

(September 2021)

PERFORMANCE CRITERIA
FOR

SECTION 11 77 00

RADIOLOGY EQUIPMENT
09/21

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GENERAL

This Performance Criteria specifies the requirements for radiology 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 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 E84 Standard Test Method for Surface Burning Characteristics of Building Materials
- B. ASTM D4157 Standard Test Method for Abrasion Resistance of Textile Fabrics (Oscillatory Cylinder Method)
- C. ASTM 2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

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
- B. Mammography Quality Standards Act
- C. Compliance Program Guide Manual 7386.003 Field Compliance Testing of Diagnostic (Medical) X-ray Equipment

1.1.9 Digital Imaging and Communications in Medicine (DICOM)

- A. DICOM Part 14 Grayscale Standard Display Function

1.1.10 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 will be selected from the manufacturer's standard options for the specified model unless noted otherwise.
- B. All fabrics (upholstery or drapery) must meet the appropriate fire test associated with each type of fabric as outlined by testing within the reference standards.
- C. All fabrics (upholstery) must meet the appropriate resistance to abrasion test associated with each type of fabric as outlined by testing within the reference standards.
- D. All product finishes and fabrics (upholstery or drapery) must meet industry standards for infection control and performance.
- E. All product finishes must be capable of maintaining sheen and color through warranty period when using industry standard cleaning and disinfection solutions.
- F. All display panel surfaces must maintain clarity through warranty period when using industry standard cleaning and disinfection solutions.
- G. All equipment that have components that are meant for reuse must be autoclavable or able to withstand industry standard cleaning and disinfection processes.
- H. Electrified equipment must be 115 Volt 15 amp maximum unless noted otherwise.
- I. Casters provided must be designed for use on the installed floor finish.
- J. 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.
- K. 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.

2.1.2 Computed Tomography (CT)

X6240 – Radiographic Unit, Computerized Tomography (CT)

X6245 – Rad Unit, Computerized Tomography, (CT), HP

- A. Display must be high brightness and high-resolution display of patient and equipment parameters. Display must be adjustable and readable in any ambient light level. Images must be displayed immediately after exposure. All warnings must be indicated on display.
- B. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or

easily disinfected if being reused.

- C. Equipment must maintain nominal operating temperatures using internal cooling mechanisms.
- D. Hardware must include internal storage of [500] [____] GB of data, with additional removable storage media options. Must be compatible with DICOM image transfer and storage.
- E. The gantry must have user friendly control panels for easy positioning. Gantry opening must be at least [78] [____] centimeters in diameter.
- F. CT must be a [64] [____] slice system.
- G. Rotation/scan time must be less than one second.
- H. Patient table/couch must have a minimum load bearing capacity of [650] [____] pounds.
- I. Provide technology/software to reduce CT dose to patients.

2.1.3 Contrast/Media Injectors

X6195 – Injector, Angiographic

X6196 – Injector, CT

- A. Display must be LCD/LED high contrast touchscreen with continuous display of measured parameters.
- B. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
- C. Provide various mounting options (mobile with casters, wall, table, and ceiling mount). The mounting bracket must be supplied by the manufacturer.
- D. Design must accept standard size syringes from 50ml-200ml and have a flow rate of 0.1ml to 10ml/sec on 0.1ml increments.
- E. Must have a minimum scan delay of 0-300 seconds in 1 second increments
- F. Provide a syringe heat maintainer to minimize loss of heat from pretreated contrast.
- G. Must have a maximum of 6 phases.

2.1.4 Computed Tomography (CT) Support

X9340 – Phantom, CT, Head

X9345 – Phantom, CT, Body

X9346 – Phantom, CT Performance

- A. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
- B. Phantom material must be [Polymethyl-Methacrylate (PMMA/Acrylic).]

