

DEPARTMENT OF THE ARMY HUNTSVILLE DIVISION. CORPS OF ENGINEERS P. O. BOX 1600 HUNTSVILLE. ALABAMA 35807-4301

AT

ATTENTION OF

April 4, 1990

Contracting Branch A (CEHND-CT-A)

71

Subject: Draft Specifications for Medical Diagnostic Imaging Support (MDIS) System

TO PROSPECTIVE OFFERORS

MDIS is state-of-the-art technology for an image management and communication network for use by radiology and medical communities. The system will provide clinical-quality digital imaging (acquired from all radiologic imaging modalities) for medical diagnosis including storage and archiving.

Huntsville Division may act as the acquisition agency for the joint Army and Air Force requirements for MDIS. Since MDIS is state-of-the-art technology, Huntsville Division is offering draft specifications for industry review and comments as a part of market research.

You are encouraged to review and provide comments on the draft specifications to this office by April 23, 1990. This is not a solicitation. All responses are voluntary and the Government is not negotiating or calling for offers. When comments are provided, a point of contact would be helpful.

You are encouraged to suggest alternatives to the Government approach and provide suggestions for obtaining and sustaining competition.

Please submit your comments in writing. All responses will be treated confidentially and will be acknowledged in writing. The point of contact in this Division is Contract Specialist, Ms. Henrietta Wright, US Army Engineer Division, CT-A, Huntsville, PO Box 1600, Huntsville, AL 35807.

Sincerely,

D. Aldridge

Chief, Contracting Division

# MDIS

# Medical Diagnostic Imaging Support System



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DR Performance Work Statement (PWS)

> Version: 0.9 ifc as of: 28 March 1990

Prepared by: MDIS Technical Development Team

Acquisition Administered Through: US Army Engineering Division, Huntsville

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# **MDIS System**

# Performance Work Statement

# (Version: 0.9 ifc)

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# Part I. MDIS System Overview

#### 1. MDIS System Summary.

#### 1.1. Introduction.

#### 1.1.1. General.

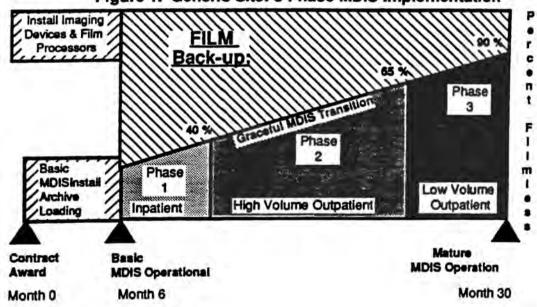
The Medical Diagnostic Imaging Support (MDIS) system is a network of computer-based digital devices to effectively manage medical diagnostic images. MDIS will significantly improve the quality, productivity and efficiency of medical radiologic practice as a major component of military health care. These specifications detail the performance requirements for an MDIS system at both large medical treatment facilities (MTF) and smaller MTFs requiring expert diagnostic imaging support. The system shall provide connectivity for image and patient data management in a multi-building MTF environment- referred to as an intra MTF system- as well as transfer of images and associated patient data between MTFs. In some cases these MTFs can be separated by hundreds of miles- referred to as an inter-MTF system.

#### 1.1.2. System Sites.

The first large MTFs to receive MDIS systems are Madigan Army Medical Center (MAMC), Fort Lewis, Tacoma, Washington, Wright-Patterson Air Force Base (WPAFB), Dayton, Ohio and Brooke Army Medical Center (BAMC), Fort Sam Houston, San Antonio, Texas. The smaller MTFs projected to receive this technology initially include Luke AFB, Phoenix, Arizona, Langley AFB, Hampton, Virginia, MacDill AFB, Tampa, Florida. Nine intra-MTF and nine inter-MTF follow on sites are also projected under this acquisition. The form and functionality of the small MTF systems shall be the same as the initial large implementations, though on a smaller scale. This acquisition includes complete "turn-key" installation at each individual location.

#### 1.1.3. Time-Phased Installations.

Intra-MTF systems will be put into operation in a time-phased implementation plan over a period of 12 to 36 months after an initial delivery order is placed with the contractor. Typically, larger MTFs will institute a two or three phased planning process for up to two or three years. This approach is designed to totally integrate MDIS systems technology into routine clinical use at an MTF. The contractor shall provide MDIS systems solutions that stress a phased implementation with special focus on a sophisticated, total solution for the MTF over a period of time consistent with clinical utility and systems reliability. Inter-MTF 'hub and spoke' teleradiology systems will be implemented in a more expedited fashion to meet immediate clinical needs; however the contractor shall also insure that basic capability is also in place at the hub MTF to guarantee future expansion-both between and within facilities. The following figure depicts a generic site MDIS implementation.





#### 1.2. Basic Function.

#### <u>1.2.1. General.</u>

The function of the MDIS is to communicate and manage high quality digital radiologic image examinations for use in diagnosis and consultation by clinicians and other health care providers. The MDIS system is a network of computer based medical devices that (a) accepts digital diagnostic images, (b) communicates radiology information to and from the Composite Health Care System (CHCS), (c) archives and manages images and related data, (d) displays and presents images and data at workstations for consultation and interpretation and, (e) communicates images and data to and from remote sites.

#### 1.2.2. Basic Parameters.

The system must preserve the full fidelity of the acquired image quality for image interpretation as images are generated by various radiologic imaging devices. In addition to the existing imaging devices listed above, the MDIS system requires computed radiography to acquire conventional radiographic images in a direct digital format as well as film digitizers to convert hard copy film images to digital format. The system shall include archiving of images and related patient information with minimum hardcopy output. The number and sophistication of the soft copy image display workstations shall be dependent upon radiology department current and forecasted workload at each site. The transfer of images and patient data in the intra-MTF and inter-MTF configurations shall be done through networks and commercially available data grade links to meet throughput requirements in paragraph 6 below. The solution provided shall be modular and provide building blocks for all systems.

1.3. System Description.

<u>1.3.1. General.</u>

The generic MDIS system shall include all hardware, firmware and software to effectively manage and communicate diagnostic images and associated data throughout the network. This system is composed of image acquisition devices, data storage, data archive, image review stations, diagnostic reporting stations and image communications within and between MTFs. Where appropriate, the MDIS System must be integrated with the DOD standard, Composite Health Care System (CHCS) to facilitate efficient network operations and data management. In addition, the MDIS system shall provide for stand alone data entry and use of demographic data and result reporting where the CHCS is not installed or, if installed, when it is off-line.

#### 1.3.2. Supported Imaging Devices.

The system shall support at least the following modalities but are not limited to: conventional film/screen radiography (CF/SR), computed tomography (CT), magnetic resonance imaging (MRI), ultrasound (US), nuclear medicine (NM), computed radiography (CR), digital fluoroscopy (DF), digital subtraction angiography (DSA), and positron emission tomography (PET). The contractor shall provide a specific method for CR capability as well as the ability to induce hardcopy film based images into the system when required. The contractor shall provide complete installation, as specified for each individual location, including interfaces to local power, water, sewer, communications, and data links.

#### 1.3.3. MDIS Subsystems.

- 1.3.3.1. General. The MDIS System consists of 4 subsystems:
  - a. The Image Acquisition Subsystem
  - b. The Image Output and Display Subsystem
  - c. The Image Database and Storage Subsystem
  - d. The Communications Network Subsystem

1.3.3.2. The Image Acquisition Subsystem shall provide:

a. Computed Radiography: Reusable phosphor plate radiographic systems to acquire conventional x-ray images in digital format.

b. Digital Film Digitizers: to convert conventional film images to digital format.

c. Standard Interfaces to Digital Imaging Devices: to integrate imaging devices, such as computerized tomography (CT), magnetic resonance imaging (MRI) and digital subtraction angiography (DSA), through an American College of Radiology (ACR)/National Electrical Manufacturers Association (NEMA) standard interface.

d. Video Interfaces: to integrate video imaging devices such as ultrasound imaging systems.

e. Paragraph 3 provides detailed subsystem performance parameters.

1.3.3.3. The Image Output and Display Subsystem shall provide:

a. Hard Copy Digital Film Output: this capability shall be on demand causing images to be produced from such devices as laser film printers.

b. Soft Copy Image Display (SCID): this capability shall be from two classes of display workstations- one for primary image interpretation and one for secondary clinical review.

c. Paragraph 4 provides detailed subsystem performance parameters.

1.3.3.4. The Image Database and Storage Subsystem shall provide:

a. Database Management: maintains the information integrity of the system to insure proper flow of images and data in and out of image storage to the clinical setting.

b. Interface to Hospital Information System (HIS): a two-way interface between MDIS and CHCS is required in a mature MDIS system.

c. Image Examination Storage: images and related patient data shall be stored in a combination of short-term storage and permanent long-term archive devices to efficiently manage images and data. This need may require the use of both magnetic as well as optical storage.

d. Paragraph 5 provides detailed subsystem performance parameters.

1.3.3.5. The Communications and Network Subsystem shall provide:

a. Image and Text Data: a combination of communications capability to physically transmit images and data. In many connections, high speed networks using optical fiber or dedicated phone lines may be required. The communication media and protocol must support user transparent network operation which is detailed in paragraph 6 below.

b. Intra-MTF Network Capability: provides for the actual communications to move images within a medical treatment facility- either within or between buildings.

c. Inter-MTF Network Capability: provides for the actual communications for movement of image between medical treatment facilities- sometimes referred to as teleradiology.

d. Paragraph 6 provides detailed subsystem performance parameters.

#### 1.3.2. Fail Safe Operation.

1.3.2.1. General. The MDIS system shall include safeguards to prevent loss of critical functions and data. To insure a high level of system availability the system shall continue operation and minimize inconvenience in the event of failure of components.

#### 1.3.2.2. System Failures- are defined as follows:

a. Soft failure of a component - requires a task to be repeated. No data is lost as a result of this failure.

b. Soft failure of the system - requires retransmission of data or redirection of data to another working path, but does not involve any loss of data.

c. Hard failure of a component - the component malfunctions and requires corrective maintenance or replacement. Any component failure resulting in loss of data is a hard failure.

d. Hard failure of the system - an emergency situation which requires corrective maintenance. The system cannot perform its function.

Paragraph 11 addresses maintenance responses to these failures.

1.3.2.3. Uninterruptible Power Source (UPS)

The Contractor shall supply, at the option of the Government, a UPS at any site-specific modality or piece of equipment. UPS ratings shall be commensurate with the KVA rating of the specified equipment and provide a minimum of 20 minutes operation.

#### 1.3.3. Turnkey Installation.

The MDIS system acquisition includes full "turn-key" installation as described in paragraph 9. The system shall include all equipment cabinetry, racks, stands, console surfaces for input devices, and other items necessary to provide a suitable working surface for the equipment. Ergonomically designed chairs shall be provided for all workstations when required.

#### 1.3.4. Benchmark Evaluation.

The government will conduct a benchmark test, prior to award, as described below. The government will test at two levels of performance: (1.) at the system component level and (2) at the fully integrated system level. The database at the test site shall contain a full variety of images obtained from the full range of digital image acquisition devices. The site must also present for testing the full range of workstations, output devices, storage devices, interfaces and communications networks. Testing shall include form, fit and function as applied to performance capabilities, functionality, end purpose, objectives and design criteria. It shall be possible to test a system in an under load situation as defined below. Network simulation will also be used to evaluate systems performance.

#### 2.0. MDIS System References.

# 2.1. Applicable Documents.

At the time of award of a delivery order, the most current version of the following applicable standards shall apply to MDIS system performance at a specific site.

#### 2.1.1. NFPA Standards.

**10 Portable Fire Extinguishers** 

13 Installation of Sprinkler Systems

70 National Electrical Code

72E Auto Fire Detectors

99 Health Care Facilities

101 Safety to Life from Fire in Buildings and Structures

#### 21.2. Department of Defense Instructions & Directives

In their entirety without individual reference.

#### 2.1.3. Army Regulations.

To be determined.

#### 2.1.4. Air Force Regulations.

AFR 88-15 Criteria and Standards for Air Force Construction

AFR 88-50 Criteria for Design and Construction of Air Force Health Facilities

AFR 88-40 Sign Standards

#### 21.5. International Conference of Building Officials Publications

Uniform Building Code, 1985

#### 2.1.6, Illumination Engineering Society (IES) Publications.

CP-29-78 Lighting for Health Care Facilities

1981, IES Lighting Handbook, Application Volume

1984 IES Lighting Handbook, Reference Volume

# 2.1.7. Institute of Electrical and Electronics Engineers (IEEE).

602-1986 IEEE Recommended Practice for Electrical Systems in Health Care Facilities

**IEEE Communications Standards** 

Medical Information Bus P1073

#### 2.1.8. Federal Publications.

Uniform Federal Accessibility Standards, 1984

Federal Information Resources Management Regulations (FIRMR) in their entirety without individual reference to include:

Hardware Standards (Interchange Codes and Media)

Software Standards

**Programming Language Requirements** 

Telecommunications Standards

Hardware Standards (Transmission)

Hardware Standards (Character Sets)

Software Standards (Documentation)

Federal General Standards (Data Standard Representations and Codes)

Federal Information Processing Standard (FIP) Publications in their entirety without individual reference.

Military Standards.

Mil Std 1472D, Human Engineering Design Criteria for Military Equipment, Systems, and Facilities.

# 2.1.9. The Joint Commission on Accreditation of Health Care Organizations (JCAHO)

Accreditation Manual.

2.1.10. American Society for Testing and Materials (ASTM) Publications.

In their entirety without individual reference.

2.1.11. American College of Radiology (ACR)-National Electrical Manufacturers Association (NEMA) Standards.

ACR-NEMA Standard 300-19XX

ACR-NEMA Data Compression Standard PS-2

#### 2.1.12. Occupational Safety and Health Act Regulations.

In their entirety without individual reference.

# 2.1.13. Other Publications.

NAPHCC National Standard Plumbing Code

National Standard Plumbing Code (SPC)

Uniform Plumbing Code (UPC)

MICA National Commercial Industrial Standards

ASHRAE Handbook on HVAC Systems Applications

ASHRAE Handbook of Fundamental Requirements

SMACNA Duct Construction Standards

2.1.14. Certification of Listing and Approvals.

Certified copies of approvals issued by Underwriter Laboratories, FMRC, CSA, CYTEC or other nationally recognized testing laboratory showing compliance with applicable standards shall be provided. Written evidence of submission to the FDA of hardware, firmware and software descriptions and good manufacturing practices shall be provided.

2.2. Definition of Terms. To be developed.

# Part II. MDIS Subsystems Performance

#### 3. Image Acquisition Subsystem.

#### <u>3.1. General.</u>

Image acquisition shall be accomplished through the various traditional methods of radiologic practice as described in part 1 above. Direct digital acquisition is a requirement of the MDIS system. The contractor shall provide interface solutions for both digital diagnostic imaging modalities and conventional radiography using computed radiography and laser film digitizers according to the performance parameters described in the paragraph below.

<u>3.1.1.</u> Autorouting. At the image acquisition site, there shall be a capability to route image examinations to any hard copy printer or soft copy image display on the network as an exam is completed. This function is termed autorouting.

<u>3.1.2. Emergency Routing.</u> There shall be a emergency examination override feature that interrupts processing of an existing on going study and allows processing and routing of a 'STAT' image to a softcopy image display or hardcopy printer device on an expedited basis.

#### 3.2. Computed Radiography (CR).

**3.2.1.** General. The contractor shall propose CR acquisition methods which employ reusable stimulable phosphor plate technology as a replacement for conventional film/screen technology. Proposed CR devices shall be compatible with existing cassette type X-ray imaging systems and its operational aspects shall be functionally equivalent to or better than the present film based system. Retrofit of cassette handling capability on radiographic devices to accommodate CR cassettes is not acceptable.

<u>3.2.2. Specific CR Performance.</u> Due to variations in clinical requirements and workload factors, three versions of CR performance (high, medium, and low) are required as described in the following table. Site specific solutions may include all three levels of performance.

		<u> </u>	
Computed Radiography	Performance Requirements*:		
(CR) Attribute:	High	Medium	Low
Throughput ** (plates / hour)	60	40	20
Multiple Plate Size Processing ***	Yes	Yes	No
Input Stacking Capacity (Plates)	30	10	NA
Standard Spatial Resolution- Minimum: 2.5 lp/mm	Yes	Yes	Yes
High Spatial Resolution- Minimum: 5.0 lp/mm	Yes	Yes	No
Dynamic Resolution- Minimum: 10 Bits/pixel	Yes	Yes	Yes
ACR/NEMA fully compliant	Yes	Yes	Yes
Image Processing	Yes	Yes	Yes
Max Footprint	NA	NA	10 sq ft Desktop

Figure 2. Requirements for Computed Radiography

NOTES: •

Numerical entries represent minimum acceptable performance levels, except where indicated otherwise.

 Measured from patient registration until the time the image is available to the MDIS network.

\*\*\* Varying plate sizes typical of those used in conventional radiography.

<u>3.2.3. Additional Requirements.</u> In addition to the requirements contained in the above table the CR device must have the following capabilities:

- 3.2.3.1. Device Diagnostics. The CR device shall perform self diagnosis and report error or fault conditions to the device operator and the MDIS network as described in paragraph 6.
- 3.2.3.2. Image Retention Time. Exposed image plates must be capable of being held for up to four hours without a loss of observable image fidelity. This means that signal decay on the phosphor plate shall not degrade beyond 95% of its original acquisition value after 4 hours.
- 3.2.3.3. Image Processing. The device shall have automatic and userselectable image processing capabilities which are selected in accordance with each anatomical region, projection and information requirement. Pixel dimension information shall be communicated to the network for mensuration. The CR user shall have the ability to manually override the automatic setting and enter new image processing parameters. The user shall also have the capability to modify automatic image processing protocols.
- 3.2.3.4. Patient Radiation Dose. Patient radiation dose needed to acquire the diagnostic image shall be less than or equal to that normally required to produce the same image of identical quality using conventional screen/film techniques.
- 3.2.3.5. Preview Monitor. The device shall be equipped with a preview monitor which permits previewing of images prior to complete processing. The CR device shall allow the user to abort unacceptable previewed images without further processing.
- 3.2.3.6. Examination Terminal. An examination terminal shall be provided for the technologists to view patient identification

and examination information. The device shall provide the user with the ability to select or modify examination data. Any changes made to this information must be communicated back to the radiology information system. Technologists shall be able to add or delete examinations from this terminal. The terminal must allow the technologist to associate patient identification and examination information with the image plate(s) being used for the examination.

3.2.3.7. Image Quality Control. The contractor shall provide a means to compute the mean amplitude and standard deviation of acquired image pixel values within user specified regions of interest. The technique provided shall also allow the technician to compute and plot line spread and contrast transfer functions. The user shall be able to perform these functions while the device is in the clinical operating mode. In addition, the contractor shall provide a means to perform device sensitivity and linearity tests. These tests shall be capable of being conducted in the service or operational mode.

#### 3.3. Interface from Digital Modalities.

3.3.1. General. The contractor is responsible for providing a fully functioning interface to all digital modalities. This includes providing both the modality and MDIS network sides of the interface, where necessary. This interface shall accept and introduce digital images and associated text data produced from digital acquisition devices, as described in paragraph 1, into the MDIS network.

<u>3.3.2. Systems Performance.</u> The performance of this interface shall not constrain the throughput from the imaging devices. Image transfer to the network shall require no more than a single key stroke equivalent. Systems throughput is discussed in detail in paragraph 6 below.

3.3.3. Direct Digital Acquisition (DDA). The contractor shall provide an ACR/NEMA standard interface as described in paragraph 6. This interface shall preserve the contrast and spatial resolution as well as image parameters (e.g. CT numbers, MR signal intensities) of the original acquisition device.

<u>3.3.4. Direct Video Acquisition.</u> The contractor shall provide an interface to introduce ultrasound images into the MDIS network. A video interface is an acceptable acquisition method if a direct digital interface is not available on the ultrasound unit.

#### 3.4. Film Digitizer.

<u>3.4.1. General.</u> Due to variations in clinical requirements and workload factors, two levels of digitizer performance, (high output and low output), are required as described in the table which follows.

#### 3.4.2. Film Digitizer Requirements.

5.0		
Requirements for:	High Output	Low Output
Sheet Feed	Yes	no
Spot Size	Variable	fixed
Minimum Spot Size	Not larger than 200 microns	Not larger than 200 microns
Dynamic Range	10 bits	10 bits
Throughput	120 Sheets/Hour at maximum resolution	30 Sheets / Hour at maximum resolution

Figure 3. Film Digitizer Requirements

#### 3.4.3. Additional Requirements.

3.4.3.1. Film Sizes. The film digitizers shall accept conventional x-ray films from 8"x10" up to 14"x17". The device must be able to determine the film size automatically. It shall auto-adjust the laser spot size accordingly.

- 3.4.3.2. Automatic Sheet Feeder. The high output digitizer shall be able to accommodate an automatic sheet feeder. This sheet feeder must be able to hold and automatically feed a minimum of 10 x-ray films of intermixed size.
- 3.4.3.3. Presentation To Network. The digitizer must introduce a series of images into the network in a reasonable time- on the order of 30 seconds or less for each image.
- 3.4.3.4. Network Interface. The interface between the film digitizer and MDIS network shall be ACR/NEMA compliant.
- 3.4.3.5. Preview Monitor. If the digitizer is not used in conjunction with a local workstation, the contractor shall provide an image preview monitor at the digitizer. The digitizer shall allow the user to abort unacceptable previewed images.
- 3.4.3.6. Device Diagnostics. The device shall perform self diagnosis and report error or fault conditions to the device operator and the MDIS network.

#### 4. Image Output and Display Subsystem.

#### <u>4.1 General.</u>

Image display and outputs consist of hard and soft copy outputs. Hard copy outputs include films produced from a digital laser imager and radiologic teaching slides from a 35MM slide device. Soft copy outputs are defined as images produced on imaging workstation monitors using digital data. The contractor shall propose methods of accomplishing both means of display according to specific performance parameters described the paragraph below.

#### 4.2. Laser Film Imager.

The MDIS system shall include laser multiformat imagers with the following performance features. The number of imagers at each site will be based on the volume of images produced.

#### 4.2.1. Film size.

The imager shall be able to record images in multiple film sizes, including  $14 \times 17$  inch,  $14 \times 14$  inch,  $11 \times 14$  inch,  $10 \times 12$  inch, and  $8 \times 10$  inch. This performance feature may be met through the use of appropriately sized film magazines. The imager shall provide at least six image formats- 2:1, 4:1, 6:1, 9:1, 12:1, and 15:1. The imager shall be capable of carrying 12 bit pixels from the input to output digital to analog converter in the device.

#### <u>4.2.2. Safety features.</u>

The imager shall be equipped with interlocks or warning lights that prevent double exposure, exposures with film in the wrong position, incompatible film sizes, and improper film insertion and removal.

#### 4.2.3. Laser Imager Operation.

Image selection and film format shall be controlled from a only specifically designated workstations as identified by the systems manager. The imager shall print the image as it was acquired or stored on the archive, including as an option any image overlays and patient data when specified at the time of print request. Requests for printing shall run in background mode and will not compromise the workstation while the image is being printed. The imager shall be capable of receiving images only from specially authorized workstations on the network and shall print the requester identifier on the border of the film.

#### 4.2.4. Automatic Film Handling and Transfer.

The imager shall include an automatic bulk film load system. Two loading magazines for each film size specified above capable of holding 100 or more films each must be provided. Two receiving magazines for each film size specified above capable of receiving at least 100 films each shall also be provided. The laser imager shall automatically transfer films to a commercially available, stand-alone film processor. This processor must have a cycle time of no more than 90 seconds, and be capable of processing at least 200 sheets of 14 x 17 inch film per hour. Only ambient water shall be necessary for normal processor operation; water temperatures from 40 to 90 degrees F (4-32 degrees C) shall be acceptable.

