mobile cart or trolley supplied by the manufacturer.]

**D.** Provide construction that is free of sharp edges, resistant to corrosion, and splash proof. External parts will allow for thorough cleaning and disinfection. Components contacting patient must be disposable or easily disinfected if being reused.

**E.** Hardware to include internal storage with optional connection to EMR/EHR as well as wireless, Ethernet, or USB to PC connectivity for data transmission. [Printer must be included integrated within unit].

**F.** Options for adult, pediatric, and neonatal patients must be supported by equipment.

**2.1.6 Scales/Stadiometers (Diagnostic)**

**A.** Adult/Pediatric Scales

**M4020 - Scale, Person Weighing, High Capacity**

**M4030 - Scale, Sit/Stand**

**M4040 - Scale, Weighing, 300 Pound Capacity**

**M4045 - Scale, Wheelchair, Portable, 1000 lb Capacity**

1. Display must be LCD high contrast designed to be readable by patient and attendant. Display text must be readable in any ambient light level.

2. Accuracy must be better than .2 lbs [90 gm].

3. Platform at standing scales must be non-slip low profile. Wheelchair scales must have a ramp for accessibility.

4. Functions must include Auto Zero at startup, TARE, HOLD, BMI, and kg/lbs display.

5. Handrail option must be available. Provide handrail as standard on all bariatric scales.

6. Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission. [Provide connection to external printer.]

7. Power typically to be provided through AC adapter, with internal rechargeable [or disposable alkaline] battery for use when mobile.

8. Materials may include metal, aluminum, and ABS plastic. Finish to be enamel/powder coat or chrome plated. Keypad must be sealed to liquids. Construction to be corrosion, impact, and scratch resistant. External parts will allow for thorough cleaning and disinfection.

9. [Height rod option to be included. Readings may be digital or mechanical. Range must be up to 78 inches [198 cm] with 1/8 inch markings.]

**B.** Infant Scales

**M4010 - Scale, Infant, 0-35 Pounds**

1. Display must be LCD high contrast designed to be readable by patient and attendant. Display text must be readable in any ambient light level.

2. Accuracy must be better than .2 oz/4 gm with maximum 15 second read time. Computer to automatically average readings for active infant.

3. Provide a platform with adjustable feet for leveling.

4. Functions must include Recall, reweigh, zero, and grams/lbs/oz display

5. Scale must be designed for cart or tabletop use.

6. Hardware to include wireless, Ethernet, or USB to PC connectivity for data transmission or connection to external printer.

7. Power typically to be provided through AC adapter, with internal rechargeable [or disposable alkaline] battery for use when mobile.

8. Materials may include metal, aluminum, and ABS plastic. Finish to be enamel/powder coat or chrome. Keypad must be sealed to liquids Construction to be corrosion, impact, and scratch resistant. External parts will allow for thorough cleaning and disinfection.

9. [Height rod option to be included. Integrated ruler on tray with range must be up to 22 inches [59 cm] with markings in cm and inches.]

**C.** Height Measuring

**M4050 - Height Measuring Device, Precision**

1. Display must be LCD high contrast designed to be readable by patient and attendant. Display text must be readable in any ambient light level.

2. Height range: up to 22 inches for Infant; up to 88 inches for Pediatric & Adult.

**2.1.7 Dispensers (Support)**

**A.** Soap, Sanitizer, Lotion

 **A5070 - Dispenser, Liquid Soap, SS, Surface Mounted**

1. Unit must be satin finish Stainless Steel with a corrosion resistant valve. Push-in type and operable with one-hand.

2. Surface mounted; Top fill; Heavy duty hinge with key lock lid; Vandal resistant concealed mounting.

3. Must have a minimum capacity of 40 fluid ounces.

 **A5075 - Dispenser, Soap, Disposable**

1. Disposable soap dispenser; Designed to accommodate soap cartridge or replaceable bag and valve.

2. Must be surface mounted, High-impact ABS plastic.

3. One handed dispensing operation; Touch-free or manual.

4. Must have an 800 ml capacity. Foam or Liquid.

 **A5076 - Dispenser, Hand Sanitizer, Free Standing**

1. Hand sanitizing dispenser stand (Free-standing). Dispenser Sold Separately.

2. Dispensing height range 42.5 to 44 inches. Unit must be ABA compliant.

3. Shal have a low-profile baseplate designed to maximize stability. Light weight for ease of mobility.

 **A5077 - Dispenser, Hand Sanitizer, Hands-Free**

1. Unit must be ABA compliant capable.

2. Unit must be touch free operating, foam or liquid and include site window and floor/wall protector.

3. All units must be 700 ml minimum capacity.

4. Materials must be High-Impact ABS plastic.

 4. Battery must be included.

 **A5085 – Dispenser, Paper Cup, SS, Surface Mounted**

1. Unit must be ABA compliant capable. Surface mounted. Touch free or one hand push. Include site window and floor/wall protector must be provided.