2.1.5 Dental Imaging

A. Intraoral Systems

X6600 – Radiographic Unit, Dental, Wall Mounted, 7 mA

- 1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
- 2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
- 3. Provide various mounting options (mobile with casters, wall, table, and ceiling mount). The mounting bracket must be supplied by the manufacturer
- 4. All cables (i.e. power, communication, and /or USB) must be fully concealed within system.
- 5. Arm must be easy to move and have anti-drift capability.
- 6. Tube support arm must have a minimum reach of 75 inches.
- 7. Tube cone length must be [8 inches] [12 inches].
- 8. Provide an automatic exposure control facility. Include remote controlled exposure switch.
- 9. Provide an audible and/or visual alert during exposure.
- 10. [Provide internal USB connection to allow dental image sensor to have connectivity back to computer].
- 11. [Provide integrated digital sensor system].

B. Extraoral Systems

X5500 – Radiographic Unit, Cephalometric

X6500 – Radiographic Unit, Dental, Panographic

X6505 – Radiographic Unit, Dental, Panographic & Cephalo.

X6510 – Radiographic Unit, Dental, Cone Beam, 3-D Imaging

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
3. Provide charge-coupled device (CCD) sensor technology.
4. [Under panoramic modality, there must be five radiological exam options: panoramic, segmented panoramic, maxillary sinus, lateral temporomandibular joint (TMJ) x2, and lateral TMJ x4.]
5. [Under cone beam 3-D imaging modality, the field of view range must be minimum [5x4 cm to 11x10 cm].]
6. Provide an automatic exposure control facility. Include remote controlled exposure switch.

C. Dental Picture Archiving and Communication System (PACS)

X6605 – Imager, Dental, Digital Image

1. System must have the latest DoD approved Operating System (OS).
2. Display must be high brightness and high-resolution display of patient and equipment parameters. Display must be adjustable and readable in any ambient light level. Images must be displayed immediately after exposure.
3. System must support all dental imaging modalities.
4. Hardware must include internal storage of [500] [___] GB of data, with additional removable storage media options. Must be compatible with DICOM image transfer and storage.

D. Digital Sensors

X6610 – Sensor, Dental Imaging System

1. Sensor must be durable and resistant to shocks, bites and drops.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
3. Sensors must integrate with the facility imaging software/management system.
4. Provide different sensor sizes to accommodate various patients.
5. Provide sensors that have the option to connect by USB [and/or wireless].

2.1.6 General Radiology

A. Stationary Equipment

X2120 – Scanner, Bone Density, Full Body

X4600 – Radiographic Unit, Veterinary, 30kW, Floating Top

X5100 – Radiographic Unit, 80 kW, Chest, Digital

X5700 – Radiographic Unit, 65 kW, Non-Tilt Table

X5900 – Radiographic Unit, 80 kW, Non-Tilt Table

1. Display must be high brightness and high resolution color display of patient and equipment parameters. Display must be adjustable and readable in any ambient light level. Display images immediately after exposure. All system warnings must be indicated on display.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
3. Cables must be fully concealed within system.
4. Equipment to maintain nominal operating temperatures using internal cooling mechanisms.
5. Automatic exposure control facility required. Include remotely controlled exposure switch.
6. Hardware must include internal storage of [500] [___] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.
7. Unit to use hardware and software modularity for future system upgrades.
8. Patient table/couch must have a minimum load bearing capacity of [650] [___] pounds.
9. Patient table/couch must be height adjustable to allow for easy patient transfer.
10. [Upholstered pads for table/couch must offer firm support with minimum compression.]
11. [Unit must include ability to transmit images wirelessly.]

B. Mobile Equipment

X4790 – Radiographic Unit, Mobile, Digital

1. Display must be high brightness and high resolution color display of patient and equipment parameters.

- Display must be adjustable and readable in any ambient light level. Display images immediately after exposure. All system warnings must be indicated on display.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
 3. Base to include four wheels with braking capability. Imaging to use articulating arm for imaging from any patient position and tube stand counterbalance for rotation in all directions.
 4. Cables must be fully concealed within the arm system.
 5. Equipment to maintain nominal operating temperatures using internal cooling mechanisms.
 6. Automatic exposure control facility required. Include remotely controlled exposure switch.
 7. Hardware must include internal storage of [500] [____] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.
 8. Unit must be able to operate from main power (plugged in) or battery power and include low battery warning mechanism.
 9. [Unit must include ability to transmit images wirelessly.]