#### 4.2.5. Ouality Control/Calibration.

The imager shall allow the user to manually adjust image contrast and density. A digital test pattern (SMPTE or equal) shall be provided in the device for quality assurance and device verification. The imager shall also have automatic calibration capabilities, using built in test patterns and automatic densitometer feedback of film densities.

#### 4.2.6. Multiple film originals.

The imager shall produce multiple copies of the same image with one request. This feature shall be selectable from the the requestor's workstation.

#### 4.2.7. Error and Status Indication.

The laser imager shall include a self diagnostic capability which shall indicate the following error and system status conditions: film low, film empty, memory full, film feed error, printing, and alarm. These error conditions shall be reflected back to the workstation following the guidelines in paragraph six.

#### 4.2.8. Retrofit for Existing Laser Printers.

When required on a site-specific basis, the contractor shall accomplish a retrofit MDIS network interface for any on-site laser printers that currently may be directly interfaced to on-site imaging devices such as CT or MR systems.

#### 4.3. 35 mm Slide Production.

The MDIS system shall produce a 35mm slide format only from specially workstations on the network. The slides shall include any image overlays or patient data that is displayed on the image at the time of request. This function shall be accomplished automatically, with no human intervention.

#### 4.4. Soft Copy Image Displays (SCIDs).

**<u>4.4.1. General.</u>** The MDIS system requires two classes of workstations for soft copy image display (SCID), the diagnostic workstation and the clinical workstation. The following table describes the required performance for these two workstations. Workstations shall be provided with an ergonomically designed chair for the operator

when required. The following narrative following the table describes the individually required performance attributes in detail.

#### SEE WORKSTATION TABLE

#### ON THE FOLLOWING TWO PAGE INSERTS

#### 4.4.2, Display Monitors.

- 4.4.2.1. General. Each workstation shall be configured with from one to eight monitors. Two classes of monitors are required- class A and class B.
- 4.4.2.2 Class A and Class B Monitors. The class A monitor shall have no less than a 2048 by 1680 pixel matrix size. The class B monitor shall have no less than a 1280 by 1024 pixel matrix size, and can be used in a portrait or landscape mode depending on the workstation configuration. The screen size of either monitor shall be no less than 19 inches and no greater than 23 inches diagonally.
- 4.4.2.3 Data Sets Available to the Monitors. The full data set of acquired images (e..g. 2K by 2.4K 10 bit CR images) shall be available for viewing when the diagnostic workstation is configured with class A or B monitors. The clinical workstations for remote viewing will be configured with class B monitors. These clinical workstations shall utilize 1K by 1.2K by 8 bit downsampled data sets for computed radiographic images; other modalities will utilize appropriate matrix size but all will be downsampled to not more than 8 bits of dynamic range for remote viewing. The utilization of mensuration, text annotation, and graphics annotation as defined below shall not reduce the number of gray levels of

# DRAFT TABLE SCID

1  Monitor Type  Class "A" or "B"  Class "C only"    2  Number of Display(s)  1-8 Monitors  1-2 Monitors    3  Spatial Resolution  IK x 1.2K & 2K x 2.5K  IK by 1.2K    4  Viewable Raster Diagonal on Monitor  19" to 23"  15" to 23"    5  Brighmess (Luminescence)  2K, >25 F-Lamberts  IK >7 F-Lamberts    6  Gray scale display  Gray Scale (BBin)  Gray Scale (BBin)    7  Flicker Free  ym  ym    8  Monitor Calibration  ym  ym    9  Brighmess Uniformity Degredation  <2%  <2%    11  Spot Size Variation  <2%  <2%    12  Prame Buffer  12 Bits  8 bits or graster    13  Anniliary Output for Slave Monitors  ym  ym    9  Prictorial Patient Directory  ym  ym    1  Prictorial Patient Directory  ym  ym    2  Worklist  ym  no    3  Display on single Monitors  ym  ym    4  Image Restrangement  ym  ym    5  Paging within Monitors  ym  ym    6  Worklist Charter  ym  ym    7		WORKSTATION HARDWARE	Diagnostic Workstation	Clinical Workstation
2  Number of Display(a)  1-8 Monitors  1-2 Monitors    3  Spatial Resolution  IK x 1.2K & 2.5K  IK by 1.2K    4  Viewable Raster Diagonal on Monitor  19" to 23"  IK Data Set(down asmplact)    4  Viewable Raster Diagonal on Monitor  19" to 23"  IK Data Set(down asmplact)    5  Brightness (Laminescance)  2K, >25 Ph-Lamberts  IK, >70 Ph-Lamberts    6  Gray scale display  Gray Scale (Bits)  Gray Scale (Bits)    7  Flicker Free  yes  yes    8  Monitor Calibration  yes  yes    9  Brightness Uniformity Degradation  <2%	1	Monitor Type	Class "A" or "B"	
Mix and Match  IK Data Set(down sampled)    4  Viewable Raster Diagonal on Monitor  19" to 23"  19" to 23"    5  Drightness (Luminescence)  2K, >25 Pr-Lamberts  1K, >70 Pr-Lamberts    6  Grey scale display  Grey Scale (SBits)  Grey Scale (SBits)    7  Picker Pree  yes  yes    8  Monitor Calibration  yes  yes    9  Brightness Uniformity Degredation  <25	2	Number of Display(s)	1-8 Monitors	· · · · · · · · · · · · · · · · · · ·
Mix and Match  IK Data Set(down sampled)    4  Viewable Raster Diagonal on Monitor  19" to 23"  19" to 23"    5  Brightness (Luminescence)  2%, >25 Pr-Lamberts  1%, >70 Pr-Lamberts    6  Grey scale display  Grey Scale (SBits)  Grey Scale (SBits)    7  Picker Pree  yes  yes    8  Monitor Calibration  yes  yes    9  Brightness Uniformity Degredation  <25	3	- •	1K x 1.2K & 2K x 2.5K	
4  Viewable Raster Diagonal on Monitor  19" to 23"  19" to 23"    5  Brightness (Luminescence)  2K, >25 Fr-Lamberts  1K, >70 Fr-Lamberts    6  Grey scale display  Grey Scale (SBits)  Grey Scale (SBits)    7  Flicker Free  yes  yes    8  Monitor Calibration  yes  yes    9  Brightness Uniformity Degredation  <25.		•	Mix and Match	-
6  Gray scale display  Gray Scale (SBits)  Gray Scale (SBits)    7  Flicker Free  yes  yes    8  Monitor Calibration  yes  yes    9  Brightness Uniformity Degredation  <2%	4	Viewable Raster Diagonal on Monitor	19" to 23"	•
6  Grey scale display  Grey Scale (381s)  Grey Scale (381s)    7  Pickar Free  yes    8  Monitor Calibration  yes    9  Brighmass Uniformity Degredation  <2%	5	Brightness (Luminescence)	2K, >25 Pt-Lamberts	1K, >70 Pt-Lamberta
7  Flicker Free  yes  yes    8  Monitor Calibration  yes  yes    9  Brighman Uniformity Degredation  <2%	6	Grey scale display	Grey Scale (SB(ts)	
8  Monitor Calibration  ym  yms    9  Brightness Uniformity Degredation  <2%	7	Flicker Free	yes	
9  Brightness Uniformity Degredation  <2%	8	Monitor Calibration		•
11Spot Size Variation<5%<5%12Prame Buffer12 Bits8 bits or greater13Auxiliary Output for Slave MonitorsyesyesWORKSTATION FUNCTIONSDiagnostic WorkstationClinical Workstation1Pictorial Patient Directoryyesyes2Worklistyesno3Display on single MonitorMulti-ImagesMulti-Images4Image Restrangementyesyes5Paging within Boamyesyes6Window/Level Adjustmentyesyes7Inverse Videoyesyes8Edge Enhancementyesyes9Image Reamyesno9Image Reamyesno9Image Reamyesno9Image Reamyesno9Image Reamyesno9Image Reamyesno9Image Reamyesno9Image Reamyesno9Statistionyesno9Statistionyesno9Statistionyesno9Statistionyesno9Statistionyesno9Statistionyesno9Statistionyesno9Statistionyesno9Statistionyesno9Statistionyesno <td>9</td> <td>Brightness Uniformity Degredation</td> <td>25</td> <td>•</td>	9	Brightness Uniformity Degredation	25	•
12Frame Buffer12 Bits8 bits or greater13Auxiliary Output for Slave MonitorsyesyesWORKSTATION FUNCTIONSDiagnostic WorkstationClinical Workstation1Pictorial Patient Directoryyesyes2Worklistyesno3Display on single MonitorMulti-ImagesMulti-Images4Image Rearrangementyesyes5Paging within Monitorsyesyes5Paging within Boamyesyes6Window/Level Adjustmentyesyes7Inverse Videoyesyes8Edge Enhancementyesno9Image Reamyesno9Image Reamyesno9Image Reamyesno9State of yesno9State of yesno1Image Orientationyesno2Modality Specificyesno3Body Part Specificyesno	10	Linear & Geometric Distortion	< 2%	< 2%
13  Auxiliary Output for Slave Monitors  yes  yes    WORKSTATION FUNCTIONS  Diagnostic Workstation  Clinical Workstation    1  Pictorial Patient Directory  yes    2  Worklist  yes  no    3  Display on single Monitor  Multi-Images  Multi-Images    4  Image Restrangement between & within Monitors  yes  yes    5  Paging within Exam  yes  yes    6  Window/Lavel Adjustment  yes  yes    7  Inverse Video  yes  yes    8  Edge Enhancement  yes  yes    9  Image Ream  yes  yes    0  Image Ream  yes  yes    3  Display on single Monitors  yes  yes    4  Image Reamagement	11	Spot Size Variation	47	4%
WORKSTATION FUNCTIONSDiagnostic WorkstationClinical Workstation1Pictorial Patient Directoryyesyes2Worklistyesno3Display on single MonitorMulti-ImagesMulti-Images4Image RestrangementMulti-ImagesMulti-Images5Paging within Examyesyes5Paging within Examyesyes6Window/Level Adjustmentyesyes7Inverse Videoyesno8Edge Enhancementyesno9Image Rosmyesno1Image Colemationyesno2Modality Specificyesno3Body Part Specificyesno	12	Prame Buffer	12 Bits	8 bits or greater
Pictorial Patient Directory  yes  yes    2  Worklist  yes  no    3  Display on single Monitor  Multi-Images  Multi-Images    4  Image Restrangement between & within Monitors  yes  yes    5  Paging within Exam  yes  yes    6  Window/Level Adjustment  yes  yes    7  Inverse Video  yes  yes    8  Edge Enhancement  yes  no    9  Image Roam  yes  yes    1  Image Orientation  yes  no    2  Modality Specific  yes  no    3  Body Part Specific  yes  no	13	Auditary Output for Slave Monitors	3400	yes
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3  Display on single Monitor  Multi-Images  Multi-Images    4  Image Rearrangement	-	-	•	•
4  Image Rearrangement    between & within Monitors  yes    5  Paging within Exam  yes    6  Window/Level Adjustment  yes    7  Inverse Video  yes    8  Edge Enhancement  yes    9  Image Ream  yes    DERAULT DISPLAY PROTOCOL    1  Image Orientation  yes    2  Modality Specific  yes  no    3  Body Part Specific  yes  no	3		•	
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5  Paging within Exam  yes    6  Window/Level Adjustment  yes    7  Inverse Video  yes    8  Edge Enhancement  yes    9  Image Roam  yes    DERAULT DISPLAY PROTOCOL    1  Image Orientation  yes    2  Modality Specific  yes  no    3  Body Part Specific  yes  no		•	yw	Yte
6  Window/Level Adjustment  yes  yes    7  Inverse Video  yes  yes    8  Edge Enhancement  yes  no    9  Image Roam  yes  yes    DERAULT DISPLAY PROTOCOL    1  Image Orientation  yes    2  Modality Specific  yes  no    3  Body Part Specific  yes  no	5	Paging within Exam	•	- · · ·
7  Inverse Video  yes  yes    8  Edge Enhancement  yes  no    9  Image Roam  yes  yes    0  Image Roam  yes  no    1  Image Orientation  yes  no    2  Modality Specific  yes  no    3  Body Part Specific  yes  no		• • •	•	•
8  Edge Enhancement  yes  no    9  Image Roam  yes  yes    DERAULT DISPLAY PROTOCOL    1  Image Orientation  yes  no    2  Modality Specific  yes  no    3  Body Part Specific  yes  no	7	-	•	
9  Image Roam  yes  yes    DERAULT DISPLAY PROTOCOL    1  Image Orientation  yes	8	Edge Enhancement	•	• •
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2 Modality Specificyesno3 Body Part Specificyesno		DEFAULT DISPLAY PROTOCOL		<b></b> '
3 Body Part Specific yes no	1	Image Orientation	yes	no .
3 Body Part Specific yes no	2	Modelity Specific	<b>yes</b>	no
4 Radiologist Specific yes no	3		<b>yte</b>	<b>no</b>
	4	Radiologist Specific	<b>y</b>	<b>10</b>
IMAGE ENHANCEMENTS DEFAULT		IMAGE ENHANCEMENTS DEFAULT		• • <u>•</u>
1 Window and Lavei yes yes	1		786	
2 Inverse Video yes yes	-		-	• .
3 Edge Enhencements yes no	-			•
4 Radiologist Specific yes yes	4			

# IMAGE MANIFULATION TOOLS

1	Cursor across all acreens	<b>yes</b>	<b>yes</b>
2	Window/Level all & Individual Images	<b>396</b>	yes
3	Digital Magnifying Glass	yte	<b>346</b>
4	ZOOM	•	
	Replicated	. <b>3466</b>	
t	Interpolated	<b>796</b>	yw.
5	Sequential 90 degree rotation	•	/-
	(clockwise & counterclockwise	<b>yes</b>	yne
6	Horizontal & Vertical Flip		<b>J</b>
	(180 degree rotations)	<b>3786</b>	yes

#### IMAGE SUPPLEMENTS

with "toggied" overlays

1	Mensuration.	<b>346</b>	<b>yes</b>
2	Text Annotation		Display Only
3	Graphic Annotation	yes	Display Only
4	Hounsfield Unit Values & Statistics	yw	10
5	MRI Relevation Times & Statistics	78	20
6	Save Pull Data (For Compression)	ym	<b>y</b> ws
7	Hard Copy Generation	<b>796</b>	<b>7</b>
8	Delete	yes	yte
9	Unde (OKSE)	yes	<b>346</b>
10	Seve .	yes	no
11	Printer/Spooling Capability	<b>316</b>	<b>yes</b>
12	Autometic screen Manking	yes	<b>yws</b> . 41*

: ,,

the image when displayed simultaneously with these functions. The downsampled data image sets will accurately display any overlays associated with that image.

- 4.4.2.4. Brightness (Luminance). No less than 40 foot-Lamberts for a class "A" monitor and 60 foot-Lamberts for a class "B" monitor shall be provided.
- 4.4.2.5. Gray Scale Display. No fewer than 256 shades of gray (8 bits deep) displayed on each monitor shall be provided.
- 4.4.2.6. Flicker. Each monitor shall be flicker free at typical viewing intensity for 95% of the observers.
- 4.4.2.7. Calibration. Brightness and contrast calibration of each monitor shall be provided so that there is not less than 2% variation from monitor to monitor over the standard user maintenance period (e.g. three months).
- 4.4.2.8. Uniformity and Distortion. The monitor shall have less than 2% brightness uniformity degradation from center to the periphery. The monitor shall also have less than 2% linearity and geometric distortion from center to periphery.
- 4.4.2.9. Monitor Spot Size. The monitor spot size shall not vary by more than 5% from center to diagonal corner of each monitor.
- 4.4.2.10. Frame Buffer. No less than 12 bits deep for diagnostic workstations and 8 bits deep for clinical workstations.
- 4.4.2.11. Slave Monitors. The workstation shall have a slave monitor auxiliary output connection to produce the same single image across multiple monitors.

#### 4.4.3. Workstation Functions.

4.4.3.1. General. The contractor shall provide multiple image manipulation and enhancement functions for the

workstation. The following are the required performance parameters.

- 4.4.3.2. Pictorial Patient Directory. The workstation shall display the images from a patient's master "folder" and individual image subfolders (e.g., chest, bone, GI). Anatomic region subcategories shall be possible within each subfolder (e.g., elbow, ankle). Single or multiple images shall be easily selectable for full resolution viewing.
- 4.4.3.3. Worklist. The workstation shall automatically generate a worklist of unread exams to enable each radiologist to review the amount of the work ready for their review. The worklist can be created by radiologist or type of workstation (e.g. CT review workstation) at each as determined at each site.
- 4.4.3.4. Image Rearrangement and Display. The workstation shall display multiple reduced resolution images on a selected monitor with the ability to easily rearrange these images on the same monitor. It shall also allow rearrangement of the images easily from monitor to monitor on the same workstation.
- 4.4.3.5. Image Paging. Quick paging through multiple user selected images of an exam displayed on a single monitor shall be provided.
- 4.4.3.6. Default Display Protocol. This required function displays the images of a patient study in a user-selectable default protocol, activated each time the individual user logs on the workstation. The default display shall be modality and body part specific. It shall be a site-specific requirement- i.e. each MDIS site shall be capable of setting their own parameters.

(For example- a patient has new and previous posterioranterior (PA) and lateral chest studies to be interpreted. The radiologist viewing the study prefers to view the PA images on the central two monitors and the lateral images on the outer two monitors of a four monitor workstation. The radiologist also prefers to view the lateral images with the anterior border of the chest closest to the left monitor edge, the new PA images on the right central monitor, and the previous PA image on the left central monitor.)

Additionally, the images shall automatically be presented in an upright as well as correct right/left orientation.

- 4.4.3.7. Image Enhancements Defaults. The workstation shall include user selectable image enhancement defaults for grayscale window and leveling, variable edge enhancement, and inverse video, activated each time the individual user logs on the workstation.
- 4.4.3.8. Window and Level. The workstation shall provide for dynamic window and level through the entire image grayscale data set. This function shall occur simultaneously, for separate images on a single monitor, or occur individually for a selected image on a monitor of a workstation.
- 4.4.3.9. Inverse Video. Display of the inverse video of any selected image is required.
- 4.4.3.10. Edge Enhancement. The workstation shall process and display the image to a user selectable degree of edge enhancement.
- 4.4.3.11. Cursor. The workstation control cursor shall move easily within and between monitors in a smooth continuous manner. The cursor shall always be visible during its movement.
- 4.4.3.12. Screen Blanking. The workstation shall include automatic screen blanking with a user selectable time default.
- 4.4.3.13. Zoom. The workstation shall be able to enlarge the image two to four times and display it by simple replication of pixel

values. It shall also enlarge the image two to four times and display it by interpolating intermediate pixel values in a smooth continuous manner.

- 4.4.3.14. Image Roam. The workstation shall provide smooth continuous movement of a 1K by 1.2K window for display of a 2K by 2.5K by 10 and 12 bit image data set in the workstation memory. The zoomed images shall be viewable by the image roam function.
- 4.4.3.15. Digital Magnifying Glass. The workstation shall sample and display the full data set within a confined area to give a variable degree of zoom in a continuous, smooth manner.
- 4.4.3.16. Rotation and Flip. The workstation shall allow sequential 90 degree clockwise and counter clockwise rotation of the image as well as 180 degree flip in the horizontal and vertical axis. The final new orientation shall be saved for future retrieval.
- 4.4.3.17. Mensuration. The workstation shall compute point-to-point measurement with automatically calibrated, user selectable scales. It shall also perform angular measurement, area and perimeter measurement based on ellipses and pointing device control tracing. It shall compute and display these functions for multiple measurements simultaneously on the same image and saved them as an overlay which can be toggled on and off.
- 4.4.3.18. Text and Graphics Annotations. The workstation shall utilize and display selectable locations and orientations for graphic symbols (e.g., arrowheads and circles) and text annotation with multiple simultaneous displays on the same image. The annotated image can be saved as an overlay which can be toggled on and off.
- 4.4.3.19. Houndsfield Units and Statistics. The workstation shall be able to compute and display mean and sample standard deviation of Houndsfield unit values in the selected region of

interest (ROI), including ellipses and irregular outlines as described. This feature shall allow multiple measurements on the same image. The annotated image shall be saved and the overlay toggled on and off.

- 4.4.3.20. MR Signal Intensity and Statistics. The workstation shall be able to display MR signal intensity with the means and standard deviations in user selectable regions of interest with simultaneous display of these measurements saved as an overlay which can be toggled on and off.
- 4.4.3.21. Delete. The workstation shall be able to allow user selected auto-delete from local storage, and allow marking of selected images for no delete.
- 4.4.3.22. Hard Copy Generation. The workstation shall include a one keystroke equivalent method for image selectable hard copy generation from the workstation console. The incorporation of this function shall be capable of being controlled by the site systems administrator.
- 4.4.3.23. Command Reversal (Undo). The workstation shall be able to reverse the last one key command.
- 4.4.3.24. Save. Teaching and research images shall be saved to longterm archive using reversible compression from a one keystroke equivalent command at the workstation. Both radiology department and individual file folders shall be possible.
- 4.4.3.25. Printouts. Worklists shall be printed on demand with a one keystroke equivalent command.
- 4.4.3.26. System is working. User operations that require time delays, for example some image processing operations, should be indicated on the screen (e.g., a ticking clock icon) to let the user know that an operation is underway and the system is operating.

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4.4.3.27. Autorouting in Background. Workstation performance shall not be impeded by autorouting operations. This activity shall be accomplished in background.

## 5. Image Database and Storage Subsystem.

### 5.1. General.

The contractor shall provide an Image Database and Storage Subsystem with the following performance features indicated in the paragraph below.

### 5.2. The Image Database.

The MDIS database shall serve as patient image exam manager. As such, it shall (a.) accept and store image exams through the inter-MTF or intra-MTF network that are acquired by image acquisition devices, (b.) communicate stored images across the network on demand or by a logical auto-routing algorithm to individual workstations or hardcopy devices- either for reference with the accompanying previous radiologic interpretation or for initial interpretation, (c.) automatically restore exams according to a predetermined procedure and (d.) function in two-way interface with the DOD Composite Health Care System (CHCS) where applicable.

### 5.3 Image Storage.

Depending on system architecture, image storage may be distributed throughout several hardware components on the network. Implementations of the image storage hardware shall flow from and support the logical design of the database. These may include digital storage devices such as magnetic tape and Winchester hard drives, erasable and non-erasible optical disks and related juke boxes as well as other emerging technologies such as parallel transfer disks and optical tape devices.

### 5.4. The Logical Design - Short-term Storage and Long-term Archive.

The image database design shall make use of caching strategies to optimize cost and performance tradeoffs between image archiving efficiency and image delivery times. Specifically, logical designs are required that feature (a.) short-term storage for high demand imaging exams for fast retrieval and (b.) long-term archiving for low demand imaging exams for slower retrieval. The discussion in paragraph 6 regarding benchmarks for fast and slow image throughput times applies.

### 5.4.1. Definition: Short-Term Storage.

Images and related information that must be in the short-term storage are (a.) exams that are newly acquired in the past 24 hours, (b.) exams awaiting primary interpretation (c.) exams acquired in a period equal to the the facility's average length-of-stay for inpatients, (d.) selected historical exams for auto-routing to a clinical area according to a daily clinic appointment schedule, and (e.) selected supporting historical exams of patients who have had new image exams. Shortterm storage may be centralized or distributed throughout the system.