2. All units must be 700 ml minimum capacity and must be vandal resistant and lockable.

3. Materials may include stainless steel or high impact plastic.

 **B.** Sharps and Glove dispensers

 **A5103 - Waste Disposal Unit, Pharmaceutical**

 **A5105 - Waste Disposal Unit, Sharps, Container Shield**

 **A5106 - Waste Disposal Unit, Sharps w/Glove Dispenser**

 **A5107 - Dispenser, Glove, Surgical/Examination, Wall Mounted**

 **A5108 - Waste Disposal Unit, Sharps**

1. Unit must be ABA compliant capable. Include site window for sharps dispenser.

2. All units must be vandal resistant and lockable with universal key.

3. Wall mount or rail mount options must be available.

4. Materials must be resistant to water and may include high impact plastic or other puncture resistant material.

**C.** Shoe Cover Dispenser/Remover

 **A5100 - Shoe Cover Dispenser, Small**

1. Must be designed for Low to Moderate volumes; Minimum capacity of 55 pairs of shoe covers (One (1) shoe cover refill bundle).
2. Hands-free operation
3. No power required, Battery-free operation, portable design.
4. Stainless Steel and High-Impact ABS plastic components.
5. Approx. Dimensions: 30”L x 16”W x 12”H.
6. Compliant with Class 100/ ISO 5 cleanroom standards.

 **A5101 - Shoe Cover Dispenser, Large**

1. Designed for High volumes; Minimum capacity of 110 pairs of shoe covers (Two (2) shoe cover refill bundles).
2. Hands-free operation with heavy-duty handle attached directly to frame.
3. No power required, Battery-free operation, portable design.
4. Stainless Steel and High-Impact ABS plastic components.
5. Approx. Dimensions: 32”L x 15”W x 32”H (including handle bar).
6. Compliant with Class 100/ ISO 5 cleanroom standards.

 **A5102 - Shoe Cover Remover**

1. Must be designed for Low to Medium (10 gal.) and High volumes (33 gal). Low to Medium holds minimum capacity of 100 shoe covers. High holds minimum capacity of 600 shoe covers.
2. Hands-free operation
3. Optional HEPA Filtration to control contaminants
4. Self-Contained disposable bags.
5. Stainless Steel, Powder Coated Steel and High Impact ABS plastic components
6. Approx. Shipping Dimensions: Low to Medium Capacity- 48”L x 40”W x 21”H (including handle bar); High Capacity- 48”L x 40”W x 37”H (including handle bar).
7. Available in either 110V/120V or 220V, depending on volumes.

**2.1.8 Infection Control (Support)**

 **A5095 – Infection Control Center, Free-Standing**

 **A5096 – Infection Control Center, Wall-Mounted**

**A.** Refer MIL STD 1691 descriptions for performance requirements in this category.

**2.1.9 Radiation Waste Disposal (Support)**

 **F2030 – Waste Receptacle, Radioisotope, Lead**

**A.** Must be constructed of 18-gauge stainless steel and lined with .125” or .25” lead.

**B.** Must have a capacity of 20 quarts.

**C.** Receptacle must be lead lined with a hatch door to protect the user from contained contents.

**2.1.10 Radiology Support (Support)**

 **M3100 – Cabinet, Contrast Media Warmer, Counter-Mounted**

 **A.** Unit must provide warming temperatures between ambient 5 degrees C to 60 degrees C.

 **B.** Unit must be able to heat contrast media to body temperature 37 degrees C +/- 1.5 degrees C.

**2.1.11 Patient Transport (Support)**

**A.** Wheelchairs

 **M4705 - Wheelchair, Patient Transport, Folding**

 **M4710 - Wheelchair, Patient, Bariatric, Transport, Folding**

 **X9910 - Wheelchair, MRI**

1. Wheelchairs must have a minimum tested weight capacity of 250 lbs [114 kg] for standard and 500 lbs [227 kg] for bariatric.