2.1.7 Radiation Therapy

A. Linear Accelerators

X8700 – Accelerator, Linear, 18 MeV

X8740 – Accelerator, Linear, 6-10 MeV, Dual Energy

X8750 – Accelerator, Linear, 5-22 MeV, Dual Energy

1. Display must be high brightness and high resolution color display of patient and equipment parameters. Display must be adjustable and readable in any ambient light level. Display images immediately after exposure. All system warnings must be indicated on display.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
3. Equipment to maintain nominal operating temperatures using internal cooling mechanisms.
4. Automatic exposure control facility required. Include remotely controlled exposure switch.
5. All dosimetry, patient and unit safety related interlocks must be sensed and controlled by hardware and software
6. Safety measures to include automatic breast release after x-ray exposure and emergency switches on both sides of the gantry to release in case of power failure.
7. Patient table/couch must have a minimum load bearing capacity of [500] [____] pounds.
8. Upholstered pads for table/couch must offer firm support with minimum compression.
9. Hardware must include internal storage of [500] [____] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.

B. Brachytherapy Systems

X9400 – Afterloader, Brachytherapy

1. Display must be high brightness and high-resolution display of patient and equipment parameters. Display must be adjustable and readable in any ambient light level.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
3. Equipment to maintain nominal operating temperatures using internal cooling mechanisms.
4. Must be compatible with treatment planning system.
5. Unit must be able to automatically verify all unique applicator connections and be easily maneuverable within the treatment room.
6. Hardware must include internal storage of [500] [____] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.

C. Simulators

X8501 – Simulator, Therapy, X-Ray

1. Display must be high brightness and high-resolution display of patient and equipment parameters. Display must be adjustable and readable in any ambient light level.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a

disposable cover or easily disinfected if being reused.

3. Equipment to maintain nominal operating temperatures using internal cooling mechanisms.
4. Must be compatible with treatment planning system.
5. Patient table/couch must have a minimum load bearing capacity of [650] [____] pounds.
6. Upholstered pads for table/couch must offer firm support with minimum compression
7. Hardware must include internal storage of [500] [____] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.

D. Treatment Planning Systems

X9840 – Computer, Clinical, Nuclear Medicine

X9841 – Computer, Radio Therapy, Record/Verify

X9842 – Computer, Rad Therapy Treatment Planning

1. Display must be high brightness and high-resolution display of patient and equipment parameters. Display must be adjustable and readable in any ambient light level.
2. Systems must have multimodality image support [Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), General Nuclear Medicine, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Angiography, Radiography and Fluoroscopy, Ultrasound, and Cone Beam Computer Tomography (CBCT).]
3. Must have automated planning support for Intensity-Modulated Radiation Therapy (IMRT) and Volumetric-Modulated Arc Therapy (VMAT)
4. Hardware must include internal storage of [500] [____] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.

E. Laser Positioning Systems

X1415 – Laser Positioning System, Patient-Wall

X1416 – Laser Positioning System, Patient-Ceiling

1. Laser light must be clearly visible in any light level.
2. Wavelength must be between 450 nm – 650 nm in red, blue or green light.
3. Maximum line width at 4 meters must be 1 mm or less.
4. Provide a remote control for laser adjustment.

F. Radiotherapy Support Equipment

X8010 – Cutter, Block, Beam, Radiotherapy

X8011 – Dispenser, Lead Alloy

X8015 – Cutter, Compensator, Radiotherapy

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, corrosion resistant. Parts must allow for thorough cleaning and disinfection.