#### 5.4.2. Definition: Long-Term Archive.

This archive must contain all images and related information necessary to support (c.), (d.), and (e.) in the sub-paragraph directly above. The long-term archive shall be capable of storing the current year plus 5 additional years of imaging exams. Additionally, there are certain instances where exams must be retained for longer periodse.g. pediatric images must be retained until a patient's 21st birthday or digitized post-interpreted mammography exams shall be retained for the life of the patient. The particular archiving periods shall be sitespecific.

#### 5.4.2.1. On-Line and Off-Line Long-term Archive.

Images up to two years old may be in the on-line long-term archive. Images older than two years may be in the off-line archive.

5.4.2.2. Operations between Short-term Storage and On Line Long Term Archiving.

These operations shall be a database automatic operation— i.e. no human intervention must be required to archive or restore an image and related information between the short-term and long-term archive.

#### 5.5. Use of the Folder Concept.

Patient exams shall be managed under the metaphor of folders which contain both interpreted images and related reports. Folder organization shall be capable of hierarchical organization by patient, by exam body part.

#### 5.5.1. Folder Contents.

Exam folders shall be capable of being 'opened' on electronic image displays to provide reduced views of interpreted exam images and associated reports. The exam folder must have a capacity of at least 200 images (e.g. MR slices).

#### 5.5.2. Review of Images from Several Exam Folders.

At the display, it shall be possible to select and simultaneously review various images at full resolution from different selected exam folders.

### 5.5.3. Creation of Teaching Folders.

Additionally, the creation of teaching folders shall be possible. These folders shall hold versions of clinically useful exams and reports for medical education. Folder organization shall be both at the radiology department level and by individual physician.

#### 5.6. Use of Compression.

#### 5.6.1. General Approach.

The data compression strategy shall be site-specific and offer the option of both bit-preserving and non bit-preserving compression techniques for exam management. Reasonable compression ratio options range from 2:1 to 10:1.

## 5.6.2. Digital Microfilm Option.

A site-specific scenario where image exams can be displayed at full acquisition device resolution prior to primary interpretation followed by post interpretation long-term archiving at compression ratios of up to 10:1 shall be possible. Moreover, this post interpretation long-term archiving compression operation must be site-specific and capable of being varied by (a.) type of exam and (b.) acquisition modality. This operation is termed digital microfilm.

### 5.7. Use of Image Supplements.

The database shall retain image supplements, i.e. annotations, measurements, default viewing attributes as bit plane overlays that help in image interpretation. These supplements shall accompany the basic image during display at any reviewing workstation.

#### 5.8. Use of Exam Oueries.

User interrogations for exam retrievals from the database shall permit (a.) simple to use query techniques for the non sophisticated user and (b.) retrievals based on multiple sort of data fields as selection criteria (e.g. exam type, date, and patient birthday). This shall include an interactive capability.

## 5.9. Exam Security and Unauthorized Access.

Electronic safeguards of the exam database shall provide the equivalent level of security required for film-based image management systems. These safeguards shall prevent unauthorized access to images and exams. The contractor shall provide features and assurances that meet at least the "C2 level of trust" as defined in DOD 5200.28-STD; however, data encryption is not required.

## 5.10. Loss of Image Information.

Precautions against catastrophic loss of imaging exams shall be embedded in the database design. This includes techniques such as redundant image storage of high demand images on the short-term archive prior to long-term archiving.

### 5.11. Interfacing to CHCS.

## 5.11.1. General.

Events in CHCS produce information required by MDIS and vice-versa. As such, the imaging database shall be able to accept and automatically update transactions such as patient appointments, patient radiologic exam registration, exam orders (including updates, modifications & cancellations), and exam interpretation reports for use as management prompts within the image database. Redundant entry of common data elements in CHCS and the MDIS database is not acceptable.

#### 5.11.2. Bidirectional Nature of the Interface.

#### 5.11.2.1. From the MDIS side of the Interface.

CHCS information shall prompt the image database to do auto-routing of (a.) exam orders, (b.) pre-interpreted image exams (c.) post-interpreted archived image exams and (d.) radiographic reports across the MDIS network. This routing must be to specific acquisition and display devices both in and outside of the radiology department according to a site-unique algorithm.

## 5.11.2.2. From the CHCS side of the Interface.

MDIS data coming into CHCS from the image database shall be sufficient to prompt dynamic updating of the database.

## 5.11.3. Information Integrity.

To maintain database consistency between CHCS and MDIS the following two basic principles will be observed; (a.) consistent exam philosophy and (b.) use of common data elements.

5.11.3.1. Consistent Exam Philosophy- CHCS and the MDIS database

The radiologic exam philosophy of the MDIS image database shall match that of CHCS. For example, radiology orders in both systems must contain multiple exams for a single modality. Additionally, multiple copies of a report for patient order must be placed in each exam folder associated with that order.

## 5.11.3.2. Common Data Elements.

These CHCS data elements shall be in the MDIS database:

Name:	Element #	CHCS Descriptor		
Patient Name	1055	PNT-NAME		
Patient ID	1021	PNT-FMP		
	1373	SPONSOR-SSN		
Patient Classification	1089	PNT-RECORD-TYPE		
Patient Reg No	1091	PNT-REGISTER-NBR		
Patient Reg Suffix	1092	PNT-REGISTER-NBR-SUFFIX		
(Newborn Inpatients - AF Only)				
Referring Clinician		HCP-NAME		
Type of Procedure		PROC-TYPE		
Date of Procedure	1174	PROC-SCHEDULED-DATE		
Time	1175	PROC-SCHEDULED-START		
Procedure Location	1130	PROC-LOCATION		
Procedure Location Cmt	1132	PROC-LOCATION-COMMENT		
Procedure Location Type	1133	PROC-LOCATION-TYPE		
Procedure Inst Text	1128	PROC-INSTRUCTION-TEXT		
Order Identification No	858	ORDER-IDENTIFICATION-NBR		

NOTE: Other data elements may be required to guarantee the information integrity of both databases.

## 5.12. Database Administration.

# 5.12.1. Technical Support Personnel.

This issue is addressed in paragraph 10 below.

## 5.12.2. Management Information Reports Package.

The MDIS database design shall contain procedures for routine creation management information reports to assess database status and performance. The reports package shall be constructed to provide the database administrator with processing performance of various transactions within the database. This reports package shall feature ad-hoc report retrieval capability. It shall facilitate both clinical and technical oversight of the MDIS system operating segments.

## 6. Communications and Network Subsystem.

## 6.1. General.

Communications entails the physical method of transfer digital images, patient data and diagnostic reports from point A to point B whether it is intra-MTF, (between departments/clinics/archives), or inter-MTF in a teleradiology operation. These requirements apply to large and small MTFs alike.

#### 6.2. Intra-MTF

The contractor shall use a local area network (LAN) for image management and database management activity. The contractor, at the government's option, shall utilize an existing LAN for all or part of the network solution if it is available and feasible for use in the MTF. If the existing LAN does not meet throughput or function requirements, the contractor shall provide the total solution. Throughput requirements outlined below shall be met. Government provided LAN information, to determine acceptability for throughput and function, will be disseminated upon request prior to issue of a site-specific delivery order.

#### 6.3. Inter-MTF.

The contractor shall provide a teleradiology capability between any and all sites as identified by the government. The method is left to the discretion of the contractor but shall meet throughput requirements consistent with specific clinical and operational considerations. For high volume situations, the minimum acceptable throughput is that which will provide the capability to transmit compressed images, 14 inch x 17 inch, digitized at a resolution of 2K x 2.4K pixels x 10 bits deep at the rate of 30 images per hour. Transmission shall also permit unattended, error free, batch capability for low volume situations at a lower throughput rate. Batch transmission shall be interruptible with resumption causing no loss of data. Error detection and recovery shall be without user intervention.

## 6.3.1 Inter-MTF Compression.

Transmission compression and decompression (as opposed to database compression) capability shall be bit preserving. The contractor shall provide and install all applicable hardware/software to support the inter-MTF communications at each site. The contractor shall provide for receipt and transmission of text information (e.g. radiology reports, patient data) to and from the reading MTF and the MTF imaging the patient. It will be at the discretion of the government to install the communications link the contractor would have provided.

### 6.4. Teleradiology as an inter-MTF application.

- 6.4.1. General. The specific purpose of this capability is to provide primary interpretation capability for radiologic exams acquired at a non-radiologist manned MTF. Specially configured teleradiology equipment may be proposed to accomplish this function. The specifications for these items are described in this and part 2 of this document. The concept allows for central reading MTFs (hubs) staffed by radiologists to read digitized images transmitted via dedicated communications links from satellite MTFs. A regional approach will allow a distributed workload and can accommodate images from any Department of Defense MTF when implemented.
- 6.4.2. Unique requirements. The workstations shall possess the following attributes:
- 6.4.2.1 Review workstation: (The workstation shall be utilized in conjunction with a film digitizer.) The review workstation shall have sufficient direct access memory to hold 150 14" x 17" images, digitized at 2K x 2.5K pixels x 10 bits deep. An archiving

device shall provide storage for 110,000 images at the same resolution.

- 6.4.2.2. Radiologist workstation: This workstation, used at the central reading MTF, shall have sufficient direct access memory to receive batched, unattended image transmissions, as described in paragraph 6.3, from multiple satellite MTFs. Each satellite can be expected to transmit 100 images at resolutions described in paragraph 6.3 per 24 hour period. Archiving capability for the central reading teleradiology MTF shall be capable of storing at least two years of acquired images.
- 6.4.3. Portable Teleradiology: In addition to the inter-MTF communications links, the contractor shall propose a system for local access to the MDIS via voice-grade phone lines. Access to the MDIS shall permit images and other data to be sent to a workstation (which is connected via phone line) for local display and storage. The intent of this aspect of teleradiology is to allow remote MDIS access for radiologists on-call. This system shall support a minimum signaling rate of 9600 baud (V.32 CCITT). A security mechanism for protection of these dial-up lines from unauthorized access shall also be a part of the proposal.

## Part III. MDIS System Integration

#### 7. MDIS System Operations.

## 7.1. General.

The MDIS system shall be a functional single entity that provides radiologic image and data management support within an MTF or between supporting and supported MTFs. While performance of each MDIS component and subsystem is important, the integrated performance of the entire system is the most meaningful measure of clinical acceptability. The contractor shall provide a system that performs to the parameters specified in the paragraphs below.

### 7.2. Operational Scenario.

The MDIS system shall support the following operational scenario for radiologic practice.

## 7.2.1. Image Acquisition and Routing Activity.

7.2.1.1. Image Exam Orders. Exams are ordered in the CHCS system environment. This order entry information is sent to MDIS through the CHCS-MDIS interface. The MDIS system shall check its database for previous exams and if appropriate they are automatically restored from the long-term archive to the short-term storage after expanding the compressed image archived data set.

7.2.1.2. Network Routing. When a patient reports to the radiology department for an exam, a radiology technologist logs the order request data on the MDIS network and verifies the accuracy. The new radiology exams are acquired and following an image quality control check at the image acquisition site, the image is presented to the network. These images and associated

data shall be routed on the network to the database storage. They shall then be available on short-term or workstation magnetic storage for viewing at appropriate workstations.

## 7.2.2. Diagnostic Workstation Activity.

7.2.2.1. Image Presentation. Diagnostic workstation storage receives images and text from another storage site or directly from imaging devices. By the time a radiologist goes to a workstation, all the necessary images shall be prestaged in short-term workstation storage. Based on the preselected protocol, the worklist of images shall be presented to the users for diagnosis and review.

7.2.2.2 Image Interpretation. The radiologist selects exams from the worklist and performs interpretation. Associated cases are available on the workstation for review with the new examination. Reports are dictated at the workstation and transcribed into CHCS. Subsequently, the reports are introduced into the MDIS system along with appropriate patient data elements so that they are logically matched with the images in the patient image exam folder.

7.2.2.3. Purging Images. Upon completion of the review, following the user-set protocol (time delay, discharge, report availability, and others) the images are automatically purged from the local workstation storage on a FIFO basis to make room for additional follow-on exams.

7.2.2.4. On-demand Queries. Images that are in the short-term storage (STS) or long-term archive (LTA) shall also be viewed on demand, however longer retrieval times as described in paragraph 8 below are acceptable.

## 7.2.3. Clinical Workstation Activity.

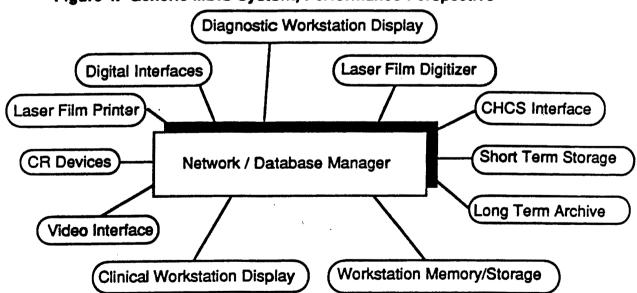
The database autoroutes downsampled images and exams to appropriately identified clinical review workstations located

]throughout the MTF. Short-term storage at these sites holds images that are available for review at the clinical workstation. A local list of available images shall be present. On an hourly basis, autorouted images shall be produced by (1) CHCS appointment schedules or (2) radiologic exam orders placed by the referring physician. Additionally, ad hoc interrogations of in STS or LTA shall be possible.

#### 7.3. Network Environment.

## 7.3.1. Generic Network Configuration.

The contractor shall provide a specific MDIS system solution that meets the generic system solution indicated in the diagram below. Emphasis shall be on efficient image and data flow without regard to specifying any particular topology. Any system solution is acceptable as long as it meets performance requirement described throughout this document. The figure below indicates a generic configuration from a performance perspective.



### Figure 4. Generic MDIS System, Performance Perspective

### 7.3.2. Loaded Network Condition.

Worst case performance shall deteriorate no more than 2.5 fold of the peak performance values. The worst case situation is defined by the period within which all the imaging systems and workstations are in full clinical operation at the busiest two hours of the clinical day at each site. This is termed a "loaded network condition" for the purposes of evaluation and benchmark testing. Peak performance values shall be provided at times other than a loaded network condition.

#### 7.4. System Integration

The contractor shall provide the MDIS network design and all system integration details. This includes meeting the appropriate data volume, traffic patterns that allows for establishment of priorities, network data contention resolution and preservation of data integrity to meet performance parameters specified throughout this document.

#### 7.4.1 Imaging Systems

Images are acquired at various imaging modalities such as CR, MR, CT and others. Once the images are acquired and processed by the acquisition device, they shall be automatically transferred to and received by the MDIS network. The entry of patient name and other demographic data shall be done only once at the image acquisition system. Dual entry into MDIS is not acceptable. The data transfer across the interface to the MDIS network must not impede the operations of the imaging device. Implementation of ACR/ NEMA interface is required for all digital imaging systems. For ultrasound imaging devices that do not support digital interface, digitized video interface at  $512 \times 512 \times 8$  bits is an acceptable image data set.

7.4.1.1. Digital Interfaces. A number of digital imaging devices are in existence at each site. Some devices will have ACR/NEMA interfaces and others may require retrofit. This information is available in the site specific section of this performance workstatement. <sup>#</sup> The contractor shall install ACR/NEMA standard interfaces to all digital imaging systems identified for MDIS network. The throughput of the MDIS side of the interface shall be equal to or greater than that of the imaging system side. Additionally, the MDIS system shall preserve full acquired image fidelity for interpretation as well as the associated patient and image supplement data describing the imaging parameters.

7.4.1.2. CR and Film Digitizer Interfaces. The MDIS shall have ACR/NEMA standard interfaces to the CR and film digitizer.

7.4.1.3. Digital video interfaces. Ultrasound and some fluoroscopy systems readily produce analog video output. Whether 512-1ine or llOO-line systems, such output is amenable to video frame digitization. This method typically limits gray scale resolution to 8 bits, but its clinical acceptability has been demonstrated. Use of such interfaces is predicated on video digitizer performance (See above).

## 7.4.2. ACR/NEMA Standard Interface.

7.4.2.1. Standards. ACR-NEMA compliance is defined as conforming to all aspects of ACR-NEMA 300-19XX- whichever standard is in effect at the time of a site-specific delivery order. The primary use of ACR-NEMA interfaces will be for connection of imaging equipment (IE) to acquisition devices or network interface units (NIU) of the MDIS. The interface between the

MDIS system and NIU or acquisition device shall be determined by the contractor, i.e. :

IE - - NIU - - MDIS Network

or

### ACR-NEMA Contractor Specific Interface

7.4.2.2. Split Implementation. Recognizing that the ACR-NEMA standards committee is proceeding towards a split implementation in emerging standards, for purposes of this performance work statement, the ACR-NEMA logical interface is defined as one which uses the upper (i.e. application, presentation, and session) layers of the ACR-NEMA protocol. These layers then operate over other hardware and protocols for the lower (i.e. transport down to physical) layers. ACR-NEMA logical interfaces may be used as specified by the contractor, except as set forth above.

7.4.2.3. Interface to Multiple Imagers. In the situation where multiple imaging devices are connected to their own computer system (for example; nuclear medicine), an ACR-NEMA compliant interface may be used between this computer system and the MDIS system NIU or acquisition device. The connections between the imaging devices and their intrinsic computer system are determined by the contractor of the multiple imaging system.

7.4.2.4. Interface to Output Devices. A secondary use of an ACR-NEMA compliant interface is between the MDIS system NIU and a laser film printer. A number of laser printers may already be in possession at the project sites. The MDIS contractor shall interface these printers to the network as a retrofit action. Refer to the site specific delivery order.

### 7.4.3. Data Base System Integration.

The MDIS system database shall be fully integrated into workstation operation. Retrieving studies at the workstation, when done outside the worklist function, shall be transparent to the user. When requested studies are in the long term archive, the retrieval time may be considerably greater than from the short term storage. If this is the case, a notice of this increase retrieval time shall be sent to the workstation and displayed. There shall also be a option to abort the requested function.

### 7.4.4. Inter-MTF Teleradiology Integration

An Inter-MTF teleradiology MDIS system shall be fully compatible to the Intra-MTF MDIS system in terms of image quality and database management system. The teleradiology devices shall be interchangeable with MDIS components and subsystems.

#### 8. Network Performance.

## 8.1 General.

Network throughput and system image quality are the two primary performance parameters of an effective MDIS system. Each parameter is affected in part by the volume and complexity of image data, frequency and volume of user requests, the degree of data compression, communication priority parameters, and data access speed of the data storage devices. The performance of the entire network shall be able to support efficient clinical operations of radiology service of the MTF. Network performance requirements are described from several perspectives. The vendor shall describe how each of the throughput requirements are addressed in the proposed system design. These performance parameters shall be available for system benchmarking.

## 8.2 Standard Image Set for Performance Measurement.

The operational response specifications assumes the following data set as a typical radiological study to be viewed at workstations.

Image	Data Set	Compression	# of Images
<u>Type</u>	Per Image	Туре	per Study
New Chest	2Kx2.5KxlO bits	bit preserving	2
Previous Chest Image		10:1	6
New CT Study 512 x 512x 12 bits		bit preserving	50
Previous CT St	udy	10:1	50

The standard exam image set consists of two types of exams-chest and CT (or MR). The chest images are obtained from a CR unit. The new exams are routed/managed with only lossless compression and previous studies have been restored from the LTA that uses 10:1 compression. (Note: Downsampling fits plain radiographic images

into 1k by 1.2k by 8 bits data sets for routing to review workstations outside of the radiology department.)

### **8.3 Imaging Systems Performance Perspective.**

Upon completion of image acquisition, the MDIS system shall provide a means to direct the images to multiple subsystems on the network. The transfer of images from the imaging system to the network shall not impede the normal operations of the imaging systems regardless of the network traffic condition (i.e. loaded or otherwise.) The image throughput performance of the CR on the network shall be same as CR functioning as an independent device. The contractor shall provide automatic image routing capability such that two newly acquired images from a CR device ( $2K \times 2.5 K \times 10$  bits with lossless compression) or CT/MRI device can be sent to and received by storage at a diagnostic workstation within 5 minutes after image acquisition under loaded network conditions. Time begins from the initiation of image transfer at the imaging system to the receipt of the new images at the local storage at the workstation.

#### 8.4. Workstation Performance.

Two categories of workstations are required for MDIS- the diagnostic workstation and the review workstation. The operational features are described in the paragraphs above.

#### 8.4.1. Diagnostic Workstation Perspective.

Diagnostic workstation performance features shall be supported by the capabilities of subsystems. Moreover, the workstation features must be given a appropriately high priority in terms of executing the database command. 8.4.1.1. Workstation storage. The magnetic storage at the diagnostic workstation shall be sufficient to store all images, new and old, that are needed for a minimum of one day's work.

8.4.1.2. Autorouting. In a routine clinical situation, the images (new and relevant previous studies) of scheduled patient cases shall be present at the diagnostic workstation image storage ready for interpretation. Diagnostic workstations shall receive images in the background without noticeable impediment to the viewing process.

8.4.1.3. Display Speed. The following description assumes a four monitor workstation. The same specifications shall apply to the workstations with more display screens. During a clinical day in a diagnostic image reading environment, the diagnostic workstation shall display on demand a list of patient cases to be read by a radiologist. Once a patient case is selected at the workstation, the full frame of the first new chest images shall be displayed in less than 6 seconds and subsequent new and old chest images shall be displayed on the 3 other screens of the workstation within the next 15 seconds. Associated text data shall be displayed within a second after the completion of the image display. Since the standard image set is a multi-modality exam, the workstation shall be capable of displaying new chest images (2 images) and new CT images (50 images) within 20 seconds of the requesting key stroke.

8.4.1.4. Viewing Long Term Archived (LTA) Images. If requested images are in the LTA, the set of images (6 chest and 50 CT images) shall be available in the workstation for display no longer than the 5 minutes after the request.

8.4.1.5. Viewing Short Term Storage (STS) Images. If the standard image set is in STS, the display time shall be less than twice that of subparagraph 8.4.1.4 directly above.

#### **8.4.2. Review Workstation Perspective.**

Review workstations are located outside of radiology department in clinic and ward settings for reference and review of diagnostic radiologic images.

8.4.2.1. Autorouting. In a ward or clinic intra-MTF situation, downsampled images (both new and relevant previous studies) of scheduled patient cases shall be at the workstation image storage ready for reading at the start of the clinical day within 1 hour after the new exam is acquired or 30 min after short term storage studies are requested.

8.4.2.2. Review Workstation Storage. The review workstation storage shall be sufficient to store a minimum of two days of images for all patients in the supported ward or clinical area in which the workstation is located. Individual site requirements may increase but will not decrease these storage values.

8.4.2.3. Display Speed. For single or dual screen review workstations, the screen image "paint" time for downsampled studies stored at the workstation shall not exceed 20 seconds for the first chest image of a study and not to exceed 10 seconds for each subsequent image. When a study consists of more images than can be displayed on the workstation monitors, the time to display the next (or previous) set of images shall not exceed 5 seconds per screen.

The contractor shall configure frame buffer size, workstation RAM size, local magnetic storage type and size, and the MDIS system interface to meet these requirements.

8.4.2.4. Viewing from STS. When the downsampled standard image set is requested from the short term storage (STS), the first image of shall be displayed within 5 minutes in a loaded network condition.

8.4.2.5. Viewing from LTA. When the standard image set is requested from the archive, assuming the the image is on-line on a storage medium (e.g. disk is in juke box), the images shall be displayed within 10 minutes in a loaded network.