2. Must include adjustment options for elevating leg rest, detachable full arm, and swing away footrests.

3. Frame must be chrome plated steel or stainless steel with baked urethane finish.

4. Seat fabric must be selected from manufacturer’s standard fabric line, impervious to liquids, readily cleanable with surface disinfectants.

5. MRI Transport must be non-ferrous and non-magnetic materials such as aluminum, stainless steel and plastic. Product must be labeled as safe for 3T MRI use in accordance to ASTM 2503.

6. The optional accessories will be available:

 a). Anti-Theft bar.

b). One arm drive.

c). Pneumatic tires.

d). IV Pole.

e). Anti-tipping/folding.

f). Seatbelt.

g). Straps.

h). Oxygen tank holder.

**B.** Patient Transfer Board

 **M4645 - Patient Transfer Device**

 1. Must be lightweight and radiolucent.

 2**.** Must be safe for patients, anti-bacterial surface and latex free.

**2.1.12 Sealer (Support)**

 **M2700 - Sealer, Heat, Plastic Bag, w/Motor, Portable**

**A.** Must have 16 to 18-inch sealing width.

**B.** Must have the ability to seal bags between 2 to 5 mm wide.

**C.** Unit must be able to seal a thickness between 6 to 8 mil.

**2.1.13 Training Manikin (Support)**

 **M1900 - Manikin, Training, ACLS/CPR**

**A.** Unit must be reasonably portable with an included carrying case.

**B.** Unit must support intubation, suction, I.V. placement, blood pressure cuff placement, ECG monitoring and defibrillation.

**2.1.14 Workstations (Support)**

**A.** Mobile

 **E0945 - Cart, Computer, Mobile**

1. Must include adjustment options for keyboard trays, monitor height/tilt and overall height adjustment from sit to stand position.

2. Workstations must include rolling casters with locking ability

3. Materials may include enamel/powder coated steel, anodized aluminum, lightweight aluminum, polymer and laminate. Finishes must be durable and easy to clean.

4. Integrated cord management must be provided.

5. Workstation must be constructed to accommodate accessories such as mouse and keyboard trays, barcode scanner holder, CPU holder, and additional storage (drawers, baskets, or other).

**B.** Wall Mounted

 **M1802 - Work Station, Computer, Retractable, Wall Mounted**

**1.** Workstation must be wall mounted with the ability to retract within 8” to 10” of wall in stored position.

2. Stations must have options for locking in the form of a badge, keypad, or keyed access. CPU compartments must be vented and provide options for keypad or keyed locking.

3. Include fingertip adjustment for keyboard trays, monitor height/tilt and overall height adjustment from sit to stand position.

 **M1803 - Workstation, Computer, Wall Mounted, Adjustable**

1. Workstation must be wall mounted with the ability to fold tightly to the wall, within 8” to 10” of wall in stored position.

2. Stations must have options for locking in the form of a badge, keypad, or keyed access. CPU compartments must be vented and provide options for keypad or keyed locking.

3. Include adjustment options for keyboard trays, monitor height/tilt and overall height adjustment from sit to stand position.

4. Materials may include enamel/powder coated steel, anodized aluminum, lightweight aluminum, polymer and laminate. Finishes must be durable and easy to clean.

5. Integrated cord management must be provided.

6. Workstation must be constructed to accommodate accessories such as mouse and keyboard trays, barcode scanner holder, CPU holders, and utility baskets.