2.1.8 Nuclear Medicine

A. Positron Emission Tomography (PET) Systems

X6250 – Rad Unit, CT/ Positron Emission Tomography PET/CT

1. Display must be high brightness and high resolution color display of patient and equipment parameters. Display must be adjustable and readable in any ambient light level. Display images immediately after exposure. All system warnings must be indicated on display.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
3. Equipment to maintain nominal operating temperatures using internal cooling mechanisms.
4. The gantry must have user friendly control panels for easy positioning. Gantry opening must be at least 78 centimeters in diameter.
5. Patient table/couch must have a minimum load bearing capacity of [400] [____] pounds.
6. Upholstered pads for table/couch must offer firm support with minimum compression
7. Must have a time of flight (TOF) resolution of [400] [____] picoseconds (ps) or better.
8. Automatic exposure control facility required. Include remotely controlled exposure switch.
9. Safety measures to include automatic breast release after x-ray exposure and emergency switches on both sides of the gantry to release in case of power failure.

10. Hardware must include internal storage of [500] [____] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.

B. Single-photon Emission Computerized Tomography (SPECT) Systems

X9830 – Scanner, Nuclear, SPECT, Dual Head

1. Display must be high brightness and high resolution color display of patient and equipment parameters. Display must be adjustable and readable in any ambient light level. Display images immediately after exposure. All system warnings must be indicated on display.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused
3. Provide a minimum tested weight capacity of [500] [____] lbs.
4. Upholstered pads for table/couch must offer firm support with minimum compression.
5. Crystal thickness must be [3/8] [____] inch.
6. Energy range must be [35-588] [____] keV
7. Provide acquisition modes [static, dynamic, gated, SPECT, gated SPECT, dynamic SPECT, whole-body, and/or whole-body SPECT.]
8. Provide motorized height adjustment controlled by a hand control and/or foot control. Table adjustment motion must be controlled and smooth.
9. Must have automatic image reconstruction.
10. Hardware must include internal storage of [500] [____] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.

C. Gamma Cameras

X9810 – System, Camera, Gamma, Mobile

1. Display must be high brightness and high resolution color display of patient and equipment parameters. Display must be adjustable and readable in any ambient light level. Display images immediately after exposure. All system warnings must be indicated on display.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused
3. Provide collimators for [Low Energy All-Purpose (LEAP), Low Energy High Resolution (LEHR), Medium Energy All Purpose (MEAP), Pinhole, Diverging, and/or Mamo.]
4. Energy range must be [50-350] [____] keV
5. Provide acquisition modes [planar, gated and/or dynamic.]
6. Motorized height adjustment controlled by a [hand control and/or foot control.]
7. Hardware must include internal storage of [500] [____] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.

D. Simulation/Treatment Planning Systems

X9825 – Nuclear Imaging System

1. Display must be high brightness and high resolution color display of patient and equipment parameters. Display must be adjustable and readable in any ambient light level. Display images immediately after exposure. All system warnings must be indicated on display.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
3. Must have integrated diagnostic [16- and 32-slice] [____] CT
4. The gantry must have user friendly control panels for easy positioning. Gantry opening must be at least 78 centimeters in diameter
5. Provide a minimum tested weight capacity of [500] [____] lbs.
6. Upholstered pads for table/couch must offer firm support with minimum compression.
7. Crystal thickness must be [3/8] [____] inch.
8. Energy range must be [35-588] [____] keV
9. Provide acquisition modes [static, dynamic, gated, SPECT, gated SPECT, dynamic SPECT, whole-body, and/or whole-body SPECT.]
10. Provide motorized height adjustment controlled by a hand control and/or foot control. Table adjustment motion must be controlled and smooth.
11. Must have automatic image reconstruction.