### 8.4.3. Output Device Perspective.

The operations of MDIS system network shall not be impeded by any hard copy devices. The interaction between hard copy device and the network shall be such that it shall queue the image print requests. The hardcopy device shall produce hard copy images on single emulsion film of image quality of preselected default values or specially processed images at an authorized user/workstation. The authorized user/workstation shall be able to direct images to any hard copy printer. The hard copy device shall communicate the operational or service status to the user and network manager.

#### 8.5. Network Response.

#### 8.5.1. Responses to Requests.

Most image service requests made from workstations or management terminals will involve movement of patient data. Once a request is made by a user at a workstation, the MDIS system shall notify the requestor the status of a request.

#### 8.5.2. Types of Requests.

The success or failure of the following requests that generates image or data transfer must be indicated to the requestor at their workstation location:

imaging equipment to database, database to workstation, workstation to workstation, transfer to a hardcopy unit, transfer to CHCS,

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CHCS to MDIS system database.

The response to these requests are for verification purposes.

### 8.5.3. Responses to Database Transfers.

A successful response to a request for data movement to the database shall mean that the database has successfully received the data and is assuming responsibility for it. This will allow the sending device to delete the data from its local data storage (if so implemented).

## 8.5.4. Warnings for Lengthy Transfers.

A request which will produce a lengthy transfer of longer than 15 seconds (for example; moving an entire set of patient studies) shall warn the user and provide periodic indication that the request is being processed. The system shall provide abort operation option during a transfer.

## 8.6. Inter-MTF Teleradiology Performance.

Teleradiology is a method of providing expert radiology diagnostic and consultation service to a distantly located clinical facility by using digital images, image transmission and text communication capability. Teleradiology can be seen as a subset to MDIS systems technology. An inter-MTF teleradiology system shall be technically compatible to MDIS system parameters such that it can exchange full image and text data with an intra-MTF MDIS system.

## 8.6.1. Teleradiology System Configuration.

A teleradiology system consists of the digital image acquisition (e.g. film digitizer or computed radiography device) device, a communication link between a remote site to a central location and diagnostic reporting capability. The primary throughput of such a network depends on the image and associated text data transmission time, image matrix size (e.g.  $2K \times 2.5K \times 10$  bits), data compression (bit preserving), and communication speed.

### 8.6.2. Acquisition Unit.

The plain radiography image acquisition device shall be able to obtain at  $2K \ge 2.5K \ge 10$  bits of data set per image and associated patient data and transmit the them over a high speed link in a batch mode. Other digital devices such as CT shall acquire the full data set for their specific modality.

#### <u>8.6.3. Reports.</u>

The contractor shall provide a means to communicate diagnostic reports back to the remote site and have the reports printed on paper form.

#### 8.6.4. Workstations.

The performance characteristics of diagnostic and review workstations are described above.

### 8.6.5. Communication Requirements.

Communication requirements are driven by the image data volume and individual clinical scenario. These are described in the site specific document.

#### 8.7. MDIS System Redundancy, Reliability, and Crisis Management.

The MDIS system shall have reasonable redundancy in the network design so that no single point of failure can cause the major breakdown of radiology service. See paragraph 8 below for systems maintenance considerations. The network shall prevent any loss of acquired images and data. The MDIS shall provide means to enter the missed images. In case a set of images or single image fails to be transmitted from a imaging system, there shall be a way to identify and restored the missing image(s). The contractor shall submit a crisis management plan for evaluation and approval to prevent catastrophic loss of images in the system.

## 8.8 MDIS Image Quality.

Interpretation image quality at the diagnostic displays shall be the full spatial and contrast resolution that was delivered to the network across the image acquisition device interface for new images requiring interpretation. Review image quality at the review work station shall deliver the downsampled data set at the spatial and contrast resolution specified in paragraph 3 above.

## Part IV. MDIS System Support

#### 9. Training.

#### 9.1. General.

The contractor shall provide a comprehensive training program to include: all instructional materials, initial/refresher training, training schedules, quick reference lists, and training program upgrades. Maintenance training is included in paragraph 8.

#### 9.1.1. Instructional Material.

9.1.1.1. General. The contractor shall provide all necessary training materials and equipment for any training course conducted (e.g., instructional texts, audio-visual materials and equipment, workstations, etc.) Each student shall be provided one complete copy of the pertinent materials at the start of the formal training program. This set of materials shall include reference materials guiding the basic procedures for using the MDIS. A complete copy of the training materials shall be retained at the conclusion of training by the responsible MDIS facility trainer for use by MDIS users as reference. All training materials (e.g., instructors' text, audio-visual materials, testing, scoring, quick reference lists and evaluation materials, etc.) shall become the property of the government.

9.1.1.2. Quick Reference Lists (QRLs). Each device shall be provided with a QRL describing basic unit mechanical and software operations. The QRL can be a laminated card for devices without a CRT or pop up screen menu that is called fr use consistently with the same keystrokes throughout the at every CRT.



## 9.2. Formal Training.

The contractor shall include a formal training program consisting of initial and refresher training, ranging in degree from the fully comprehensive system operation for the frequent user to the basic operation and familiarization for general users. The training structure shall target specific groups of MTF personnel based on the degree of system familiarity necessary for these target groups to operate the system at a skill level sufficient to permit their full functionality at their assigned health care tasks. Training shall include development of a training program through formal instructional systems development. This development effort shall include establishment of training standards detailing tasks and proficiency level, a plan of instruction to achieve proficiency levels, formal lesson plans from which instructors shall train, instructional materials, training literature, instructional exercises and examples, and testing and performance evaluation materials. Hands-on training experience shall include equipment and software identical to that provided in the actual installation.

#### 9.3. Initial/Refresher Training.

#### TRAINING TABLE

Type of User	Group Training	Individual Training
Frequent refreshe <b>r</b>	2 Hours	2 - 2 Hour sessions+ 2 hr
Occasional	1 Hour	2 Hour session+2 hr refresher
Infrequent	1 Hour	1 Hour session+1 hr refresher
Radiologic tech	8 Hours	8 Hour session+4 hr refresher
Support staff	8 Hours	8 Hour session*

\*The site can send a person(s) to factory training for in-depth coverage of system and network management and maintenance procedures.

Group training shall be accomplished in groups of no more than 10 trainees. Individual training shall be done with no more than three trainees in one group.

- <u>9.3.1. Initial/Refresher Training.</u> The contractor shall conduct initial and refresher training at the individual MTF where MDIS is to be installed. The contractor shall customize training to the specific needs of radiologists, medical staff and other frequent users, radiologic technologists, maintenance technicians, administration, ancillary personnel, and system managers.
  - 9.3.1.1. Frequent User. For radiologists and other frequent users medical staff training may require several hours. In the course of their duties, they will read large volumes of images and shall be trained by the contractor to a high proficiency in all aspects of image manipulation.
  - 9.3.1.2. Occasional Users. The contractor shall train medical staff who occasionally use MDIS to perform basic image display and manipulations.
  - 9.3.1.3. Infrequent Users. The contractor shall train nursing staff, physician extenders, and other infrequent users to operate workstations located in the clinical area in which they normally work. They will perform only basic image display and manipulations.
  - 9.3.1.4. Radiologic Technologist Users. The contractor shall train radiologic technologist users in the overall operation of the MDIS and with all types of workstations and other system components of the MDIS. Technologists will move images from various imaging modalities to the MDIS, retrieve images from both archival and central storage, and view

images during quality control procedures. They will receive training on CR, Laser Film Digitizers, and other devices.

9.3.1.5. Support Staff Users. The contractor shall train administrative and support staff on all MDIS capabilities, especially those relating to fault diagnosis, maintenance of database and integrity, and performance optimization.

#### <u>9.4. Training Schedule.</u>

### 9.4.1. Training Schedule.

The contractor shall provide a schedule for training the MTF staff. The contractor shall conduct training on site at the MTF at the convenience of the government during normal duty hours. The government has the option to request training by the contractor on weekends and evenings with reasonable notice of at least two weeks. At the option of the government, the contractor shall conduct training on a regional basis. The contractor shall integrate the training to coincide with equipment installation so that trained MTF staff are available when the contractor establishes initial operating capability.

## 9.4.2. Software Demonstration.

The contractor shall provide a site-specific software tutorial with the first deliverable. The government expects this package to permit active simulation of an operational workstation for use in training. This demonstration package shall be provided within the first set of deliverables during the post award period.

## 9.5. Training Program Upgrades.

The contractor shall provide training to the appropriate target audience when system upgrades occur. This training shall be at the level of quality equal to that of previous implementation program.

#### 10. Maintenance.

#### 10.1. General.

The contractor shall provide maintenance support for all components of the system at each site. All service shall be provided by factory trained, English speaking, technically qualified and authorized service personnel. All tools, test equipment, parts, and supplies necessary to maintain all components of the MDIS system shall be the responsibility of the contractor. The contractor shall provide a contact point for each site, for both hardware and software maintenance. The contact point shall be available 24 hours a day.

## 10.1.1. Service Support.

The size and complexity of the system shall dictate the level of service support required. The contractor shall submit a maintenance/operation plan for approval using the following guidance:

### 10.1.2. Large Facility Support.

At larger, fully integrated (networked) sites there shall be on site technical support for operating and maintaining the system. This support shall be available on site when the contractor establishes IOC and remain available on site through the warranty period including any extensions. Onsite technical support shall be available during normal daytime work hours identical to those of the radiology department site where support is provided through this contract. The contractor shall provide copies of this work experience history and educational achievements for on site technical support staff. This will include copies of training certificates, if applicable, demonstrating that the staff possesses the level of skill which shall meet the following requirements. On site technical support shall include skills in system engineering, database management, and technical computer operation, repair and maintenance. Typical staff skills which shall be required to technical support are described below.

- 10.1.2.1. System Engineer- Responsible for optimal operation of all the computer components of the MDIS system, including databases, image transmission, interfaces, and electronic image archives. This individual shall be the contractor's onsite point of contact and supervises the database/archive manager and the computer technician.
- 10.1.2.2. Database/Archive Manager-Responsible for all aspects of image archiving, both electronic and hard copy. Assures that imagery is entered into the archive in the correct format and is readily available for patient care. The individual shall be expert in the use of computers for data management and in operation of a medical center image archive.
- 10.1.2.3. Computer Technician/Trainer Responsible for maintenance and training on the system. This individual shall be trained in all aspects of computer systems maintenance and have a thorough understanding of electronic circuits and trouble shooting techniques. This individual shall be proficient in the operation of all components of the system, and fully capable of training others in the proper operation of the equipment.
- 10.1.2.4. On-Call Maintenance Support. At smaller facilities / installations, (i.e., teleradiology link only) the government will accept on-call technical support instead of on-site technical support with individuals qualified in accordance with the guidelines above.

### 10.2. Warranty Maintenance.

Contractor shall include an extended warranty for all parts and full labor of 365 calendar days following full government acceptance of the MDIS system. Warranty shall include around the clock response. The government representative shall make formal notification by phone and the response time measure shall start. During the warranty period, the contractor shall furnish maintenance service support that will include as a minimum, preventive and corrective maintenance services for the MDIS system and all associated hardware, firmware, and software components and additional accessories ordered with the MDIS system. The contractor shall provide all parts, labor, travel, and expenses necessary to perform such services at no additional cost to the government, except where maintenance is required as a direct result of abuse, misuse, willful misconduct, gross neglect or damage by the government.

#### 10.2.1. Preventive Maintenance.

The contractor shall perform all preventive maintenance (PM) services required for system hardware, firmware, and software at times convenient to the government. The contractor shall furnish a preventive maintenance plan/schedule for approval. The contractor shall schedule and coordinate PM services and obtain approval of the schedule by the government's representative at the site. PM shall be performed on individual components of the system so as not to affect the operation of the entire system.

## 10.2.2. Corrective Maintenance.

The contractor shall provide on-site hardware, firmware, and software corrective maintenance service, to include software problem analysis, associated reprogramming, and corrected software documentation. The contractor shall make every effort to affect repairs in the most expedient manner with minimum interruption to the operation of the system.

#### 10.2.3. Response Time.

During the warranty period, the contractor shall respond on-site to emergency calls within 2 hours following notification. An emergency call is defined as a hard failure of a component when no back-up is available, or a hard failure of the system that prevents the site from accomplishing its normal workload with the remainder of the system. Included in routine failures are all soft failures and hard failures of a component that has back-up capability. The contractor shall respond on-site to routine calls within 12 hours following notification by the government representative. Failure to respond to service calls in the required time frames shall result in reimbursement to the government all costs associated with putting into effect conventional film/screen radiography, CT, MRI, US, etc., until the system is restored.

#### 10.2.4. Reports of Service.

All reports of service (PM or repair) shall be documented and provided to the appropriate on-site government representative and filed with the equipment history file. At a minimum, the report shall include: a) date and time notified, b) date and time of arrival on-site, c) description of malfunction or service to be performed, d) model number/serial number and location of the equipment, e) time spent to repair, f) parts used/replaced, and g) description of service performed.

#### 10.2.5. Software, Firmware, and Hardware Support.

10.2.5.1. Commercially Available Upgrades. During the warranty period the contractor shall provide, at the option of the government representative, all current fully tested, commercially available software, firmware and associated hardware upgrades and new versions at no additional cost to the government. The contractor shall also upgrade hardware through "value engineering programs" as described in the FAR. The government's representative will test and evaluate all changes to the system under this requirement and determine whether to accept or reject them. The contractor shall provide complete, appropriate documentation, and user training for all changes to the system.

- 10.2.5.2. Newly Developed Components. Any software, firmware, and hardware which the contractor announces or may develop during the contract period, for general use with the type of equipment supplied under this contract, shall be made available to the government on the same or better basis than such items are provided to their best commercial customers.
- 10.2.5.3. Remote Diagnostic Capability. The contractor shall provide remote diagnostic capability using a communications link for remote diagnosis and correction of software problems.
- 10.2.5.9. Participation in User Groups. If the contractor supports a customer user group as a technique to maintain and develop system improvements, each individual military site will be granted user-group membership status. Moreover, owing to the magnitude and long-term nature of this contract, military sites will be granted up to 3 priority user change request each year. These priority change requests will have precedence over all other categories and priorities of user changes evolving from the customer user groups.

### 10.2.6. System Reliability.

10.2.6.1. Mean Time Between Failures. The contractor shall provide the government its estimated mean time between failures for each system component, the network supporting system and the fully operational system. The contractor shall describe the methodology used to estimate mean time between failures for each system component, the network supporting system, and the fully operational system.

- 10.2.6.2. Fault Tolerance. The MDIS system shall have fail-safe back-up mechanisms and every effort shall be made to ensure MDIS system reliability. The system shall be able to resume a database update or image transfer without loss of data in spite of an interruption due to hardware failure. The system shall detect any erroneous requests, notify the operator of the unsupported function, and suggest alternative approaches if they exist. The MDIS system shall not malfunction (i.e., crash) when confronted with commands that a particular workstation cannot perform.
  - System and Component Uptime. During the warranty 10.2.6.2.1. period, the MDIS system shall maintain a component and total system uptime of 99% monthly. Total system uptime is derived by averaging the monthly uptime of each component of the system. The uptime figures are based on normally scheduled operational hours per month which are based on 24 hour a day operation. The system downtime of one percent consists of two factors, planned or scheduled downtime and unanticipated downtime. Planned or scheduled downtime consists of approved, scheduled maintenance, archiving and other programmed unavailability of the system such as scheduled installation of software, firmware or hardware changes. This comprises three quarters percent of total system downtime while unanticipated downtime comprises the remaining one quarter percent.
- 10.2.6.3. Penalties. Failure to maintain the specified system uptime during any one month of the basic warranty period shall result in an extension of the warranty period by one month for the system. Failure to maintain component uptime of 99% during any three consecutive months, or to maintain a component uptime of 90% during any one month of the warranty period shall constitute grounds for the removal of the component from the site at the contractor's

expense, and replacement or a reimbursement of the system's cost to the government at the government's option.

#### 10.3. Post Warranty Service.

The contractor shall provide one year (12 month) service programs for each system provided for each of five years following the end of the warranty period. The scope of the services provided and the requirements for system reliability shall be at least the same as provided during the warranty period, including all parts, labor, system hardware, firmware, and software changes and periodic user training.

#### 10.3.1. Follow On Years.

Each annual program may be exercised up to thirty days after the end of the warranty period for the first option year, and up to thirty days after the end of the previous year's program for year's two through five. If an option year is not exercised, then all subsequent options are void.

#### 11. Complete Installation.

#### 11.1. General Requirements.

#### 11.1.1. Standard Products:

Material and equipment to be provided shall be the standard products of manufacturers regularly engaged in the manufacture of the products. Products out of production at the time a delivery order is written are not acceptable.

#### 11.1.2. Nameplates.

Major components of equipment shall have the manufacturer's name, address, type or style, component serial number and catalog/model number on a noncorrosive and non-heat sensitive plate which is securely attached to the equipment.

#### 11.1.3. Full Installation.

The contractor is responsible for determining code requirements, design data, and other factors necessary to design and install the system at each location. All items of work not detailed in this specification and all data not furnished by the government, but required by the contractor for complete system installation, are the responsibility of the contractor to request and obtain. The contractor shall provide an Installation Plan providing time frames for submittal and approval of post award installation plans. Approval for the contractor to proceed with installation of the MDIS System shall be contingent upon the government's approval of design submittals and written notification to proceed with installation.

## 11.1.4. Installation Requirements.

- 11.1.4.1. Rigging: The contractor shall be responsible for the safe, physical movement of equipment from the delivery point at the final destination, to the area of installation and uncrating of the equipment.
- 11.1.4.2. Removal: The contractor shall remove rubbish and debris from the site daily, unless otherwise directed. Burning is not acceptable. Contractor shall store all materials which cannot be removed daily in the area specified by the contracting officer.
- 11.1.4.3. Damages: All existing work that is damaged or defaced as a result of the contractor's installation work shall be restored by the contractor as directed and approved by the contracting officer, at no additional cost to the government.
- 11.1.4.4. Existing Utilities: Contractor shall check the location of existing utilities required to remain in place/service and those designated to be removed. Contractor shall protect, maintain, remove and/or cap utilities as necessary in accordance with local codes and regulations.
- 11.1.4.5. Utility Connections: Contractor shall connect to designated utilities in a manner conforming to the nationally recognized code covering the specific utility and at a time satisfactory to preclude disruption to existing functions or clinical services. Contractor shall provide at least two days (48 hours) notice to the contracting officer's on-site representatives prior to making any tie-ins.

### 11.1.5. Post Award Data Submittals.

The contractor shall provide all documentation required for post-award project planning. The contractor shall provide all user, operator, preventive maintenance and service documentation, to include software documentation, and documentation concerning additional accessories. Unless specifically prohibited, the contractor shall grant to the government royalty free rights to reproduce in whole or in part any and all such documentation for government use. Any software considered proprietary must be identified. It must be available for use by government personnel for the life of the equipment. The government will not be responsible for any separate licensing fees.

#### 11.2. Turn Key Installation.

The contractor shall propose complete, fully operational installation of the system "turn-key". Not later than 60 days prior to installation, the contractor shall provide to the government "blue line" drawings and accompanying fully descriptive text. These documents shall fully define and illustrate all proposed changes to heating, ventilation, (e.g. air exchanges, etc.) and air conditioning systems (e.g., loads, designed/rated operation of all computer equipment, etc.); utility connections, chases and conduits to include illumination; plumbing; communications; room drains; improvement to floor loading capacities; penetrations of fire and load bearing walls and finished floors; and other changes to the characteristics of the existing physical plant necessary for the contractor to install a fully operational system. The contractor must assess and describe the requirements for moving equipment through facility doorways and corridors and on to elevators to the installation sites. The description shall include an assessment of door widths and heights and dynamic and static distributed point loads of the equipment and certification that equipment the contractor proposes to install can pass safely and easily to all installation locations. If the

physical structure must be modified to permit transport of the equipment to the installation site, the contractor shall be fully responsible for the modifications and for restoring the modifications to their original condition at no additional cost to the government.

#### 11.2.1. Fire Detection and Suppression Systems.

The contractor shall design, install, and test any modifications to the existing fire protection and detection system. The contractor shall be fully experienced and qualified in the installation of preaction sprinkler systems. The fire protection and detection design shall be certified by a registered professional engineer. The contractor shall be Underwriter's Laboratory certified for the installation and testing of fire protection, detection, and alarm systems and possess a valid state fire sprinkler contractor's license. The system shall be approved by the base or post fire marshal after installation. The contractor shall perform pressure and flow test and provide test results to verify the waterline tie-ins provide an adequate water supply for fire protection.

#### 11.2.2. Fire Detection Systems.

#### 11.2.2.1. Smoke Detectors.

Where additional fire detection system components are required to comply with applicable codes, the contractor shall furnish and install photoelectric type smoke detectors as required. The smoke detectors shall be Underwriter's Laboratories listed. Each detector shall contain a visible, red LED alarm indicating light, which shall remain lit following detector actuation until the fire alarm system is reset manually. Location and spacing of the detectors shall be in accordance with NFPA 72E and the manufacturer's recommendations. To prevent damage from water, detectors under raised flooring shall be installed such that they are elevated above the structural floor/deck. The number of detectors shall be sufficient to comply with applicable codes and standards.

#### 11.2.2.2. Design and Interface.

The contractor shall design and install any changes to the fire detection system such that each device shall be interfaced to the local building fire alarm panel. The output shall be compatible with the local building panel for transmission of the fire alarm signals to the central fire station. Contractor shall furnish and install all necessary additional equipment (i.e., wiring, conduit, zone cards) to provide transmission of the fire alarm signals to the central fire station.

#### 11.2.2.3. Automatic Shutoff.

The fire detection system shall automatically shut off all power, including UPS, to the MDIS System, subsystems, ancillary equipment and HVAC equipment where the central computer equipment is located whenever an alarm is activated.

#### 11.2.3. Fire Suppression.

#### 11.2.3.1. Sprinkler Systems.

Where additional automatic pre-action sprinkler system capability is required to comply with applicable codes and standards, the contractor shall provide and install additional components as defined in NFPA 13 to provide sufficient fire suppression coverage. The sprinkler system design shall be based on the requirements and recommendations of NFPA 13. The contractor shall connect the sprinkler system to the existing sprinkler system or with a water source identified by the government's on-site representative. Connection shall be in accordance with NFPA 13. A floor drain shall be provided as stated in paragraph 11.2.4.

#### 11.2.3.2. Signaling Devices.

Any additional manual fire alarm stations required to comply with applicable codes and standards shall conform to the applicable requirements of Underwriter's Laboratories 38 and be of the double action type. Any additional signaling devices required to comply with applicable codes and standards shall conform to UL 464. Audible devices shall be 15 (dB) signal above ambient. Visual devices shall conform to NFPA 72G and may be coupled with the audible signal device.

#### 11.2.3.3. Auxiliary Fire Suppression.

Where required to comply with applicable codes and standards the contractor shall furnish and install the appropriate type and quantity of portable non-ferrous halon fire extinguishers in accordance with NFPA 10.

#### 11.2.4. Plumbing Requirements.

The contractor shall comply with all applicable local codes to connect interior storm, sanitary, water (hot and cold) and vent drains and equipment. Storm and sanitary drain piping shall be of no-hub cast iron soil pipe fittings. Vents shall be either threaded galvanized or non-hub cast iron. Polyvinyl chloride (PVC) piping and fittings may be substituted for all piping identified in this paragraph with the exception of piping containing hot water. Hot water with a temperature not exceeding 180 degrees Fahrenheit may be run in polyvinyl dichloride (PVD) piping. No material containing lead shall be used anywhere in the potable water system. All hot and cold water piping above ceilings, below floors, and where concealed shall be insulated to comply with applicable codes and standards. All brackets, wall plates, stops, aerators, escutcheon plates, drain stoppers, and all plumbing accessories shall be provided to assure a complete, finished installation. Shut-off valves shall be provided at the water connection point and at points of use (e.g.,

film processors) to facilitate maintenance without interruption of service. A floor drain of appropriate size shall be provided at the film processor location and in the computer equipment room if not already available in these locations.