**2.1.15 Clinical Furniture (Treatment)**

**A.** Manual Stationary Blood Draw Chairs

 **M1410 - Chair, Laboratory, Blood Drawing, w/Storage**

 **M1411 - Phlebotomy Arm, Wheelchair Accessible**

1. Must have a minimum tested weight capacity of 400 lbs [181 kg].

2. Chair must allow for adjustment in overall height and include lift or flip up arms that lock in place when in use.

3. Additional storage options must be available.

4. A minimum of 2 inches [5.08 cm] of padding must be provided for patient’s comfort.

5. Frame may be enamel/powder coated steel, chrome plated steel, or stainless steel.

**B.** Manual Reclining Blood Draw Chairs

 **M1400 - Chair, Blood Donor, Recliner, Manual or Pneumatic**

1. Must have a minimum tested weight capacity of 325 lbs [147 kg].

2. Chair must allow for adjustment in manual recline and include pneumatic tilt.

4. A minimum of 2 inches [5.08 cm] of padding must be provided for patient’s comfort.

5. Frame may be enamel/powder coated steel, chrome plated steel, or stainless steel.

6. The optional accessories must be available:

1. IV Poles.
2. Footrests.
3. Casters.

**C.** Powered Blood Draw Chairs

 **M1405 - Chair, Blood Donor, Recliner, w/Motor, Armrest**

1. Must have a minimum tested weight capacity of 300 lbs [136 kg].

2. Chair must allow for powered adjustment in seat height, arm heights and recline.

3. A minimum of 2 inches [5.08 cm] of padding must be provided for patient’s comfort.

4. Frame may be enamel/powder coated steel, chrome plated steel, or stainless steel.

5. The optional accessories must be available:

1. Wall saver/hugger chairs.
2. Tray attachment.
3. Footrest.
4. Casters.
5. Remote control.
6. IV Pole.
7. Heat and massage.
8. Cup holder.

**2.1.16 Exam and Treatment Chairs & Tables (Treatment)**

**A.** Manual Exam & Treatment Tables

 **M9025 - Table, Examination/Treatment, With Cabinet**

 **M9055 - Table, Exam, Orthopedic**

1. Must have a minimum weight capacity of 400 lbs [181 kg] at all adult tables.

 2. Manually operated adjustable backrest must be provided.

3. Must have a retractable nonslip steel footstep.

4. Integral paper roll compartment must accept 21 x 3.5 inches [53 x 9 cm] standard roll size, 14 inch [36 cm] acceptable at pediatric tables.

5. Must have at a minimum one convenience receptacle hospital grade 115 VAC, 5 amp.

6. Storage capacity within table base must be a minimum of 250 cu. in.

 7. Stirrups must be multi positional, with lateral and length adjustment stowable within table.

 8. A minimum of 2 inches [5.08 cm] of padding must be provided for patient’s comfort.

9. Base must be 18 gauge steel with baked enamel, powder coat, or epoxy paint finish.

 10. The optional accessories must be available:

a). Exam light LED adjustable gooseneck with integral table mounting bracket.

b). Patient assist rails in stainless or powder coated steel. Removable without tools.

c). Accessory rails on both sides of table factory installed.

d). Heated drawers.

 **B.** Powered Exam & Treatment Chairs

 **M4915 - Chair, Exam/Treatment, ENT, w/Adjustable Light**

 **M4920 - Chair, Exam/Treatment, Podiatry, w/Motor**

 **M4925 - Chair, Exam/Treatment, With Motor**

 **M9030 - Chair, Examination/Treatment, Surgical, ENT**

 **M9035 - Chair/Table, Exam/Treatment, Combination Unit**

1. Must have a minimum weight capacity of 400 lbs [181 kg].

2. Powered lift, tilting, and foot rest independently electronically controlled. With maximum 22 inch [56 cm] low access seating height.

3. Include minimum one convenience receptacle hospital grade 115 VAC, 5 amp.

4. A minimum of 2 inches [5.08 cm] of padding must be provided for patient’s comfort.

5. Base must be [stainless steel] steel frame with baked enamel, powder coat, or epoxy paint finish.

6. The optional accessories must be available:

a). Integral paper roll compartment to accept 21” x 3.5” standard roll size.

b). Exam light LED adjustable gooseneck with integral table mounting bracket.

c). Hand and foot control capability.

 **C.** Powered Exam & Treatment Tables

 **M9065 - Table, Examination, Proctology, Electro/Hydraulic**

 **M9066 - Table, Examination, Treatment, Electro/Hydraulic**

1. Provide a minimum weight capacity of 400 lbs [181 kg]. Bariatric exam tables must have a minimum weight capacity of 800 lbs [363 kg].

2. Powered lift, tilting, and foot rest must be independently electronically controlled. With maximum 22 inch [56 cm] low access seating height. Provide 19 inch [48 cm] maximum low access seating at bariatric tables.

3. A minimum of 2 inches [5.08 cm] of padding must be provided for patient’s comfort.

4. Include minimum one convenience receptacle hospital grade 115 VAC, 5 amp.

5. The optional accessories must be available:

a). Integral paper roll compartment to accept 21” x 3.5” standard roll size.

b). Exam light LED adjustable gooseneck with integral table mounting bracket.

c). Hand and foot control capability.

d). Patient restraint straps.

e). Patient assist rails in stainless or powder coated steel. Removable without tools.

f). Accessory rails on both sides of table factory installed.

**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--**