12. Hardware must include internal storage of [500] [____] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.

E. Nuclear Medicine Measurement System

X9500 – System, Uptake, Thyroid, Mobile

1. Display must be touchscreen LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, corrosion resistant. Parts must allow for thorough cleaning and disinfection.
3. The equipment must have multi-purpose spectrum analysis instrumentation used for uptake studies, wipe tests, and bioassay.
4. System must be capable of displaying patient testing results for analysis and review.
5. Must have a multichannel analyzer with 1024 channels.
6. Must have a maximum count rate of 150,000 cps.
7. Provide a 2 inch diameter NaI (TI) well counter with collimated lead shielding.
8. Provide a neck phantom and built in storage space.
9. Hardware must include internal storage of [500] [____] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.

F. Radiopharmacy/Hot Lab Support Equipment

X9310 – Cart, Transport, Radium

X9315 – Safe, Storage, Radium

X9320 – Shield, L Block, Radium Handling

X9500 – System, Uptake, Thyroid, Mobile

X9805 – Stand, Injection, Nuclear Medicine

1. Bodies must be constructed of metal with factory baked enamel or powder coat finish, laminate, or phenolic. Surface must allow for thorough cleaning and disinfection.

2.1.9 Women's Health

A. Mammography

X5430 – Radiographic Unit, Mammography, Digital

1. Display must be high brightness and high resolution color display of patient and equipment parameters. Display must be adjustable and readable in any ambient light level. Display images immediately after exposure. All system warnings must be indicated on display.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
3. Equipment to maintain nominal operating temperatures using internal cooling mechanisms.
4. [System must have FDA approved digital breast tomosynthesis capability.]
5. Must have automatic image reconstruction
6. [System must have 2D and/or 3D imaging technology.]
7. Automatic exposure control facility required. Include remotely controlled exposure switch.
8. Safety measures to include automatic breast release after x-ray exposure and emergency switches on both sides of the gantry to release in case of power failure.
9. Hardware must include internal storage of [500] [____] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.

B. Biopsy Equipment

X5435 – Breast Biopsy System, Stereotactic

X5440 – Table, Breast Biopsy, Floating Top

X5445 – Table, Breast Biopsy

1. [Provide a minimum tested table weight capacity of [500] [____] pounds.]
2. Must be compatible with commonly used biopsy devices.
3. Patient surfaces and table body must be antimicrobial, non-porous, and impervious to fluids. Parts must allow for thorough cleaning and disinfection. Table base must be enamel/powder coated steel.
4. Provide motorized height adjustment controlled by a hand control and/or foot control. Table and/or system adjustment motion must be controlled and smooth.
5. Upholstered pads for table/couch must offer firm support with minimum compression.
6. [Base must include four wheels with braking capability.]

2.1.10 Magnetic Resonance Imaging (MRI)

X9900 – MRI System, Open

X9905 – MRI System, Super Conductive

- A. Display must be high brightness and high resolution color display of patient and equipment parameters. Display must be adjustable and readable in any ambient light level. Display images immediately after exposure. All system warnings must be indicated on display.
- B. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
- C. Magnetic field must be [1.5] [___] Tesla and have a field-of-view of [50] [___] centimeters.]
- D. Bore opening must be [70] [___] centimeters in diameter and a depth/length of [145] [___] centimeters.]
- E. Patient table/couch must have a minimum load bearing capacity of [550] [___] pounds.
- F. Provide imaging applications for [Neuro, Body, Breast, Cardiac, Vascular, Musculoskeletal (MSK), and/or Pediatric.]
- G. Provide coils for [head, neck, body, abdomen, spine, breast, knee, shoulder, and cardiac.]
- H. Hardware must include internal storage of [500] [___] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.
- I. [Provide phantom for calibration of MRI.]

2.1.11 MRI (Support)

X9915 – Detector/Screener, Ferrous Metal

- A. Include visual and audible alarms.
- B. MRI compatible products must use 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.]
- C. Must be wall mounted, built into door frame (recessed), or free standing with base.