## <u>11.2.5. Heating, Ventilation, and Air Conditioning Systems</u> <u>Requirements.</u>

The contractor shall comply with applicable codes and standards for HVAC design criteria and to insure computer equipment is installed for designed/rated operation. The contractor shall provide exhaust systems for the film processors and to comply with applicable codes and standards for air flow and exchanges. The contractor shall provide all grilles, registers, and diffusers necessary to provide a complete, usable, finished ventilation system. The contractor shall design and install all ductwork to comply with applicable codes and standards. Ductwork and refrigeration drain lines shall be insulated in accordance with MICA National Commercial and Industrial Insulation Standards. The HVAC design shall be certified by a registered professional engineer. Written certification that the system has been properly balanced to comply with applicable Associated Air Balance Council or National Environment Balancing Bureau Standards shall be provided by the contractor.

#### 11.2.6. Electrical System Requirements.

The contractor shall provide power and communications conduits to support equipment requirements, and provide all associated wiring, switches, outlets, and terminals in accordance with National Electrical Code regulations and system requirements and applicable codes and standards for communication. The contractor shall be responsible for tieing into a designated power source and distributing power to meet the electrical specifications of the MDIS System, associated subsystems, and ancillary equipment. Energy efficient lighting shall be used for general illumination when required. Each room/area shall be separately controlled by conveniently located wall switches. Any additional wall outlets provided by the contractor and connected to emergency power shall be appropriately identified by color and embossing "EMERGENCY POWER". The electrical calculations and circuit design for the entire project shall be reviewed and certified by a licensed engineer.

#### 11.2.7. Power Conditioning.

Contractors must visit each installation site on the schedule and survey its electrical power system to determine the system's adequacy for operation of the offered MDIS System. The contractor is responsible for ensuring that electrical power meets the quality requirements of the commercial warranty for the MDIS System, and that the system will not be damaged due to electrical power problems, including brown outs, total power interruptions, electrical surges, sags, electrical storms, and other likely electrical perturbations. Image quality shall not be degraded due to electrical power problems. A particular type of Uninterruptible Power Source (UPS) is not specified. The contractor shall select and install a UPS appropriate to the requirement for graceful shutdown of the system at each site. Any transient suppression device provided shall be Underwriter's Laboratories listed and incorporate silicon semiconductors as the primary surge protection components. The device shall have at most a five (5) nanosecond response time to the transient, a line to neutral voltage protection threshold which starts at no more than 220 volts peak, a maximum peak voltage protection level of 300 volts, and shall not short circuit the alternating current (AC) power line at any time. A visual indicator of the status of the primary surge protection components shall be incorporated within the device. When required, the contractor shall provide necessary equipment, such as transformers, disconnects, power distribution panels, and other power related equipment.

## 11.2.8. Communications Requirements.

When required as part of a delivery order, the contractor shall provide and install all data communications equipment (DCE) within the MTF. Included are cabling, transmission media, devices, and communications interface units. The contractor shall be responsible for appropriate coordination through and approval by the local military communications managers to the local telephone company or other local communication agent for any modifications to the interfaces between government owned and government or privately leased communications links.

11.2.8.1 Use of Government Furnished Communications. The contractor may also be required to develop a solution that incorporates communication embedded network capabilities that may exist.

# 12. Receipt of Deliverables.

To be developed.

# 13. Acronym Listing.

13.1. AC	- Air Conditioning
13.2. ACR	- American College of Radiology
13.3. AEI	- Architectural and Engineering Instructions
13.4. AFB	- Air Force Base
13.5. AFR	- Air Force Regulation
13.6. AR	- Army Regulation
13.7. ASCII	- American Standard Code for Information Interchange
13.8. ASTM	- American Society for Testing and Materials
13.9. ASHRAE	- American Society Heating & Refrigeration & Air Engineers
13.10. BAMC	- Brooke Army Medical Center
13.13. CD ROM	- Compact Disk Read Only Memory
13.12. CAI	- Computer Assisted Instruction
13.13. CDRH	- Center for Devices and Radiological Health
13.14. CF/SR	- Conventional Film/Screen Radiography
13.15. CHCS	- Composite Health Care System
13.16. COTR	- Contracting Officer's Technical Representative
13.17. CR	- Computed Radiography
13.18. CSA	- Canadian Standards Association
13.19. CT	- Computed Tomography
13.20. CYTEC	-
13.21. DA	- Digital Angiography
13.22. DBMS	- Director of Base Medical Services
13.23. DCE	- Data Communications Equipment
13.24. DDA	- Direct Digital Acquisition
13.25. DF	- Digital Fluoroscopy
13.26. DHHS	- Department for Health and Human Services
13.27. DSA	- Digital Subtraction Angiography
13.28. FDA	- Food and Drug Administration
13.29. FIPS PUBS	- Federal Information Procession Standards Publications
13.30. FMP	- Family Member Prefix

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13.31.	FMRC	-	•
13.32.	HF	-	Hard Failure
13.33.	HIS	-	Hospital Information System
13.34.	HVAC	-	Heating, Ventilation, and Air Conditioning
13.35.	IEEE	-	Institute of Electrical and Electronics Engineers
13.36.	IES	-	Illumination Engineering Society
13.37.	IOC	-	Initial Operating Capability
13.38.	JCAHO	-	Joint Commission on Accreditation of Health Care
			Organizations
13.39.	LAN	-	Local Area Network
13.40.	MAMC	-	Madigan Army Medical Center
13.41.	MDIS	-	Medical Diagnostic Imaging Support
13.42.	MRI	-	Magnetic Resonance Imaging
13.43.	MTF	-	Medical Treatment Facility
13.44.	MICA	-	
13.45.	NAPHCC	-	
13.46.	NEMA	-	National Electrical Manufacturers Association
13.47.	NFPA	-	National Fire Protection Association
13.48.	NM	-	Nuclear Medicine
13.49.	NRTL	-	Nationally Recognized Testing Laboratory
13.50.	OKSE		One Key Stroke Equivalent
13.51.	PA	-	Posterior-Anterior
13.52.	PET	-	Positron Emission Tomography
	Reserved for		
	Reserved for		
13.55.			Preventive Maintenance
13.56.			Pictorial Patient Directory
	PVC		Polyvinyl Chloride
	PVD		Polyvinyl Dichloride
	QAE		Quality Assurance Evaluator
13.60.			Radiology Information System
-	SMACNA		
13.62.			Soft Copy Image Display
13.63.			Soft Failure
	SMPTE		Society of Motion Picture and Television Engineers
13.65.	SSAN	-	Social Security Account Number

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13.66. SPC	- Standard Plumbing Code
13.67. UL	- Underwriters Laboratories
13.68. UPC	- Uniform Plumbing Code
13.69. UPS	- Uninterruptible
13.70. US	- Ultrasound
13.71. WPAFB	- Wright-Patterson Air Force Base

13. Bibliography - to be developed.

#### APPENDIX A

#### Clinical Scenario

#### Large Intra-MTF MDIS Systems

#### **Basic Workload Parameters:**

100,000 Inpatient Plain Radiography Images / year (exposures) 300,000 Outpatient Plain Radiography Images/ year 400,000 Digital Images / year (CT, MR, US) All images acquired digitally in phase 1 Assume 250 work days/ year

#### Phase 1:

Primary Clinical Activity– Diagnosis made by soft copy for Inpatient images (400/day) Diagnosis made by soft copy for ER & ICU images (320/day) Other Outpatients read by hardcopy digital image (900/day)

Acquisition:

5 CR devices: 2 large, 3 small or intermediate (e.g. Agfo or AC1-like equivalents) CT (2ea) & MR acquired by direct digital interface US images by video frame grab 3 each laser film digitizers

Display/Output:

6 each four screen diagnostic displays

1 each two screen diagnostic displays displays

7 each two screen review workstations

3 each laser film printers retrofit from CT & MR

Storage: 20 G magnetic short term storage one juke box- 10:1 digital microfilm option

Basic CHCS Interface, Image Database & Communications

#### Phase 2:

Primary Clinical Activity-Digital Images for clinic areas. Soft copy reading outpatient images

#### Acquisition:

Intermediate CR (e.g. Agfo or AC1 like equivalents) in clinic. (Teleradiology link from clinic)

#### Display:

6 each four screen diagnostic displays 24 each review workstations in clinics and wards (downsampled 1K images)

#### Storage:

10 G additional magnetic storage Second Juke box

Expanded CHCS Interface, Image Database & Communications

#### Phase 3:

16:04

Primary Clinical Activity– Expanded Soft Copy Interpretation Expanded Image Referral Service to Wards and Clinics

Display:

11 each review workstations

Mature CHCS 2 way interface, fully mature Image Database & Communications

#### Clinical Scenario - Medium Intra-MTF MDIS

Use same basic approach as large MTF but scale workload size of MDIS to 65% of large MTF

#### Clinical Scenario - Small Intra-MTF MDIS

35% of large MTF.

# APPENDIX B

# Clinical Scenario - Medium Size Inter-MTF MDIS System

Image Acq Method-	Laser Digitizer of Tabletop CR; digital interface other modalities
Image Matrix-	2K X 2.5K for plain film
Image Grey Scale-	10 bits
Data Compression-	2:1 to 10:1
Communications-	56 kbs or shared T1
Communications Throughput-	80 to 90% efficiency
Image Workload-	7000 to 12,000 Plain Image Equivalents per year
Workstations-	One Diagnostic and One Clinical Review
Archiving Method-	Hardcopy or single platter optical (upgradeable to juke box)
Report Transmission-	Via fax or electronic data
Upgradeability-	To multiple spoke support and/or inter-MTF MDIS

## APPENDIX C

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CHCS

Functional Description for Radiology version 3.2

(Information Copy)

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SECTION 1. GENERAL

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1.1 Purpose of the Functional Description. This Functional Description for Radiology is written to provide:

- a. The system requirements to be satisfied which will serve as a basis for mutual understanding between the user and the developer of the Composite Health Care System (CHCS).
- b. A basis for the development of system tests for evaluation of system performance.
- c. A means for showing the required relationships and data flows between automated Radiology functions and other automated functions in the CHCS.

<u>1.2 Project References</u>. Direction for the preparation of this Functional Description has been provided by the Tri-Service Medical Information System (TRIMIS) Program Office (TPO).

The following references are applicable to the history and development of the project:

- a. Tri-Service Medical Information Systems (TRIMIS) Programs Tasking Assignment, 11 July 1974. (Supercaded by DoD Directive 6000.5).
- b. Tri-Service Medical Information Systems (TRIMIS) Program, Data Administration and Architecture Alternatives Analysis, 0014-1-0AFD, 1 Oct. 1981. This document constitutes the Project Request.
- c. Radiology Detailed Functional Requirements, Computed Sciences Corporation, June 1981.
- d. DoD Standard 7935.1-5, Automated Data Systems Documentation Standards, 13 September 1977.
- e. Interface Functional Description for Patient Administration, Libra Technology, 24 September 1981.
- f. Interface Functional Description for Order Entry/Results Reporting, Libra Technology, 26 March 1981.
- g. Interface Functional Description for Radiology, Libra Technology, 14 September 1981.
- h. Federal Information Processing Standards Publication, Computer Security Guidelines for Implementing the Privacy Act of 1974, May 1975.

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Explanation, Libra Technology, 27 July 1981.

- J. Initial Project Objectives and Evaluation Criteria, TRIMIS Medical Review Groups, Tri-Service Medical Information Systems Program Office, 2 August 1977.
- k. DoD Manual 5000.12M DoD Manual for Standard Data Elements, 26 June 81.
- 1. Radiology Detailed Functional Requirements, Computer Sciences Corporation, 12 June 1981.

1.3 Terms and Abbreviations. The following is a list of terms, definitions, or acronyms used in this document.

CHCS	Composite Health Care System
CRT	Cathode Ray Tube
DEERS	Defense Enrollment Eligibility Reporting System
DoD	Department of Defense
D/P	Display/Print
FD	Functional Description
FHP	Family Hember Profix
HCP	Heelth Care Provider
1/0	Inputs and Outputs
MAISRC	Major Automated Information System Review Council
MTF	Medical Treatment Facility
P	Print
PAD	Patient Administration
PAS	Patient Appointment and Scheduling
PTID	Patient Identification (Consists of FMP and Sponsor SSN)
SSN	Social Security Number (Sponsor)
TPO	TRIMIS Program Office
TRIMIS	Tri-Service Medical Information Systems
UCA	Uniform Chart of Accounts

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#### SECTION 2. SYSTEM SUMMARY

2.1 Background. The goal of the TRIMIS Program is to acquire standardized automated data processing capabilities that improve the effectiveness and economy of DoD Health Care Delivery. The Major Automated Information System Review Council (MAISRC) has approved an evolutionary approach for the TRIMIS Program. Initial efforts were designed to provide validation of Functional Requirements and gather experience in site preparation, system installation, and training in system utilization. Subsequent to this activity, selected demonstration and feasibility projects efforts have been undertaken to facilitate the operations of multiple work center functions within an MTF or clusters of MTFs that share or provide care to common or overlapping communities of beneficiaries. The present effort is intended to facilitate the sharing of common data in an integrated environment, standardization of functions, and use of standard data elements within an integrated Composite Health Care System. This document describes the requirements for the Composite Health Care System (CHCS).

The mission of the TRIMIS Program Office (TPO) as stated in DoD Directive 6000.5, includes the following:

- a. Improve the effectiveness and economy of health care delivery administered by the military medical departments, through the application of standardized automated data processing techniques to health care information systems.
- b. Centralize and coordinate the application of existing technology and development of standardized automated systems design to meet Tri-Service Functional Requirements in the medical area.
- c. Adapt advanced data automation technology to health care delivery and streamline, modernize, and standardize DoD medical information systems.

The military health care system supports 168 military hospitals: 130 in the-United States and 38 oversess. Twenty-eight percent, or 47, of these hospitals are greater than 100 beds. These larger facilities account for more than two-thirds of the total workload of the military health care system. One hundred and twenty-one hospitals have less than 100 beds. The smaller facilities account for less than one-third of the total workload and are often located in remote locations supporting widely differing patient populations.

A significant feature of the military health care system is the volume of outpatient care provided by all the facilities, both large and small. Unlike the civilian health care system where private physicians give the bulk of outpatient care in their offices, the military health care system provides its ambulatory care to the entitled population in the hospital clinics by hospital staff. The amount of outpatient care provided in military hoopitals - 85-106-PS medical treatment facilities [hospitals, clinics (facilities without inpatient beds), and troop medical clinics/dispensaries] is several times greater than that provided by otherwise similar civilian systems.

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2.2 Objectives. The TRIMIS Program Office has defined the following specific objectives for the CHCS:

- a. Share core functions among all authorized users in the HTF work centers.
- b. Standardize functional communications throughout the HTF.
- c. Provide a flexible and powerful framework for the growth, development, and evaluation of functions and workload.
- d. Provide high system reliability with graceful failure of functions as described in the basic CHCS technical and functional specifications.

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- e. Share patient administrative and clinical data with all authorized users within the MTF.
- f. Integrate the functional medical information and requirements of various work centers to ensure the capabilities to collect, store, modify, retrieve, and report MTF level patient and management transaction data.
- g. Limit redundant collection of data to the extent required by the MTF.
- h. Provide for standardized order entry and results reporting for all medical information within the system.
- i. Protect the security and privacy of patient and staff information.
- j. Collect administrative data as a by-product of health care delivery ..... for purposes such as UCA, budgeting, QA, etc.
- k. Improve the quality of patient cars as a result of more thorough collection, better organization, and more timely and accurate availability of patient information.
- Reduce the time to transmit information on admissions, dispositions, transfers, patient status, patient care orders, and dispositic results within the MTF.
- n. Interface with non-CHCS systems which share or require information from the CHCS work centers.
- n. Provide interface to non-CHCS systems such as DEERS, Food, Logistics, without active involvement of MTF staff in routine interactions:
- a. Prevent the loss or degradation of functional medical information through the provision of standard failure contingency and security capabilities.

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2.2.1 Radiology Objectives. Radiology work center specific objectives will be derived from the IRIMIS Summary Functional Requirement (Ref. 1.21) and Medical Review Group (Ref. 1.2j) for the Radiology Department. Quantification of resource savings will not be included at this time, since benefits analysis for the CHCS will be performed and a subsequent reference added at a later time.

2.3 Existing Methods and Procedures. This section describes existing methods and procedures in a typical MIF. The typical medium-to-large MIF hospital has 110 to 1000 operating beds and provides services for 110,000 to. 1.2 million clinic visits annually, with the majority of MIFIe hospitals having less than 500 beds and less than 800,000 clinic visits annually. In addition, there are numerous clinics which provide significant levels of ambulatory care while not operating any inpatient beds. The sections below provide a broad overview of the existing methods and procedures and are not intended to be either all inclusive or rigidly definitive. The Jacksonville Vendor Site Guide is available from the IPO, and provides a specific description of the existing methods and procedures employed in a moderate-sized military MIF.

2.3.1 Major Deficiencies. Major deficiencies in the current manually operated medical information systems revolve around two primary issues:

a. Communication and documentation of patient clinical care.

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b. Providing administrative information to promote organizational effectiveness.

2.3.1.1 Clinical Information Deficiencies. In the current manual mode of operation, all patient information is included in a manually-prepared patient medical record. Each patient's outpatient record is the sole repository for information relating to all outpatient care received. Copies of the inpatient narrative summary and the inpatient treatment record are included in the outpatient record. A completely separate health care documentation system maintains information regarding inpatient services rendered. There is therefors, even in the ideal situation, no complete health record for a patient. Patient data from impatient cars are often not available to the outpatient clinician after discharge of the patient and outpatient services data are not easily accessible to the provider to assist in inpatient care. Outpatient information is available for impatient care only through the outpatient treatment record, with the possible exception of the prenatal record. The. quality of the contant of the data maintained in either record may be variable: patient data may not be available or not available in a timely manner for care; the legibility of data varies by provider; there is extensive manual manipulation required for displaying data in a clinically useful format: data may be incomplete, misfiled, and subject to transcription error: data

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needed in more than one location in the record or in multiple records must be entered or transcribed redundantly. These problems directly affect the ability of providers to render optimum health care services.

In addition to problems with the quality of documentation, the current manual system requires health care workers to spend an excessive amount of time in clerical activities. The HCP must manually communicate orders either in writing or through the telephone, examine results individually and often follow-up, either by telephone or by a visit to the ancillary work center to obtain the results. All compilation of data for reports must be performed manually. Many of the orders or actions by the HCP must be duplicated by writing a comment in the patient's record as well as completing a requisition or prescription for the desired service. The follow-up to locate missing data causes decreased efficiency on the part of the provider and may, in some situations, increase the length of stay for patients within the system. Redundant writing of orders in the record and on a requisition decreases time available for the physician to see patients, while occasionally resulting in inaccurate or incomplete entry in one or both locations.

In the manual system, meaningful quality assurance is difficult. Quality assurance activities are limited to retrospective audits of documented care. The documentation may take on more importance than the actual quality of care itself.

In the current system, patient care planning is difficult and poorly documented. The manual support systems are limited to textual reference material and consultations. There is no support in identifying patient problems and no concurrent quality control checks on the care ordered.

2.3.1.2 Administrative Deficiencies. In the current manual systems, administrative data are collected separately from the activities of providing care. Data may not be captured or may be captured incompletely. Changing the format or content of administrative reports is difficult because the entire report must often be reworked, sometimes with differing data elements. Consequently, administrators hesitate to request reports which might be administratively useful, due to the increased workload on already overstressed staff.

Scheduling petients for appointments using the manual system is difficult for 85-109-PS both patients and personnel. There is a limitation in management effectiveness, due to the lack of accurate and timely information on staffing workload and evailability of providers and resources. Patients have difficulty in making appointments. Staff scheduling, especially of Department of Mursing personnel, consumes an inordinate amount of time of nursing managers under the manual system.

Risk management reporting (that is, analyzing incident reports and compiling. statistics about the performance of the institution, especially regarding potentially compensable events) is time consuming. It is difficult to identify trands because of the very limited manipulation of data that is possible

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in a manual system. The data utilized for all management reporting lacks consistency and, therefore, has a negative impact on the quality of management planning.

Workload reporting currently is completely separate from providing services, both administrative and clinical. Each area within an MTF must provide periodic reporting of workload processed and staffing utilized for consolidation into reports forwarded to higher headquarters. The data used to compile these reports varies in consistency and accuracy both within an MTF and between MTFs due to varying interpretations of regulations about how counts are to be collected, and the staff available to perform this administrative activity. Since work centers derive no immediate benefit from accurate reporting, immediate pressures of patient care often take precedence over data capture activities. This inconsistency and inaccuracy of data can be expected to have negative effects on the entire system's ability to accurately manage its resources.

2.4 Proposed Methods and Procedures. The proposed methods and procedures to be automated are based upon the references listed in Section 1.2 and discussions with representatives from the TRIMIS Program Office, and incorporates the proposed procedures from the Radiology Interface Functional Description (Ref. 1.2.g).

The military radiology departments vary in both size, training requirements, and type of services offered. The extent of the automated procedures varies from radiology department to radiology department. Methods by which each radiology department operates are sufficiently similar to permit development of a standardized Radiology automated information system. Unique MTF requirements can be supported by user-defined and maintained system files and features.

The following subsections present the proposed automated Radiology functional requirements identifying functional interfaces where they occur.

2.4.1 Patient Identification. This set of functions enables the authorized. user to identify the individual for whom a procedure is to be performed. These steps are described in the paragraphs below.

2.4.1.1 Unique Patient Identification. Patients are uniquely identified by an authorized user entering either the patient's unique number (FMP and sponsor's SSN), or his current or any previous inpatient register numbers. The system locates the patient's identification data and displays it for the user's review.

The system shall continue with the selected function (e.g., order entry, ordermaintenance).

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2.4.1.2 Patient Candidate Search. When the unique patient number and current register number are unknown, the user enters one of the following search keys:

- a. Patient's full name. and date of bisth.
- b. Patient's former name.
- c. Last name or partial (minimum of five characters) last name (e.g., Johnston could be found by entering "Johns"). Soundex of patient last names shall be performed.
- the d. Sponsor's social security number elene.
  - e. Patient's sex and/or date of birth.

The system locates all patient records that correspond to the entered search key and displays candidate lists with sufficient information to permit selection of the desired patient record. The user selects the desired patient from the list, receives a display of the required patient data, and the system continues with the selected function. When no match is found, or the user rejects all candidates, the user is prompted to register the patient. The registration data is required to establish the patient's unique identification in the system and to collect his demographic data.

2.4.2 Registration. Registration procedures are performed by the user and updates can be entered. A mini-registration subset of registration data for patients shall be provided.

2.4.2.1 <u>Mini-Registration</u>. In the event that the patient's data cannot be retrieved because of system problems (e.g., equipment failure) or because the patient has not been registered at the MTF, the user receives a displayed message and is prompted to enter the registration data. These data are used by the PAD functions to maintain the validated registration data.

for an emergency patient or when the patient's identity is unknown, the system user is prompted to register the patient and enter a temporary patient identification number. When more information becomes available, the "John Doe" registration is updated.

2.4.2.2 Registration Uodate. When the user determines that the registration data displayed are inaccurate, these data are updated by entering the correct information via terminal. The changed registration data are used by the PAD functions to maintain the validated patient registration data. Any registration data element can be updated.

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<u>2.4.2.3 Merger/Delete</u>. If an erroneous patient record exists in the eyetem . 86-109. For a patient with a correct record, the two records shall be marged under the correct PIID and the orraneous record deleted without re-entering the data. Requirement deleted.

2.4.3 Order Processing. This set of procedures facilitates the entry and maintenance of HCP orders for radiology procedures. The user shall order radiology procedure(s) and the system shall assign patients to available appointments for specific procedures in specific rooms. The users within the 86-103-Radiology Department also have the ability to enter orders. In the entry of HCP orders for X-rays, free text shall be available for the user to enter patient history data.

2.4.3.1 Order Entry. Requests for radiology procedures are initiated by entry of an order or order group (multiple radiology procedures) into the 86-110-F system by an authorized user. Order entry shall be performed at either the wards, the clinics, or the Radiology Department.

The user enters orders after uniquely identifying the patient, as discussed in Section 2.4.1.

The authorized user identifies to the system the procedures to be ordered and enters procedure-specific data necessary for the order as well as patient history data. The system edits the data and displays messages about invalid data to facilitate correction of the data. The MTF shall specify the required data fields. The user may elect not to enter data in non-required fields. The system alerts the user, via displayed warning messages, of the following situations:

- a. The authorization level of the requesting HCP does not permit him to. request this specific procedure. The user will receive a message 86-110-RD indicating the appropriate phone number to contact the Redialogy Department for approval scheduling.
- b. The procedure requires a radiologist's authorization prior to performing the procedure. The user will receive a message indicating 86-110-RD the appropriate phone number to contact the Radiology Department. For approval scheduling.
- c. The procedure being requested for the patient is a potentially similar or duplicate procedure.

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When the HCP is not authorized (as defined by the HTF) to order a specific procedure, the system displays a message to that effect and terminates the order. The system will not retain these orders and they may be reordered by an HCP with proper authority.

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When a radiologist's authorization is needed prior to confirmation of the order, the user is informed by the system. The order is entered into the system and authorizations are obtained in the manner defined in Section 114.2.2.

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When a procedure order is identified as a potential duplicate or similar procedure to any procedure performed within the last two weeks and/or scheduled; the authorized user is notified. The user may then proceed with entry of that order, or he may abort the order process.

The user receives a display of secondary preparation procedures ordinarily associated with the requested procedure. Each selected secondary preparation procedure order can be entered as a separate order by the user, but the system does not require the user to re-enter the patient identification data for each secondary order. It is retained until the user indicates that he has completed entering orders for that patient or identifies a new patient.

After the order is entered into the system, the user may be prompted to make an appointment for the patient. Procedures are scheduled using data in the system files; the system shall proceed to the appointing function shown in Section 2.4.4.3.

2.4.3.2 Order Maintenance. An authorized user may modify or cancel orders for radiology procedures.

The authorized user identifies the order from a display of a patient's orders for radiology procedures. The display for order identification contains order data sufficient to identify the order and its current status. The user indicates the order of interest and receives-notice.of.whether the order can be modified.

For orders that may be modified, the user requests the complete order to be displayed and/or printed. The user enters the data to be modified. The HCP requests that an order be cancelled or modified at any point, until the patient arrives.

2.4.3.3 Order Review. The radiologists receive reports on orders awaiting authorization prior to the procedure being performed. This information also may be displayed at the user's request. If a procedure requires a radiologist's approval, the system will notify the user. The radiologist's authorization shall be entered into the system. If the order is disapproved, the user may cancel it, as directed by the HCP and the radiologist. If the patient arrives for treatment before the authorization is received, the order is handled according to department procedures (authorization entered as above or procedure cancelled).

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2.4.4 Procedure Scheduling and Patient Appointing. This sat of procedures assists the authorized user in appointing patients within the Radiology Department utilizing user-created schedules and schedule templates.

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2.4.4.1 Schedule Maintenance. The authorized user will be able to declare 85-032-RD rooms open or closed for a user-specified date and time range. The system will produce a listing of patients whose appointments for radiology services: should be rescheduled or cancelled because the room in which the procedure was originally scheduled is unavailable.

2.4.4.2.a. Patient Appointing. The cyctom will provide three methods for. patient\_appointing; automated appointing, asnual appointing, and rediationthereov consisting. When the radiology order is received by the Radiology Department, the system will assist an authorized user in providing an appointment for the patient and completing the physician's order. The system will provide three methods for patient appointing: automated, user-specified, and radiation therapy appointing.

(1) Automated Accounting. The user will specify the date on or which 85-028-RD the appointment(s) is acceptable and the department section in which 85-029-RD the procedure(s) is to be performed. The system will select the an-. pointment date, time, and room based on the algorithm which will minimize the total time between the date for which the appointment is." acceptable and exam completion for all examinations which are re-85-038-RD quested. If multiple rooms have the same time opening, the system will select the room with the highest preference based on MTF specified room preferences. A patients' previous appointments, mobility status, procedure duration, contract media consideration, prep times, room availability, room schedule, and the rooms by which the procedures can be performed shall all be considered by the algorithm. If multiple procedures are to be performed on one patient, all proce-85-111-RD dures shall be scheduled consecutively in the same room, provided that particular room can accomodate all the procedures. The system will display the proposed appointment schedule to the user for acceptance or rejection. The user will accept or reject the system-selected appointment(s) or any portion thereof. If the user rejects the system-selected appointment(s) or any portion thereof, the system will automatically provide the user with the option of manually appointing the procedure without requiring that the patient be reidentified.

(2) User-Controlled Accountment Selection - User-Specified Appointing. The user shall enter the department/section in which the 85-024-RD procedure is to be performed and one or more of the following ap-85-025-RD pointment parameters: date, time, time range, or room. When an appointment is selected, the system will check for all conflicts. In this mode the user may overbook rooms and/or patients and override 85-026-RD system warnings.

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(3) Schedule and Report Radiation Therapy. The system will provide - 85-025. for the user to schedule and report radiation therapy procedures.

2.4.4.2.c. Appointment Cancellation. The system will provide for the user to cancel appointments for radiology services. The system will make the time(s) and room(s) released through cancellation available for other appointments. At MTF option, the system will print a notice at an MTFspecified location to inform the requesting health care provider and/or inpatient ward that the patient's appointment(s) has been cancelled. The system will provide for the user to generate a report of cancelled procedure appointments and/or orders.

<u>1.4.4.7 General Accounting</u>. When order entry has been completed, the system 85-027-RD will go to the appointment process. The user may enter the preferred appointment information (cogoy date, time), or may request the next available date and time for the procedure ordered, or may review a display of the evailable dates and times. When a satisfactory appointment time is located by the system, the user indicates this and the system assigns it to the patients

The system else electo the user, via displayed warning message, when there is a contrast media conflict with a completed or coheduled precedure (e.g., en TVR is coheduled too close to en Upper CI).

The user may change a patient's appointment date and/or time by cancelling the undetisfactory appointment time with the appropriate reason and then may reappoint to an available time. When an appointment is cancelled, the system automatically makes that time available for appointing.

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Some procedures require that a patient have multiple appointments: For example, a patient may require appointments at 10.00 a.m. Henday through Fridayfor six consecutive weeks. The user enters the appointment eritoric indicating that appointments are to be made for a specific time for the required number of days and frequency. The dystem then displays all of the patient's appointments for user acceptance. When the desired time is already filled, the user is notified by a displayed message and must coloct another time of accept the evetom colocted appointment for that day.

For orders requiring a radiologist's authorization, the patient will not be appointed before authorization is obtained. When the authorization is denied, the requesting WCR-is notified by the system. When an authorization is required prior to an appointment, the order is held. When euthorization is encored, the radiology user can appoint the patient and the patient is nucritici.

2.4.4.3 Schedule and Accountment Inquiry. An authorized user may 85-029-R request for review (display or print) schedules and patient appointment in--formation. The user enters the information required to identify the schedule(s) or patient(s) of interest. The user receives a display or hard copy print of the information requested.

2.4.5 Procedure Logging. In support of departmental operations, the Radiology user enters data pertaining to the patient's visit.

a. <u>Patient Arrival.</u> Patients shall be arrived. Using a quick entry method such as lists, menus, light pens, bar codes or other user-friendly device, the user shall indicate that the patient has arrived. When the patient has not arrived for an MTF-specified time period, the patient becomes a "no show". The system provides a No-Show Report that lists the patients' names and other information.

When the user "arrives" the patient, the system may alert the user to the need for additional registration data. The user proceeds to register the patient as described in Section 2.4.2.

For walk-in patients, the user in a single function may request/enter a procedure, register a patient (if necessary), and arrive the patient. The system shall display the next available appointment time.

The system shell print a Procedure Work Sheet and the required labels at 85-014-RD appropriate printers (e.g., fleek card at front deak, pull notice in library, etc.) when a petient-hes-errived for a procedure entered for the current deter. Redielegy woors may betch print these products, in user-specified order, for petients appointed for procedures on future deter.

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The user may print a Procedure Worksheet and the required labels (as describ- 85-014ed in Section 3.2.3.3 and 3.2.7.1) at appropriate printers (e.g., flash card at front desk, pull notice in library, etc.). The worksheet and labels will be produced when a patient has arrived for a procedure entared for the current date. Radiology users.may print worksheets and labels in user-specified order for patients with future-dated appointments and/or procedures. The user may reprint a user-specified number of worksheets and/or labels on demand.

The Procedure Worksheet, which shall contain all request data, will be used to record the procedure start and stop times, number of exposures and types and sizes of films used, retakes and additional views, technician performing procedures, the room in which the procedure was performed, the radiographic technique factors and the reasons for repeats of exposures, and films or complete procedures of the technician giving the examination. These inputs shall be in machine-readable form and the data from the worksheets may be entered via a keyboard terminal. The subfolder, master folder and individual procedure labels shall be human and machine readable. The flash card label shall be human readable as a minimum. In-addition; the worksheet shall have sufficient space for the radiologist to enter a handwritten STAT report.

b. <u>Patient Departure and Quality Assurance</u>. When the procedure has been completed, the quality endurance control technician reviews the images and determines if additional views or additional procedures are required, or if the patient may be released. The system shall allow the user to automatically use default values for film usage (which have been previously defined for each procedure) if the film usage for the procedure was the standard value. He identifies the procedure to the system and enters if the examination was completed or aborted, added procedures, and other data from the Examination Worksheet. For procedures which must be repeated, he enters the reason and/or reason code.

2.4.6 Results Processing. The images produced during a radiology procedure are read and interpreted by a radiologist.

CHES provides the ward and clinic user with inquiry, results category, and/or cartified radiographic reports.

2.4.6.1 Results Entry. To enter results data, an authorized user identifies the appropriate patient and procedure(s) and then enters the result data.

Pre-defined texts may be entered by authorized radiology users and stored by 85-106-RD the system for use in the results entry process: When a predefined text has 85-107-RD been entered, is employed, the user may enter the result code via terminal of by scanning a bar code; or through another user friendly device. The predefined text may be modified by the user efter the results ere entered, as 85-105-RD part of the results entry process, if required. When the result is not a predefined one, the radiologist may dictate the text of the report and an authorized user may enter it into the system using word processing capabilities provided by the system.

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The unapproved result report shall be available for editing by an authorized user and the user is prompted to complete the editing step and indicate approval of the text.

One or more authorized reporting radiologists must review and approve all results prior to releasing them for inquiry display to the ward and clinic users or for report generation. An authorized radiologist may, at the time of results entry, or following a request for a display of the results report, and indicate electronically his approval electronically, or he may review a printed copy of the results report and sign it. The radiologist's approval for all reports printed shall be entered into the system with exceptions indicated. Once the report has been approved, the original report cannot be altered. Additional information must be amended to the original report, leaving the original report intact.

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2.4.6.2 Results Reporting. After review and approval by an authorized radiologist, the patient's final results report becomes available for inquiring or reporting. For STAT results, the report is automatically printed and/or queued for printing at the requesting ward or clinic or other user-specified location upon radiologist approval.

The ordering physician receives on-demand a result category report containing the radiologist's assigned results category for each procedure requested. The result categories include: normal, abnormal, incidental, or change from previous. The report is also available upon request at the wards or clinics. Routine diagnostic result reports are batch printed by the system for distribution as specified by the MTF. Distribution criteria permitted shall include the capability to print inpatient reports at the inpatient's current location as stored in the system. Result reports for dispositioned inpatients are distributed to the inpatient medical records area or other areas designated by the MTF.

To facilitate result reporting, the most current information on the inpatient's location is made available when an inpatient order/result is printed by the system. <u>Certified reports can be modified only by an amended</u>. 85-076-RD -report.

2.4.6.3 Results Induiry. An authorized user may inquire about a patient's order and result information in the system. The user enters the information identifying the patient (see Section 2.4.1, Patient Identification), requests: the specific information desired (e.g., order status, examination results); and specifies the specific output mode (display or printed).

The user also may request order/result status for all patients under the care-of a specified HCP or requesting location.

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2.4.7 Image Library Management. The image library is responsible for maintaining patient radiographic image folders and related procedure histories. Each patient's master folder contains all radiographic images associated with that patient. Images are stored by procedure type in subfolders. The locations of all image folders must be known at all times. The Image Tracking procedure is used for providing folder locations within the Radiology Department; the Loan Control procedure is used to identify folder borrowers and locations which are external to the Department. The system shall produce machine readable labels to support this function.

2.4.7.1 Image Tracking. Orders for procedures for the current day will Automatically generate a request for image folders in the designated library. For previously scheduled patients, the user can request a pull list for a specified date and time. Because the image's location must be known to the system at all times, the MTF may have automatic code/character reader input, such as bar code readers, at various station locations in the Radiology Department. To allow the user to automatically recognize and enter the folders' current location into the system. As each folder is moved within the Radiology Department, the user may track its current location by allowing the system to acan the folder label. The system will automatically update the folder's location upon scanning the label.

2.4.7.2 Loan Control. Radiographic folders are loaned to authorized HCPs. A list of eligible borrowers shall be maintained by the system.

When an authorized HCP requests a patient's folders the loan request is entered into the system. If bar code labels are used, the user may use a light pen or other techniques to enter the HCP, PTID, subfolder, and berrower's location mumbes. folder, patient, borrower and location data. The borrower's identification is only entered once during the check-out process, and will be automatically provided for multiple folder. requests... The date and time of the-loan are sutematically supplied by the system and appended to the borrower's data.

When folders are returned to the image library, the clark checks in the folders using machine readable labels may check in returned folders using a quick entry technique to read the labels or by direct keyboard entry. The system will extensically indicate the folder's current location as residing within the image library where checked in. Alternately, the folders being returned can be shocked into the library using keyboard entry.

An authorized user also may request a list of overdue loans, the borrowers and, the borrower's location - st. MIF option, the folders and/or folder. locations. This list will be used to notify borrowers to return the borrowed folders. The list should be sorted in user-specified order.

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2.4.7.3 Teaching/Special Interest File. When the radiologist has indicated that certain exams are to be entered in the Teaching/Special Interest file, the American College of Radiology (ACR) anatomical and pathological codes and/or free text for the case are entered. The system shall provide for Teaching and Special Interest Files. These files need not be physically separate but records shall be designated as part of the Teaching File and/or part of the Special Interest File. Each of these file records shall have multiple ACR codes and comments fields for each procedure (minimum of 200 characters). The system shall provide for logical searches ('and' and 'or', as a minimum) for multicle ACR codes and patient's demographic data for either Special Interest and/or Teaching files. These searches shall produce a list of patient records which include the patient's demographic data, ACR codes, comments and any interpretations.

2.4.7.4 Transfer Listy Image Transfer Designation. The system shall print/display a Transfer List of master folders in a specific library which have had no activity for a user-specified period of time. On user request, the master folders not to be transferred are entered and all other folder locations shall be moved to the new specified location.

2.4.7.5 <u>Selvece-Liety</u> Image Salvage Designation. The system shall print/ display a Salvage List of master folders with no activity for 5 years (or other MIF-designated time period). The user shall locate these folders and indicate those not to be salvaged. On user request, the remaining patients on the list shall be deleted from the system. At MTF option, no teaching orspecial interest files shall be deleted. The system shall allow any record to be marked, "not to be salvaged."

2-4-2---Henadement-Support, --- The system-maintains data to calculate workload and-other-statistics and produces specific reports.

2.4.8.1. Statistics. Data for workload reports and other required statistics shall be collected outomatically.

2\_A\_8:2\_\_Heneseest Records -- Reports are produced an request -- These reports -- subled -- workload -- other transform usage, UCA - reports and other reports -- which -- are needed to -support higher -- commands -- These -- reports -- ore defined -- in-Section J.1.

2.A.S.J. Electronic-Hessear-Board, Hesseages may be left for system users to

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2.4.8 Hensoment Support: The radiology user will have the capability to - 85-115calculate statistics and generate workload, quality control and quality assurance reports for management used by the Radiology Department. In addi-. tion. Radiology users will have access to a CHCS electronic message board.

2.4.8.1 Management Reporting. Authorized radiology users may request the calculation of statistical data and the generation of workload and other management reports. These reports may include radiology quality control. monitoring data, quality assurance information and workload statistical reports formatted according to user-specifications: and DoD, military-specific\_ and/or MTF requirements.

2.4.8.2 Electronic Message Board. The radiology user will be able to leave and retrieve messages using an electronic message board capability specified in the CHCS FD. Section 2.4.2.2.1.8.

2.4.9 System Management. The system shall provide for maintenance of system files and equipment configuration.

2.4.9.1 System Security. The system shall provide for entry, assignment. maintenance and output of user access codes, passwords and the functions users are allowed to perform. These codes shall be printed on request of an authorized user only.

When a user enters his assigned code, the system verifies it. The user is not able to initiate any function prior to verification of this identification, nor any function for which he is not authorized. Any attempt to access." the system with invalid access codes shall result in a console message identifying the attempted code, date, and time of attempted access and terminal.

The user also is prevented from accessing functions that are limited to certain authorized terminals if he is requesting to perform the function atan unsuthorized location. The allowable locations are defined in the systems table.

أراريها ومجبه بمداو محمد هكلاتها 2.4.9.2 Table Meintenance. Only authorized users may enter, modify, deleter. or add entries to tables specified by the MIF. When an addition; deletion, --or change is not allowed to an existing table, the system informs the suthorized user of the limitation(s). Otherwise, the system accepts the user input and adjusts the tables. The system shall print on request all data entered into system. entered into system. 

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2.4.9.2.1 Schedule Creation and Maintenance. To create a radiology schedule for use in patient appointing, the authorized user enters the days and hours of operation, the availability of room/room group(s) in order of preference, the procedure(s) to be performed, and any time restrictions per procedure available per day by patient type (e.g., inpatient/outpatient). This information is retained by the system to perpetuate schedules on an MTF-specified basis.

The authorized user may overbook certain procedures. Overbooking is appointing additional patients for an appointment time that is ordinarily considered full.

An authorized user has the capability of changing or cancelling an existing schedule due to unavailability of a room(s), equipment failure, or for other reasons. The user identifies to the system the schedule change, start and stop: dates and/or times. The system automatically updates the schedule and automatically prints a list of any appointments affected by the change. The radiology staff then notifies the patients of their cancelled appointment(s). "Patients are then re-appointed.

2.4.9.3 Ad-Hoc Reporting. The system shall provide an of hos report genera-05-093-Ri tion espaniity: Authorized users may generate reports using any data availauto-in-the system. In order to generate an of hos report, the user shall especify cata elements to be included in the report as well as report cutput peremotors (i.e., report period, cert order, etc.). The report shall be availeble to the user within 24 house of request. Reference CHES FD Section 2.4.2.2.2.8.

2.4.9.4 <u>Archiving</u> Archive/Purge System Data. The system shell provide for 85-092-R long term, off-line storage of MTF-specified data and records for an MTFdesignated time frame. The system shall provide for the storage of all crehived data using a format and a medium (such as magnetic tape) which facilitates the recontry of these data into the system. Reference CHES Section 3.2.6.4.

<u>2.4.9.5 Record Purdo</u>, The system shall be capable of purging records on an 85-094-RD individual basis. The system also shall be capable of purging all records which meet user specified criteria (e.g., purge all patient records with no setivity subsequent to a west specified date).

2.4.10 Summary of Improvements. Refer to the Preliminary Cost Benefit Analysis, Arthur D. Little, Inc. from the TPO.

2.4.11 Summary of Impacts. The following sections describe the impact of CHCS. on the military medical treatment system and its users.

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2.4.11.1 User Organization Impacts. CHCS will have a profound impact on the... organization. For the first time the HCP will be able to view all pertinent information related to the provision of medical care on a patient in a rapidly retrievable, user-controlled format. The manual mode of operation will be supplemented with automated functions. The day-to-day delivery of patient care will be enhanced by the patient data base, enabling immediate access to information by authorized users. Communication of orders and results will be facilitated.

The MTF command and administration will be supported by current information in making decisions. Upward reporting will be more accurate and timely, without taking resources away from the provision of care. Information will be available as a by-product of care. More timely information will allow minimizing inventories, maximizing the utilization of personnel, and monitoring the activity of the organization.

Quality assurance will be enhanced by the capability to concurrently monitor the management of patient cars without intruding on the patient-provider relationsnip. In addition, the CHCS will support the identification, tracking. and documentation of quality assurance activities of the organization.

The system administrator will have a new position in the organization. The maintenance of the data base, control of the system functions, and the security of the system will be critical to the functioning of the MTF.

Most personnel will require training to utilize the system before taking on patient care responsibilities. Training of new personnel and maintaining skills of the personnel will be a new mission of the MTF.

2.4.11.2 User Operational Impacts. The CHCS will be an integrated system of patient and facility data management and communication. The end result of the integrated system will be the availability of data bases containing patient clinical and administrative information: In addition, facility resource information will be available to support the management of the medical treatment facility. Extensive patient care planning, documentation, and quality assurance will be possible as a result of the integration of data and functions within the CHCS. All users will benefit from the patient clinical and administrative data base. Functions which would not be available or cost favorable cost-benefit ratio.

2.4.11.3 User Development Impacts. The MIF will be involved in preparation forthe system. The MIF will develop local tables and files, establish the patient. data base, and train users to operate and utilize the system. Support will be provided to the MIF in initial training, ongoing training, and in the development of the initial tables and files. Support also will be provided during system initialization of MIF-developed tables and files and the loading of the patient data base. Additional guidance as to the scope and source of this support will be available from the IPO.

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2.5 Assumptions and Constraints. CHCS assumptions and constraints apply in general. Specific Radiology assumptions and constraints follow.

The following assumptions apply to the Radiology function 2.5.1 Assumptions. of CHCS.

- a. An integrated automated CHCS System will handle requirements for DEERS eligibility checking, registration, and patient location in the MIF.
- b. Policies and procedures at individual MTFs may vary according to Service specific regulations, workload, environmental considerations. and professional preferences.
- c. An automated Radiology function will interface with or be integrated with the following TRIMIS and DoD Standard Automated Systems:
  - (1) Patient Appointment and Scheduling (PAS).
  - (2) Patient Administration (PAD).
  - (3) Laboratory.
  - (4) Pharmacy.
  - (5) Food Servicer Clinical Dietetics.
  - (6) Defense Enrollment Eligibility Reporting System (DEERS).
    (7) Uniform Chart of Accounts (UCA).