2.1.12 Radiographic/Fluoroscopy (R/F)

A. Stationary Equipment

X1200 – Lithotripter, Extracorporeal

X6175 – Radiographic/Fluoro Unit, Angio, Biplane, Digital

X6185 – Rad/Fluoro Unit, Remote, 80 kW, 90/90 Table

X6190 – Radiographic/Fluoro Unit, Cardiac, 100 kW, Digital

X6340 – Rad/Fluoro Unit, 65 kW, 12" I.I., 90/15 Table

X6400 – Rad/Fluoro Unit, 80 kW, 15" I.I., 90/90 Table, DIG

X6535 – Rad/Fluoro/Tomo Unit, Urologic, Digital

- 1. Display must be high brightness and high resolution display of kV, mAs, and timer. Display must be adjustable and readable in any ambient light level. Display images immediately after exposure. All warnings must also indicate on display.
- 2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
- 3. Cables must be fully concealed within system.
- 4. Equipment must maintain nominal operating temperatures using internal cooling mechanisms.
- 5. Automatic exposure control facility required. Include remotely controlled exposure switch.
- 6. Hardware must include internal storage of [500] [___] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.
- 7. Provide hardware and software modularity for future system upgrades.
- 8. Patient table/couch must have a minimum load bearing capacity of [500] [___] pounds.
- 9. Upholstered pads for table/couch must offer firm support with minimum compression.

B. Mobile Equipment

X4890 – Rad/Fluoro Unit, Digital, Mobile, C-Arm

- 1. Display must be high brightness and high resolution color display of patient and equipment parameters. Display must be adjustable and readable in any ambient light level. Display images immediately after exposure. All system warnings must be indicated on display.
- 2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow

for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.

3. Provide a base with four wheels with braking capability. Must have an articulating arm for imaging from any patient position and tube stand counterbalance for rotation in all directions.
4. Cables must be fully concealed within the arm system.
5. Equipment must maintain nominal operating temperatures using internal cooling mechanisms.
6. Automatic exposure control facility required. Include remotely controlled exposure switch.
7. Hardware must include internal storage of [500] [___] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.

C. Support Equipment

X7000 – Center, Mixing, Barium

1. All surfaces that could come in contact with liquids or gasses must be non-porous, impervious to fluids, non-ferrous, corrosion resistant. Parts must allow for thorough cleaning and disinfection.

2.1.13 Stereotactic

X4200 – Stereotactic Surgical System

- A. Display must be high brightness and high resolution color display of patient and equipment parameters. Display must be adjustable and readable in any ambient light level. All warnings must indicate on display.
- B. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
- C. Provide a navigation camera with optical technology to assist with orientation and positioning.
- D. Navigation camera must be mounted on an arm with increased range of motion to accommodate various procedures and approaches.
- E. Provide an uninterruptible power supply [with a minimum of six minutes.]
- F. Must be able to process and display 2D and 3D images for HD anatomical detail.
- G. Hardware must include [wireless, Ethernet, HDMI or USB to PC connectivity for data transmission.]
- H. Hardware must include internal storage of [500] [___] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.
- H. [Must be able to interface with intraoperative imaging systems (iMRI, iCT, C-Arms, and/or O-Arms) to orient surgeons with 3D images of patient anatomy.]

2.1.14 Ultrasound

A. Ultrasound Scanning Equipment

X2100 – Scanner, Ultrasound, General Purpose

X2105 – Scanner, Ultrasound, Cardiac (Echo)

X2106 – Scanner, Ultrasound, Intra-Cardiac Echo

X2107 – Scanner, Ultrasound, Intravascular

X2110 – Scanner, Ultrasound, Pulsed Doppler

X2112 – Scanner, Ultrasound, Ophthalmic

X2115 – Scanner, Ultrasound, Obstetrical

X2125 – Scanner, Ultrasound, Portable

X2126 – Scanner, Ultrasound, Portable, Urinary Retention

X2127 – Scanner, Ultrasound, Central Venous Access

1. Display must be flat panel high resolution color display at least 15 inches wide. Display must be adjustable and readable in any ambient light level.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
3. Unit must be mounted on a trolley designed for the equipment with wheels capable of braking.
4. Equipment must maintain nominal operating temperatures using internal cooling mechanisms.
5. System must be able to connect to a wide range of available transducers. Provide [four] [___] active connection ports for multiple transducers.
6. Hardware must include internal storage of [500] [___] GB of data, with additional removable storage media options. Include compatibility with DICOM image transfer and storage.
7. [Provide connection port for external color or black and white printer.]