  - (8) Logistics.
- d. The interfacing logistics system will represent the Tri-Service requirements for an automated logistics system and will be developed at a later date.
- e. CHCS and all interfacing systems will be operational and on-line 24 hours per day, seven days per week, with the exception of downtime for scheduled maintenance.
- f. An interfaced and integrated automated CHCS System for selected. functions will replace the stand-alone Radiology systems currently in use at an MTF.
- g. Procedures to maintain the privacy of the system's medical data will be determined and enforced by the administration of the MTF in accordance with Military Department regulations and Federal Law.
- h. The necessary physical security of the computer room and terminals in the MTF will be determined and enforced by the MTF.
- i. The security of the off-site data storage location will conform to DoD standards.
- j. A Uniform Chart of Accounts system specifies the requirements for DoD cost accounting.

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2.5.2 Constraints. For implementation of an automated Radiology function, the personnel at the individual user site must be aware of the following constraints.

- a. The current staff at an MTF will require training in the use and operation of the Radiology Function.
- b. The functions will use standard data elements and codes approved by DoD and supplied by the TRIMIS Program Office (TPO).
- c. The Privacy Act of 1974 governs availability of private and personal data.
- d. The Radiology functions will be implemented and operated by existing personnel where practical.

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#### SECTION 3. DETAILED CHARACTERISTICS

3.1 Specific Performance Requirements. This section describes the performance requirements for the proposed Radiology functions. The output requirements are grouped for ease of reference into the following function:

- a. Patient Identification.
- b. Registration.
- c. Order Processing.
- d. Procedure Scheduling Patient Appointing.
- e. Procedure Logging.
- f. Results Processing.
- g. Image Library Management.
- h. Management Support.
- i. System Management.

The output requirements for each of the Radiology functional components are listed in the following subsections by their automated data base names. Because the data base software accepts names of 30 characters or less, the data base names are often abbreviated.

The output descriptions, associated timing requirements, and data content will be found in Appendix C, arranged alphabetically.

3.1.1 Patient Identification. The following describes the output requirements -that support Patient Identification.

- a. 0-PNT-UNIQUE-ID-DISPLAY.
- b. Q-RAD-PTID-CANDIDATE-LIST.

3.1.2 Patient Registration. The following describes the output requirements that support Patient Registration.

- a. O-RAD-MINI-REG-DISPLAY.
- b. O-REGISTRATION UPDATE-DISPLAY.
- C. O-EXTENDED-REGN-DISPLAY.

3.1.3 Order Processing. The following describes the output requirements that support Order Processing.

- a. O-RAD-UNAPPROVED-ORDER-DISPLAY.
- D. O-RAD-SECONDARY-ORDER-DISPLAY.
- C. O-RAD-ORDER-HODIF-DISPLAY.
- d. O-CANCELLATION-HGHT-RPT.

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- e. O-RAD-PNT-ORDER-DISPLAY.
- F. O-FLASH-CARD-LABEL.
- g. O-MASTER-FOLDER-LABEL.
- h. O-SUBFOLDER-LABEL.
- 1. 0-PNT-TRANSPORTATION-NOTICE.
- j. O-PROCEDURE-LABEL.
- K: 0-PROCEDURE-WORKSHEET.
- 1. O-LOAN-FOLDER-LABEL.

3.1.4 Procedure Scheduling and Patient Accounting. The following describes the output requirements that support Procedure Scheduling and Patient Appointing.

- a. O-RAD-APPT-SCHEDULE-DISPLAY.
- b. O-RAD-APPTS-AVAIL-CAND-LIST.
- c. O-RAD-APPTS-RESCHED-OISPLAY.
- d. O-RAD-NEXT-AVAIL-APPT-DISPLAY.
- e. O-RAD-APPT-CHANGE-NOTICE.
- f. O-RAD-THER-TERM-RPT-DUE-NOTICE.
- q. O-SCHED/APPT-INQUIRY-DISPLAY.
- h. Q-RAD-SCHED-TEMPLATE-CAND-LIST.
- 1. O-RAD-SCHED-TEMPLATE-DISPLAY.

3.1.5 Procedure Loaging. The following describes the output requirements that support Procedure Logging.

- a. O-APPT-NO-SHOW-REPORT.
- b. O-QC-REPEAT-FILM-REPORT.
- C. O-PNT-QUALITY -ASSURANCE-RPT.
- d. O-EXAM-HISTORY-INDEX.

3.1.6 Results Processing. The following describes the output requirements that support results processing.

- a. O-RAD-RESULTS-DISPLAY.
- b. O-UNAPPROVED-PROCEDURE-RPT.
- C. O-AMENDED-RESUL IS-RPT.
- d. O-RAD-RESULIS-INQUIRY-OSP/RPT.
- e. O-RAD-RESULIS-CATG-NOTICE.
- T. O-APPROVED-RESULTS-RPT.

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3.1.7 Image Library Management. The following describes the output requirements that support image Library Management.

- a. O-IMAGE-LOCATION-ROST-DSPLY.
- b. 0-IMAGE-LOCATION-CAND-LIST.
- c. 0-RAD-FOLDER-PULL-LIST.
- d. O-RAD-FOLDER-PULL-NOTICE.
- e. O-BORROWER-LOAN-OSPLY-RPT.
- f. O-SPEC-INT/TEACH-RECORDS-LIST.
- g. O-SPEC-INT/TEACH-FILE-REC-OSP.
- h. O-CAND-SALVAGE-LIST.
- i. O-SALVAGE-LIST.
- j. 0-CAND-TRANSFER-LIST.
- k. O-TRANSFER-LIST.

3.1.8 Management Support. The following describes the output requirements that support Management Support.

- a. 0-ABORTED-PROCEDURES-REP.
- b. O-RAD-OUTSTANDING-PROCS-RPT.
- c. O-REPORTED-PROCEDURES-RPT.
- d. O-PROCEDURE -ELAPSED-TIME -REPORT.
- e. O-FILM-UTILIZATION-REPORT.
- r. O-RAD-DEPT/SECT-ACTIVITY-REP.
- g. O-TECHNICIAN-ELAPSED-TIME-RPT.
- h. O-RESULT-RPT-ELAPSED-TIME-RPT.
- i. 0-RAD-WORKLOAD-RPT.

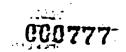
3.1.9 System Management. Reference CHCS FD for output requirements.

3.1.10 Accuracy and Validity. The Radiology function shall edit all data entered for accuracy and validity. Validity checks determine that the entered data is valid. Accuracy edits check data in two or more fields for accuracy. Data transmitted between internal functions and interfacing systems are subject to the error checks described below.

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3.1.10.1 Data Entry Edits. The system shall perform validity edits on all input data and generate appropriate error messages for terminal display. Consistency checks shall be made (e.g., if pregnant, sex must be female). The system shall have the capability to suspend these edits in the event of mass casualty or other circumstances requiring extensive data input.

<u>J.1.10.2 Codes. Pre-defined Values and Abbreviations</u>. The system shall accept coded, abbreviated, and other entry values for data items and relate these data to allowable values as defined in the MTF input/edit tables.

3.1.10.3 Data Transmission. Data transmitted between internal functions and interfacing systems will be subject to error checks including:

- a. Internal data element checking of telecommunication data.
- b. Internal application checking and acknowledgement by the receiver of telecommunication data.
- c. Data set integrity checking of the data base before and after executing backup and failure recovery operations.

3.1.11 Timing. The Radiology function response time requirements are listed below.

All Radiology data must be available to internal functions and other work centers for inquiry display and/or result reporting immediately after the Radiology data base is updated. All data from other work centers must be available to Radiology for processing after the appropriate work center data base is updated.

3.1.11.1 Interactive Response Time. Interactive processing occurs when the user communicates with the system in a conversational manner; that is, the content of the user's input is in response to and limited by the preceding system output. Terminal interactive response time will be no longer than three seconds for 90% of interactive functions. The average response time for the remaining 10% will be no longer than 10 seconds. Response time is measured from the moment the "return" key is pressed until the moment the first response character of continuing requested output appears on the screen at speeds equal to one-half the baud rate of the device. MultI-patient data base searches, and multi-patient file updates are excluded from the response time. requirements. Terminal response time requirements do not apply to external system interface activity, the generation of output products, reports, or any other batch operations.

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<u>3.1.11.2 On-Demand Response Time.</u> Output is produced on-demand when its production is requested either explicitly (e.g., the user requests a label torbe printed) or implicitly (e.g., the completion of registration will automatically cause a registration form to be printed). On-demand response time requirements are measured in terms of internal work center (i.e., intra-Radiology) output oroduction.

There are two response time requirements for an on-demand output. The first response shall be for single item/single patient output and shall be measured from the time the request is completed until the moment the continuous output is either initiated or is queued until the printer is available. The average response time for this activity should not exceed ten seconds.

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The other response time requirement is for multi-patient reports, lists or other outputs and shall be measured from the time the request is completed until the continuous output starts printing. On-demand output of this type shall be initiated within ten minutes of the request completion defined as completion of the data retrieval and sorts.

These timing requirements do not apply to delays caused by inoperable printers. Multi-patient data base search functions and external systems interface activity are excluded from these requirements.

3.1.11.3 Scheduled Turnaround. Multi-patient batch reporting turnaround time snall not exceed two hours (24 hours for ad hoc reports) measured from the time a request is initiated in the system by the operator to the time the requested report has completed output.

3.1.11.4 Interface Interactive Search. The interface interactive search timing requirements shall be met when a user performs a function which retrieves data from another system or subsystem for immediate display on the terminal or printer. The specific requirements for searches of this type shall be defined in the future.

3.1.11.5 Interface Interactive Uodate. The interface interactive update timing requirements shall be not when the system sends unsolicited data to another system or subsystem which is to be filed or displayed, immediately upon receipt of the data. The specific requirements which shall apply remain to be specified. in the future.

3.1.11.6 Interface Batch Communications. The interface batch communications timing requirements shall be met when the system uses a scheduled distribution to transmit batch report data to another system. The specific requirements which shall apply remain to be specified in the future.

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|----------|-------------------|---------------------------------------------|-----------|
|          | (•)               | Unique Patient Identification               |           |
| -        |                   | Patient Candidate Search                    |           |
|          | 8                 | istration.                                  | · .       |
| 0.       | леg               |                                             | •         |
|          |                   | Mini-Registration                           |           |
|          | (2)               | Registration-Updated Update Registration    | 86-121-1  |
| c.       | Order Processing. |                                             | •         |
|          | (1)               | Order Entry                                 |           |
|          |                   | Order Maintenance                           |           |
|          | (3)               | Product Production Generate Output Products | 86-121-RD |
|          |                   | Order Inquiry                               |           |
| d.       | Proc              | edure Scheduling and Patient Appointing     | •         |
|          | (1)               | Schedule Maintenance                        |           |
|          | (2)               | Patient Appointing                          | 86 194    |
|          | (3)               | Schedule/Appointment and Appointing Inquiry | 86-121-RD |
| e.       | Procedure Logging |                                             |           |
|          |                   | Patient Arrival                             | • •       |
|          |                   | Departure and Guality Accusence Control     | 86-121-RD |
|          | (3)               | Meintain Exam History Index                 |           |
| r.       | Resu              | lts Processing                              | · · ·     |
|          | (1)               | Results Entry                               |           |
|          |                   | Results Reporting                           | -,        |
|          | (3)               | Results Inquiry                             |           |
| -        | Inec              | e Library Management                        | -         |
| g.       |                   |                                             |           |
|          | (1)               | Image Tracking                              | · ·       |
|          | (2)               |                                             | · • • • • |
|          |                   | Special Interest and Teaching File          | ۰ ۱       |
| <b>.</b> |                   | Image-Transfer Designation                  | ۰.<br>۲.  |
|          | (5)               | Image Salvage Designation                   |           |
| h.       | Hana              | gement Support                              | •         |
|          | (1)               | Management Reporteing                       |           |
|          |                   | -Statistics                                 | £5_097_90 |
| (4)      |                   | Electronic Message Board                    | QJQJATW   |
|          |                   | Report-Runging- Archive/Purge System Data   |           |
|          | (4)               | Ad Hoc Reporting                            |           |

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i. System Management

(1) System Security

(2) Table Maintenance

References are made in the following sections to data objects found in the automated data base used to support this document. All references to the Appendixes in which these data objects are found areato the Technical Appendix of this document.

The data base software accepts object names of 30 characters or-less. Therefore, the data object names are often abbreviated ... The data base input names are located in Appendix 8 and the outputs in Appendix C under the corresponding PSA name, with a description and listing of the data elements\_. contained in the data object. For ease of reference, the abbreviated names are listed in alphabetical order within their appendix. Data element names are abbreviated in the automated data base. The full name is found in the CDD.

3.2.1 Patient Identification. The Patient Identification (PTID) functional component shall identify the patient for whom Radiology service is requested and shall automatically access the patient data store to obtain patient data. The system shall provide for patients to be identified uniquely or through a candidate search. The system shall not require the user to re-enter patient identification data if multiple functions are performed for a specific patient (e.g., order entry and appointing). The system shall retain the patient identification information until a different patient.is.identified or the session is terminated. These capabilities are discussed in the following paragraphs.

3.2.1.1 Unique Patient Identification. The system shall provide an authorized user to identify a unique patient directly by entering the family member. prefix and sponsor's Social Security Number. 

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The system shall supply the Radiology user with the demographic information for ... the selected patient.

The PAD function also shall be responsible for supplying an extended registration report. These data are combined with the demographic data necessary to process an order. These data shall be automatically undated by PAD functions when there is a change - A disposition indicator and the discharge date shall be provided by PAD to notify the Radiology Department of an inpatiant's discharge.

A summary of the UNIQUE-PATIENT-IDENTIFICATION functional subcomponent is. contained in Technical Appendix A. 

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3.2.1.2 Patient Candidate Search. If the patient's current or last previous inpatient register number or FMP and sponsor's SSN are not available, the system shall display a candidate list of patients as a result of entering one of the following search criteria:

- a. Patient's full name.
- b. Patient's former name.
- c. Last name or partial (minimum of five characters) last name (e.g., Johnston could be found by entering "John"). Soundex of patient last names shall be performed.

a. Sponsor's social security number.

- d. Lost four digits of sponser's seciel security rumber and patient-
- e. Patient's sex and/or date of birth.

This functional subcomponent shall locate all patient records which correspond to the above keys and display a candidate list that contains the patient's name, unique number, and date of birth. Multiple displays shall be presented under user control if all selected patient records cannot be displayed at once. The user will select the desired patient from the list and shall be prompted to continue with the selected function (e.g., Registration, Order Entry, etc.).

A summary of the PATIENT-CANDIDATE-SEARCH functional subcomponent is contained in Technical Appendix A.

3.2.2 Patient Registration. The Radiology functional components shall provide a minimal registration function if the patient has not been previously registered. They shall also provide for an update of all existing. registration data. This function shall be entered on request or if a patient identified does not exist in the data base shall return the user to the selected function on completion. These capabilities are discussed in the following paragraphs.

3.2.2.1 Mini-Registration. The Mini-Registration functional subcomponent snall provide the following capabilities:

- a. This functional subcomponent shall allow the user to enter the datament elements (See I-RAD-MINI-REE-DATA, Apendix B). Data edits shall be performed and error messages displayed, as necessary. A flag shall. on be assigned submatically to the registration data and remain until the data has been verified by the Patient Administration Office.
- b. A "John Doe" shall be registered in the system by entering a pseudo. The name and pseudo identification number. A flag shall be assigned automatically to the registration data and to permit complete registration to be performed by PAD when more information becomes available.

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A summary of the MINI-REGISTRATION functional subcomponent is contained in . Technical Appendix A.

3.2.2.2 Update Registration. The user shall be able tomenter any registration data element and the system shall update the patient's record automatically. A flag shall be assigned automatically to the new or changed registration data and remain until the data has been verified by the Patient Administration Office. Registration data that is generated or modified at other ancillary work centers shall be made available to PAD. PAD, in turn, shall make available any update of relevant data to Radiology.

The system shall provide for the authorized user automatically to merge two patient records into a single record under the correct patient ID without data entry. Following the completion of the merge option, all results reports and other information from the two patient records shall be stored and shall be retrievable under the correct patient ID. Ac-post-of the mergeoperation, the system shall provide for the user to delete errorous patient records.

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A summary of the UPDATE-REGISTRATION functional subcomponent is contained in Technical Appendix A.

3.2.3 Order Processing. The Order Processing functional component shall "66-122-RD provide for order entry into the system. These orders shall be entared by an authorized ward or clinic user, and shall be transmitted by the system to the processing location. through Museing or directly into Rediclegy. Order Processing shall consist of order entry and order maintenance. These functions are discussed in the following paragraphs.

3.2.3.1 Order Entry. An order received by the Radiology Department for a BG-122-RD procedure or procedures shall be entered by an authorized ward or clinic user 86-110-RD through Hureingr - the system. Orders or order groups also shall be entered directly into Rediology - the system by Radiology Department users.

Radiology shall support the order processing function as follows:

a. Although some data entry may be optional and/or MTF-specified, the

- system-shall determine data. collection prompts or screens, consistency checks, data.edits to be performed, prevention of dupicate or similiar (procedures within a single; order, etc.
- b. Requirement deleted.
- c. The system shall provide for entry of the procedure priority, ranging from STAT to\_routine; which shall indicate the urgency
  - assigned to performing the-procedure.

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- d. The system shall give the user the option of entering coded or free-text order comments on the Radiology order.
- Other secondary orders specified by the system files associated with the procedure requested shall be displayed (e.g., to Food Service forfasting blood sugar), and the user shall have the capability to select. and enter them as separate orders.
- f. STAT and priority orders shall be processed and printed ahead of routine orders.
- g. The system shall identify procedures for Radiology service which require the approval of a Radiologist before the procedure may be performed. The system shall provide for entry and retrieval of the approving radiologist. The telephone system may be used to obtain the. approval and then the approval code may be entered.
- h. The system shall provide identity of a procedure to be performed on the nursing unit with portable equipment.
- The system shall provide for the same procedure to be performed at multiple locations in the MTF. This will affect available rooms which must be location specific.

A summary of the ORDER-ENTRY functional subcomponent is contained in Technical Appendix A.

3.2.3.2 Order Maintenance. The system shall provide authorized users with the ability to modify Radiology orders (e.g., add, change, or delete data) or to cancel Radiology orders. An order modification may be entered by an authorized were user through the system. Mursing or by a Rediology oper directly into the 86-123-RD Rediology functioner. The system shall provide the following order modification requirements:

- a. The system shall provide identity of the order to be modified by entering the data elements and a range of dates (See I-RAD-PNT-ORDR-ENTRY-DATA). The system shall display all orders within that range and provide for selection of a specific order for modification. If multiple procedures share an order, the system shall provide for theprocedure to be modified to be identified.
- b. If the appropriate criteria have-been met to include the-condition that the order may be modified, the system shall provide for supplying the modification data to Radiology and updating of the existing order data. An order may be modified by Nursing if the patient has not been arrived. The system shall provide for identifying the modification transactions affecting a Radiology order.

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a Rediclogy user unless the patient has been arrived. The system shall provide the following order cancellation requirements:

- .c. Provide order identification as described in a: above.
- d. Provide for cancellation of all Radiology orders using the selection of "all" pending orders.
- Require entry of free text or-coded data specifying the reason for-. cancellation.

A summary of the ORDER-MAINTENANCE functional subcomponent is contained in Technical Appendix A.

3.2.3.3 Product-Production Generate Output Products. The system shall 86-121-RD produce automatically the following outputs for each procedure requested inconjunction with the order processing functional subcomponent. They shall beproduced when the radiology user indicates that the patient has arrived for a . procedure requested for the current date. Radiology users also may request ... that these products be batch printed, in user-defined sort order, for all procedures for which patients are appointed for a user-specified range of dates. The system shall also provide for the user to reprint a user-speci-85-014-RD fied number of any or all of these products.

a. Procedure Worksheet. The system shall print this form for recording procedure data on procedure start and stop times, supply utilization, and. radiology technique factors. The worksheet data shall be entered on a. . ..... machine readable form. ..... 1 40 1 . . . . 1.1 .....

b. Patient Transportation Notice. This notice shall be printed for each inpatient scheduled to receive service in the Radiology Department at .: \*\*\*\*\*\* Sec. the option of the MTF. . ... 1. . -----

c. Flash Card Label. The system shall print a flash-card label for: each procedure order when the petient is arrived. The flash card label is a inexposed with the file and contains the patient's identification: ---

d. Procedure Label. The system shall print this machine/human readable افتر شۇمە 👘 👘 مەدە دە دەپەن . label for each procedure requested. 86-121-RD ومجاري ومنهزهم والالجار والمراجع 202

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A" summary of the ORDER PRODUCT PRODUCTION- GENERATE-OUTPUT-PRODUCTS functional subcomponent is contained in Technical Appendix A. and the second sec

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3.2.3.4 Order Inquiry. The Order Inquiry functional subcomponent shall print and/or display (user option) a patient's pending radiology orders for the data range specified. These data shall be accessed by performing the PTID function (Section 3.2.1.1) and requesting a display or print out of a specific patient's order data. In addition, the radiology user shall have the order inquiry capabilities specified in the CHCS FD, Section 3.2.1.1.

A summary of the ORDER-INQUIRY functional subcomponent is contained in Technical Appendix A.

3.2.4 Procedure Scheduling and Patient Accounting. The procedure scheduling functional component provides for patient appointing, schedule maintenance, and schedule/appointment inquiry. The system shall provide for the authorized user to indicate those procedures that must be scheduled. When these procedures are ordered, the system shall notify the user to appoint the patient. If the procedure requires a radiologist's approval, and the approval has not been obtained, it may be held for later appointment. All other procedures shall be appointed by the system at the time scheduled or left unappointed.

3.2.4.1 Schedule Maintenance. The system shall, using radiology schedule parameters, creste schedules and the system shall perpetuate existing schedules.

The system shall provide for entry of information regarding available rooms, 85-061-RD and room groups in which the procedure can be performed in priority sequence, procedure duration by mobility status, restriction on patient types, and the times the procedure may be performed. The system shall provide for the entry 85-062-RD of the department/section for each room and room group. The system shall provide for the-entry of information on contrastimedia constraints, preparation delay times, standard film usage data, standard UCA procedure weights, and information on whether radiologist approval is required for a procedure, for each procedure defined. Gnce entared by the radiology user, 85-064-RD these data shall be maintained in system tables as part of the schedule template information, and shall be provided for inquiry, updating, and achedule creation on request.

The system shall maintain achedules for holidays, weekends and each operating day. Rease shall be declared operational or non-operational by time, data, or data renger. These schedules shall be available for a MTF-specified time period for appointing not to exceed one year. Schedules will and patient arrivals shall be maintained for at least two weeks after the schedule data. The system shall provide for entry of procedures to be performed by time of day, day of the week, and by room. The system shall provide for procedures to freeodures may be performed in multiple locations as well as in multiple rooms at a specific location. Room preference priorities shall be specified. A schedule template shall be used by the system to automatically extend the schedule. 86-117-RD

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The system shell provide an authorized user the capability to declare - rean 85-03 open. closed, operational or non-operational. When - rean is closed as be comes inoperable, the system shall create a file of orders which are affected and which will require rescheduling. The system shall permit an authorized user to display/print this file of orders and reschedule these orders without requiring that the order be completely reentered. Rescheduled orders shall be deleted from the file.

The system shall provide an authorized user with the capability to declare a room open or closed for a user-specified date and time range. The system shall list appointments which require rescheduling or cancellation because they occur on the date and/or in the time range during which the room is. closed. The system shall reprint this listing on demand. The system shall allow an authorized user to reschedule these appointments by entering only new data (e.g., new date, new time, room, patient type, mobility status) through the appointment modification function. The system shall allow an authorized user to declare rooms open; therefore cancelling an earlier "room-closed" designation. The system shall not allow patients to be appointed in rooms during the specified date and time range; that they are closed.