B. Ultrasound Support Equipment

- X1997 – Warmer, Ultrasound Gel, Single Bottle**
- X1998 – Warmer, Ultrasound Gel, Multiple Bottle**
- X1999 – Rack, Ultrasound Probe**

1. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.

2.1.15 Counters

- X9835 – Counter, Gamma, Multichannel**
- X9836 – Counter, Gamma, Multichannel**

- A. Display must be LCD/LED high contrast with 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. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
- C. Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission. Systems must be configured based on site specific requirements using manufacturer's standard software interface. System is to have capability to support connectivity to other manufacturer's external equipment.
- D. Include compatibility with DICOM image transfer and storage

2.1.16 Diagnostic Imaging Accessories

- X0990 – Immobilizer, Infant, With Cassette Holder**
- X3145 – Screen, X-Ray, Protective, Mobile**
- X3155 – Rack, Apron/Gloves, Mobile**

- A. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection. All components contacting patient must be protected by a disposable cover or easily disinfected if being reused.
- B. Equipment base to have a minimum four antistatic casters with braking.

2.1.17 Picture Archiving and Communication System (PACS)

- X4110 – Console, PACS, Remote View w/One 2MP Monitor**
- X4111 – Console, PACS, Remote View, 1k X 1k, 1 Monitor**
- X4112 – Console, PACS, Remote View, w/Two 2MP Monitors**
- X4122 – Console, PACS, Remote View, w/Two 3MP Monitors**
- X4124 – Console, PACS, Remote View, w/Four 2MP Monitors**
- X4160 – Information System, DIN-PACS**

- A. Display must be high resolution LCD or LED display. Display must be adjustable and readable in any ambient light level with uniform brightness and contrast. Display must be [color or monochrome.]
- B. Monitor must have In-Plane Switching (IPS) technology.
- C. Monitor must be standalone on countertop, wall mounted, or table/desk mounted using a universal bracket.
- D. Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission. Systems must be configured based on site specific requirements using manufacturer's standard software interface. System is to have capability to support connectivity to other manufacturer's external equipment.
- E. Include compatibility with DICOM image transfer and storage.

2.1.18 X-Ray Imaging – Digital (Support)

- X1420 – Imager, Laser (512x512) Din/PACS**
- X1425 – Imager, Laser (1024 X 1024) (Din/PACS)**
- X1426 – Imager, Dry Chemistry, 14" X 17"**
- X1427 – Imager, Dry Chemistry, 8" X 10" D**
- X4140 – Scanner, X-Ray Film Digitizer**
- X4150 – Processor, Computed Radiography Plate**

- A. Display must be high resolution LCD/LED display. Display must be adjustable and readable in any ambient light level.
- B. Unit must accept or process standard film sizes/images.
- C. Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission. Systems must be configured based on site specific requirements using manufacturer's standard software interface.

D. Provide compatibility with DICOM image transfer and storage.

2.1.19 Testing (Support)

T0010 – Beam Analyzer, Radiation Therapy

T0025 – Meter, Radiation Survey

T0030 – Radiation-Light Field Analyzer

X9845 – Monitor, Radiation, Area

X9847 – Monitor, Radiation, Portable

X9850 – System, Thermoluminescence Dosimetry

A. Device must ensure operation to a level that satisfies the requirements described in FDA CP 7386.003.

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 Conformité Européenne (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--