A summary of the SCHEDULE-MAINTENANCE functional subcomponent is contained in Technical Appendix A.

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3.2.4.2 Patient Accounting. The patient appointing functional subcomponent matches appointment request(s) criteria (e.g. procedure, date/time) with available time and room for a specific procedure to process a request(s) for an appointment(s).

a. The system shall provide three two modes of scheduling an appointment for a patient:

(1) Automated Scheduling. The user shall specify the first data for which the appointment(s) are accepted and the department section in which the procedures are to be performed. The system shall select the appointment data, time and room based on the algorithm to minimize the total time between the first data for which the appointment(s) is acceptable and procedure complation for all procedures which are requested. If multiple rooms have the same time opening, the system shall select the room with the highest preference for the exam based upon HTFspecified room preferences. The scheduling algorithm shall consider the patient's scheduled and previous appointments, mobility status, procedure duration; contrast media restricfions, preparation delay times, room availability, room schedules of the roomerin the department section in which the procedure can be performed and order priority.

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If multiple procedures are requested and the procedure to be performed first has been selected for acheduling by the algorithm, the remaining procedures to be performed consecutively should be acheduled immediately after the first procedure in the same room, if these procedures can be performed in that room and sufficient time is available to perform the procedure.

The system shall display the proposed appointment to the user for acceptance or rejection. The user shall accept or reject the system-selected appointment(s) or any portion thereof. If the user rejects the system-selected appointment(s) or any portion thereof, the system shall automatically provide the user with the option of manually appointing the rejected procedure(s) without requiring that the patient be reidentified or the examination data be reentered. The system shall retain a record of the user who scheduled the procedure.

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(2) User-Specified Appointing. <u>Menual Scheduling</u>. The system shall provide for the user to identify the department section in which the procedure is to be performed and one or more of the following parameters: procedure date, procedure time, procedure time range, procedure date range, and performing room. The system shall display available time ranges in which the procedure may be performed in the room selected by the user, or in the room which has the highest MTF-specified preference for the procedure in that department section if a room has not been specified. The system shall provide for the user to enter or have the system select the room and display the available time ranges for the new room selection. The user shall indicate the date and time of the appointment. The system shall retain a record of the user who scheduled the procedure.

Any conflicts identified by the system shall be identified to the user vis an appropriate warning message. After selection of an appointment time, the system shall indicate any achedule conflicts due to contrast media interference, preparation delays, or previously acheduled patient procedures or procedure room rejections. The system shall check to ensure there is sufficient time available to complete a procedure based on the patient's mobility status. All conflicts identified by the system shall be conveyed to the user vis an appropriate warning message. The system shall provide for the user to override the varnings and continue the scheduling operation if the procedure can be performed in the specified toos.

The system shall provide overbooking (multiple patients with the same appointment) only for Department of Radiology users using this mode of scheduling. . . .

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(3) In The system shall provide for the authorized user to schedule radiation therapy treatments. The system shall provide for the user to specify the number of treatments to be scheduled (to a maximum of 40 30) and the duration of each trestment. The system shall provide for the user to indicate if there are to be breaks in the treatment regimen echedule, the number of the treatments just before each the break, and the length of thebreak in days to a maximum of 30 days. The system shall provide for the user to specify the starting date of the treatment regimen and the time in days between treatments: If no date for the start of the regimen is entered, the system shall. schedule the regimen to start as soon as possible considering . the current schedule. The system shall not schedule treatments on weekends or holidays unless specified by the user. The system shall provide for the user to enter a time for the first treatment and shall schedule all subsequent appointments as near to that time as possible. Once the treatments have been scheduled, the system shall produce (print) the e-patients's accogintment schedule, for the petionter

> The system shall provide. for. the user to modify a treatment regimen. The system shall provide for the user to terminate a radiation therapy treatment series prior to completion. If the series is terminated, the system shall indicate that a results report is due. The system shall provide for the user to enter. an unscheduled unanticipated break of up to 30 days in the treatment series and to.enter s.restart-dep-date . The restart day data shall be either the day immediately, following the break period or a user-specific future date. If the user enters a brask without entering a new start data or enters a termination, the system shall make the time previously scheduled for subsequent treatments available for appointing -other espeintmente.- If the user enters a new start date with a break, all appropriate treatments: previously scheduled will be available for other:sopointments and the remainder of the regimen shall be appointed ... .....

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the cystem shell provide overbacking only for Department of alogy users using servel echeduling. 120 1 1 4 . 27

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- The system shall provide for the authorized user to modify previously scheduled appointment data. The system shall provide for the user to uniquely identify the appointment to be-modified. The system shall display the appointment information upon user request and shall provide for entry by the user of the required change data and the system shall make the appointment changes. The user shall enter: "the reason for modifying the appointment: The system shall store .... this information along with the identity of the user who performed the socialment modification.

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The system shall provide for the user to modify any or all of the following data elements in all possible combinations: scheduled room, scheduled department/section, patient type, patient mobility status, scheduled procedure date and scheduled procedure time. The system shall indicate all conflicts (see defined in section 3.1.4.12(1)) which result from modifying the appointment. The system shall provide for the authorized user to emit the function, change the appointment parameters, or override the warnings, and proceed with the appointment modification if the procedure definition permits the procedure to be performed in the room selected. The system shall permit a user to exit the function at any point during this appointment modification procedure. After the change data has been input, the system shall schedule the procedures at a new time or room and delete the previous schedule making the room available for use.

The system shall make the original room and time swallable for subsequent appointments if these parameters are changed by the user in the modification process. At MTF option, the system shall print an appointment change notice at an MTF-designated location to notify the requesting health care provider and/or inpatient ward when the date and/or time of a patient's radiology appointment has been modified.

The system shall provide for allow the user to cancel scheduled appointments. The data elements that identify the patient and specific appointment or time range are entered into the system by an authorized user to locate the desired appointment. The system shall display the patient's current appointment data if multiple data meets the criteria. The user shall choose the appointment to be cancelled and shall specify a reason. The system shall make the cancelled time available for other appointments. The user shall enter the reason for the appointment cancellation. The system shall store this information along with the identity of the user who performed the cancellation. At MTE option, the system shall print automatically a notice at an MTF specified location to inform the requesting health care provider and/or impatient ward that the appointment has been cancelled and not rescheduled. The system shall provide for the user to generate a report of cancelled appointments and/or orders.

A summery of the PATIENT-APPOINTING functional subcomponent is contained in Technical Appendix A.

3.2.4.3 Schedule and Appointing Inquiry. This functional component provides for the display or printing of department, ward or room schedules, as well as and corresponding patient appointment information by an authorized user.

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The system-shall display and/or print and sort in user-specified order thefollowing information regarding radiology schedules upon request:

a. Procedures scheduled for a specific radiology room, room group or department section for a specified time period ...

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b- Daily Radiology Department schedules.

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- c. MTF ward schedules.
- d. Available and filled appointment times for a given room, room group .... or section on a given date shall be displayed or printed with patient data and appointment times. 1.4 .... ----.... ----

........ A summary of the SCHEDULE/APPT-INQUIRY functional subcomponent is contained in Technical Appendix A.

3.2.5 Procedure Loaging. The Procedure Logging functional component shail. provide for entry of data about the procedure process. The data shall be used to update patient files, prepare statistical reports and aid in the . management of patient flow.

3.2.5.1 Patient Arrival. The system shall provide rapid means via a light pen or other user-friendly device to indicate that an appointed patient has arrived. The entry of a patient's arrival for walk-in exams shall be performed at the end of scheduling without calling another function. If labels for the exam for which the patient has been arrived have not been printed at. patient arrival, the system shall print the labels at that time.

At the option of the MTF; walk-in patients may be arrived without scheduling= following order entry. The system shall process the order minus the scheduler information as required and arrive the patient without calling another func--tion. Required labels shall be produced.

The system shall default to the current time or accept a user-entered time .... The system shall provide for input\_of. a time period after which a patient whom has not arrived will be considered. a .no-show. The system shall provide them ... Radiology products shown in Section 3:2.3.3. dine :

---------The system shall provide for the user to arrive and depart patients for each of trestment in a radiation trestment series ... Each trestment shall be trested ass separate visit on all sanagement reports and reported separately for with workload statistic compilation. المراج المشورين فيعد المعود وتوارد المواكا والع -

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3.2.5.2 Departure and Quality Assurance Control. The-system shall provide, 86-121. in addition to manual entry of data concerning each procedure, the entry of data from a machine resdable procedure worksheet such as film quality, repeat films. additional views, additional procedures, film count, radiographic teconique factors, and exposure information. Departure data input shall include the designation of a procedure as aborted (all other departures being automatically considered complete). The input shell include entry of abested procedures (all others being concidered complete). The system will shall use the current time for departure time unless a different time is entered. The system shall provide for data on completed worksheets to be machine read and/or entered vis keyboard terminal.

The system shall produce a no show report, a quality control repeat film report, and a quality assurance report on demand in user-specified sort order.

A summary of the DEPARTURE QUALITY ASSURANCE DEPARTURE QUALITY-CONTROL functional subcomponent is contained in Technical Appendix A.

3.2.5.3 Maintain Exam History Index. The system shall maintain an index of all radiciogical exams performed. This file shall contain patient's full name, rank, source of eligibility or dependency status, patient identification number, age, sex, and the date and name of each radiological examination performed. The index shall be retrievable in chronological or reverse chronological order.

A summary of the MAINTAIN-EXAM-HISTORY-INDEX functional subcomponent is contained in Technical Appendix A.

3.2.6 Results Processing. The results processing functional component shall provide for entry of radiographic interpretations, report approvals. and print requests at designated areas.

3.2.6.1 Results Entry. After a radiologist has interpreted the patient's images for a procedure, the entry of the interpretation into the system shall be accomplished by various means. The system shall provide the user a variety of specialized entry methods, entry of conventional dictation and pra-defined reports triggered by bar codes, keyboard entries, optical sense forms. or other suitable means such as verbal reporting techniques (e.g., Concuter Voice Recognition or Capacitance light pen). Any authorized entry methods shall be combined at the user's option-at any time. Example: oneparagraph of pre-defined text, keyboard entry, further pre-defined text. etc. The system shall provide text editing capabilities. The system shall combine the order data and interpretation to produce a patient report. Thesystem shall accept pre-defined results text (e.g., normal chest) and changes ... to predefined text previously indicated, if desired.

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After the results are entered into the system they shall be printed/displayed 85-095-RD on request for the radiologist's review and approval. The system shall provide for an authorized radiologist to indicate his approval electronically at 85-108-RD either the time of results entry or following a request for a display of reports he is authorized to approve.

The system shall accept additions, deletions, or corrections to the report prior to its verification. The system shall not allow an original report to: be altered once the report has been approved. The system shall accept the - 85-076-RD entry of additional information to the original report and shall print on the report the word "Amended" before the additional information. Amended reports shall carry the signature of the radiologist entering the mendment and shall require radiologist approval. The system shall provide entry of results by a reporting radiologist and approval by a staff radiologist, maintaining the -I.D.s of the two radiologists. The system shall provide for entry and maintenance of these procedure groups which each radiologist can certify approve. 85-097-RD

The system shall not display or print/release any results at wards or clinics until the results are certified.

The system shall produce upon demand a list indicating results which are pending approval for more than an MTF-specified period of time.

A summary of the RESULTS-ENTRY functional subcomponent is contained in Technical Appendix A.

3.2.6.2 Results Recorting. Certified radiology results are printed in designated areas within the MTF. Certified STAT reports shall be sutconstically printed at the requesting locations when approved. Routine reports shall be held for batch printing at MTF-epecified times or on request at in user-specified sort order at designated locations.

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For radiation therapy, one report is required at the completion of the trastment series. The system shall provide for users to enter reports for radiation therapy regimens according to these guidelines. The system also shall provide for the user to enter interim reports during the treatment regimens and to enter reports if a treatment series is terminated. Interim reports shall be clearly indicated as such.

In addition to the patient's complete results report, the system shall provide the ordering HCP with a report which lists all of the patients for whom he requested radiological procedures and the result category.

A summary of the RESULTS-REPORTING functional subcomponent is contained in Technical Appendix A.

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3.2.6.3 Results Inquiry. Result reports shall be requested at any authorized terminal. The data elements that identify a specific patient and study or studies shall be entered into the system. The system shall display and/or. 55-man.en print at a user-specified printer the requested approved reports on file for that patient. If the results are not available, the system shall provide the procedure status. Reports shall be kept on-line for an MTF-specified time period that shall not exceed three years following report certification. A means of archiving reports (such as magnetic tape) shall be provided for rapid search and re-entry of a specific patient's archived report(s) back into the system.

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A summary of the RESULIS-INQUIRY functional subcomponent is contained in Technical Appendix A.

3.2.7 Image Library Management. The Image Library Management functional component includes the two subfunctions described in the following paragraphs

3.2.7.1 Image Tracking. The system shall automatically produce the following labels/notices:

- a. Hester Folder Label. The system shall print this machine and human readable label at the time of patient arrival if not previously printed (to be attached to the patient's master folder) in the area designated by the HTF if the system has not previously produced a master folder label, or upon user demand. The user also may specify that all previously unprinted master folder labels for patients with examinations on a specified date be batch printed in a user-specified sort order.
- b. Subfolder/Library Label. The system shall print this human and machine readable label at the time of patient arrival.if not previously printed in the area designated by the HTF for use by the image library or sublibrary if this is the first procedure for the patient requiring this subfolder. The user also may request that the system produce this label on-demand. The user also may specify that all previously unprinted subfolder labels for patients with examinations on a specified date be batch printed in a userspecified sort order.
- c .- Folder Pull Notice. The system shall produce this human readable notice at the time of patient arrival if not previously printed in the MIF-specified library or sublibrary where the subfolder required for a procedure is stored. This notice will be printed when a patient is checked in for a procedure requested for the current date. If the subfolder has been loaned, this fact will be indicated on the notice along with information on the loan. The pull notice will be used by image library personnel to pull subfolders which contain images of previous examinations needed for radiologist interpretation of the current procedure.

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The system shall print on demand, a folder pull list in user-specified sorf order, in the appropriate radiology image library or sublibrary, to notify the library personnel of patients scheduled for procedures over a user-specified range of dates and the subfolders which must be pulled from the film library for these patients. The system also shall provide an option which allows users to specify that pull notices will not be printed for patients whose examinations were previously shown on a pull list.

The system shall provide for input and display of the current location of a patient's folder. The system shall automatically assign an HTF-specified initial location when folders are created such that no additional effort is. required by HTF personnel during subsequent image management transactions. When a folder is requested by Radiology personnel, the system shall accept location data and/or destination data of the folder type and patient. The: method of input chould shall be user-friendly, rapid input technique. The system shall on request display the current location of all folder types for . 85-081-R a specific patient.

The Radiology Department may have two or more locations where folders areusually retained. At these locations a light pen or other device shall beavailable for personnel to use when entering a folder's current location ...... The system shall update the appropriate folder location as it moves through the department if the users activate this feature the labels are read into the system.

If the multiple folders are to be moved to the same location, the system shall provide for the movement at these folders to be recorded without requiring that the location receiving these folders be re-entered.

When the folder is returned to the library, the system shall accept these data using a quick entry means such as a light pen or other user-friendly device to read the folder label and indicate to the system that the folder. was returned: If multiple folders are to be returned to the same location. the system shall provide for the return of these folders to be recorded without requiring that the location receiving the folders be re-entered.

The system shall print a folder pull notice in the appropriate Radiology image library or sublibrary on demand to notify the library personnel of patients scheduled for procedures.

A summary of the IMAGE-TRACKING functional subcomponent is contained in - Technical Appendix A.

3.2.7.2 Loan Control. The loan control functional subcomponent shall maintain the current location of all folders on loan from the Radiology Image Library to authorized borrowers outside the Radiology Department.

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When a patient's folder is requested, the system shall accept folder, patient and borrower identification using a quick entry technique such as light per o other user-friendly means, and shall produce, at MIF-option, a machinereadable loss label containing all information necessary to transact the loss. Multiple patient folders chall be entered without re-entering the. boseness. The borrower's identity and, at MIF option, and folder location shall also be entered. If multiple folders are to be lossed to the same borrower, the system shall provide for the entry of these losses without requiring that the borrower identification data be entared more than once. The system shall maintain location information and make it available upon request. The system shall not loan folders to ineligible borrowers.

The system shall provide for the user to record the return of loaned folders to the library. Meen a patient's folder is returned from a loan, the system shall provide for the user to enter folder, patient, and receiving location identification using a quick entry technique to read the label(s). Meen a loan is returned, the system shall automatically update the folder location and delete the record of the loan from the borrower's file. If multiple folders are to be returned to the same location, the system shall provide for the return of these folders without requiring that the receiving location be reentered. The system shall provide for the user to display/print in userspecified sort order all overdue loans that have not been returned in a userspecified time frame, and shall provide for the user to display/print the loans which are charged to a specific borrower.

A summary of the LOAN-CONTROL functional subcomponent is contained in Technical Appendix A.

3.2.7.3 Special Interest and Teaching File. Data identified as Special Interest/learning file data small normally be entered at the time of results reporting and shall be maintained in the appropriate special interest or teaching file. The system shall utilize ACR codes to represent pathological and anatomical findings. The system shall provide a special interest code to indicate the record is to be a special interest or teaching file record. At 85-047-RD MTF option, the system shall require these codes to be confirmed by an 85-046-80 authorized user before they are entered into the special interest and/or 85-048-90 teaching file. The system shall provide lists of records that include any or all ACR code ranges and/or patient demographic data, to include, at a minisum, race, procedure date range, sex, and date of birth range. For example. the radiologist may request a list of all cases in the teaching file for 85-050-RD males age 30 and over that had an ACR code of a specific value range. 85-051-RD

A summary of the TEACHING SPECIAL INTEREST CILE SPECIAL-INTEREST/TEACHING-FILE functional subcomponent is contained in Technical Appendix A.

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3.2.7.4 Immoe Transfer Designation. The system shall provide a list of folders which are eligible for transfer (no activity for an MIF-specified time). The list shall be printed/ displayed and the user shall indicate exceptions. The system shall automatically transfer these patient records from one location to another folder locations to the designated location on request. Special interest and teaching files will not be transferred. The system shall provide for the transfer of special interest and teaching files at the MIF's option.

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J.2.6 Venecoment Euccett. The system shall maintain data required for-

<u>7.2.8.1 Honocoment Reports. The system shall maintain workload statistics</u> and produce workload and UCA reports. UCA procedures (rem counts and weighted values workload) are reported by the requesting leastion, patient. 85-056-RD leastion, clinical corvice, patient type, requesting health care provider and performing leastion as specified in the cort criteria. The rem count and weighted values subtatels and totals shall be are reported by requesting = 85-057-RD weak conter (UCA Gode) for all performing work-conter corvices (Disgnestic - 85-058-RD Redielogy, Nuclear Medicine and Rediction Therepy) for specified time

A cummery of the STATISTICS functional subcomponent is contained in . Technical Appendix Ar

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3.2.8 Hansgement Support. The system shall saintain data and perform 8 statistical calculations necessary for the production of Radiology Department management reports. The system shall additionally support the radiology user with a CHIS electronic message board capability.

3.2.8.1 Management Reporting. The system shall provide for the generation of management reports for the Radiology Department. These reports shall contain statistics generated by the system and other management data in the areas of radiology quality control monitoring; quality manurance; and DoD, military-specific, and MTF-specific workload statistical reporting requirements. Management reports shall be produced for any and all divisions within the Radiology Department of the MTF and shall, at user option, contain only the data relevant to that division or subdivision. Reference Technical Accendix C for output data requirements.

Management reports shall be produced using user-specified combinations of suitiple sort criteria. Data may be subtotaled and totaled for each report parameter specified. Statistics shall be calculated using standard statistical formulas resident in system tables. The system shall calculate rew and weighted procedure counts using specific workload statistical algorithms and coded achema.

A sussary of the HANAGEMENT-REPORTING functional subcomponent is contained in Technical Appendix A.

3.2.8.2 Electronic Message Board. The system shall provide an electronic message board capability as specified in the CHCS FD, Section 2.4.2.2.1.8.

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3.2.8.3 Archive/Purge System Data Report Purging. Reference CHCS FD Section 85-092-RD 3.2.6.4. The system chall automatically purge reports following report 85-094-RD archivel 112 report data elements chall archived and then sutematically purged after NTE specified period up to three years. Special interest and temping files will not be extendically purged.

1.2.2.1 Electronic Messeco Board. The system shall provide an electronic 86-116-RD

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3.2.8.5.4 Ad Hoc Reporting. Reference CHCS FD Section 3.2.5.2.

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3.2.9 System Management. The system shall provide for input, update, and print of all user-specified file and table data.

3.2.9.1 System Security. The system shall provide a system security functional subcomponent that shall:

- a. Validate user access codes, the functions they may perform, and the type report staff radiologists may approve. The authorized user shall be able to assign, change, and delete user passwords or access codes.
- b. Limiting user access to only those radiology functions the user is authorized to perform as defined by the authorized user.

A suggery of the SYSTEM SECURITY functional subcomponent is contained in Technical Appendix Ar

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3.2.9.2 Table Maintenance. The system shall provide a table maintenance functional succomponent which shall provide entry, modification, or deletion of all tables which are facility unique.

The system shall display and/or print on demand all data entered into those tables requested for review.

A cursesy of the TABLE WAINTENANCE Functional subcomponent is contained in Teannical "prendim A.

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3.3 Inputs-Outputs. The data inputs and outputs that support the data flow among Radiology functional components and between Radiology functional components and the Radiology user or functions external to Radiology will befound in the Technical Appendix to this document, Appendixes 8 and C respectively. Descriptions for internal data flows (entities) will be found in Appendix D while those for data stores (sets) are described in Appendix E.

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3.4 Data Base Characteristics.

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3.4.1 Data Dictionary. Definitions of the data elements listed as components of the inputs, outputs, and entities described in Appendix B, C, and D will be found in the Central Data Dictionary (CDD). These definitions are arranged alphabetically.

3.4.2 Storage Requirement Estimate. Available from the TPO.

3.4.3 Growth Estimate. Available from the TPO.

3.5 Failure Contingencies. Refer to Section 3.5, Failure Contingencies, in the CHCS FD.

3.5.1 Hardware Failure. Refer to Section 3.5.1, Hardware Failure, in the CHCS FD.

3.5.2 Software Failure. Refer to Section 3.5.2, Software Failure, in the CHCS FD.

3.5.3 Manual Backup. Refer to Section 3.5.3, Manual Backup, in the CHCS FD.

3.5.4 Restoring Lost Data. Refer to Section 3.5.4, Restoring Lost Data, in the CHCS FD.

3.5.5 Radiology Priorities. If system response time becomes degraded, or if workload increases substantially, Order Processing, Results Reporting, and Patient and Order Identification would be assigned the highest priority. Patient Appointing and Image Library Management would receive the next highest priority. Likewise, if a system failure occurs, those same Radiology functions would take precedence for input of transactions after recovery within the overall CHCS assigned priority for Radiology functions. The systemshall allow the user to overwrite the current date with the earlier date of the actual transaction when inputting data after recovery.

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3.6 Security. Refer to Section 3.6, Security, in the CHCS FD.

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3.7 Interfaces. The Radiology functions will interface with UCA to provide workload data for each clinical service which uses Radiology services.

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# SECTION 4. DESIGN DETAILS.

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## SECTION 5. ENVIRONMENT.

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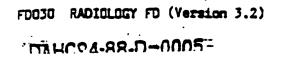
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SECTION 6. COST FACTORS.

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