GUIDANCE FOR THE CONTENT AND REVIEW OF 510(K) NOTIFICATIONS FOR PICTURE ARCHIVING AND COMMUNICATIONS SYSTEMS (PACS) AND RELATED DEVICES

1. Applicability

This guidance is applicable to picture archiving and communications systems (PACS). PACS are systems which are intended to provide transmission, storage and viewing facilities for medical diagnostic images at distributed locations. Some PACS are intended to transmit information over long distances using public phone lines (e.g. teleradiology systems). Others are intended to transmit images within a clinical facility by means of local area networks (LANs).

The guidance is also applicable to related devices which perform one or more of the functions (e.g. image transmission, storage or viewing) which may be provided in a PACS. Such devices include:

image digitizers - video and film digitizers

image communications equipment - networks and interfaces

image storage devices - video recorders and digital storage media

workstations and their components - video monitors, image processors, and image processing software

image hardcopy devices - laser printers and multiformat cameras

The guidance does not apply to general purpose devices if they are not specifically indicated or promoted for use in conjunction with medical images. These products are not considered to be medical devices and premarket notifications are not required. Examples of such devices include general purpose communications systems, data storage media and software. However, if general purpose devices are indicated or promoted for medical use, a 510(k) must be submitted. Also, if they are sold as a PACS component, they must be described in the 510(k) for the system.

2. Update for Devices Employing Lossy Compression

Data compression techniques have been utilized for medical image data communication and storage for a number of years as a means of reducing transmission time and storage requirements. However, recently there has been a marked increase in the number of PACS devices which utilize lossy data compression, i.e. compression techniques which do not preserve the original data. This increase in activity has been reflected in the number of 510(k) submissions for devices which incorporate lossy compression as a feature.

In response to these changes the Center has reconsidered the regulatory issues associated with lossy compression. In particular, consideration has been given to the suitability of lossy compression for different

medical applications such as primary diagnosis, referral and archiving. Consideration has also been given to user needs with regard to promotional material, image labeling and instructions. Related technical issues have also been considered. These include the descriptive technical information to be included in the submission, and the laboratory data and clinical studies which may be required to support a finding of substantial equivalence.

In this document the original Draft Guidance dated 02-91 regarding the content and review of PACS products has been revised to reflect these considerations.

3. Content of Notification

The following information should be included in the 510(k):

3.1 General Information

a. Name and address of manufacturer

b. Establishment registration number

c. Common and proprietary names of the device

d. Class

No formal classifications have been issued for PACS or PACS components. For purposes of determining substantial equivalence they have been considered to be accessories to medical imaging devices.

e. Applicable standards

The following standards should be referenced where applicable, and a statement of compliance or noncompliance provided:

i. Food, Drug and Cosmetic Act -

No performance standards for PACS systems or components have been issued under the authority of section 514.

ii. Radiation Control for Health and Safety Act -

Video monitors are considered to be television receivers and subject to the performance requirements of 21 CFR 1020.10.

Fiberoptic communications, laser digitizers, laser printers and optical disc storage devices utilize lasers, which are subject to the performance requirements of 21 CFR 1040.10.

Note: Manufacturers must submit initial reports for video monitors and laser products (21 CFR 1002.10). Reviewers should ask manufacturers if they are aware of this

requirement.

iii. Voluntary Standards -

The Society of Motion Picture and Television Engineers (SMPTE) has a standard test pattern for the evaluation of television monitors and film recording cameras used in medical diagnostic imaging.

The National Electrical Manufacturers Association (NEMA) and American College of Radiology (ACR) have developed the Digital Imaging and Communications Standard which is intended to provided a standard method of data exchange.

The ACR/NEMA Data Compression Standard is intended to allow the transmission of compressed image data across the interface specified in the ACR/NEMA Digital Imaging and Communications Standard. This standard is currently a draft.

The Underwriters Laboratories (U.L.) Standard No. 544 for Medical and Dental Equipment contains safety requirements which are applicable to PACS and PACS-related devices.

Reference may also be made to the draft standard ISO/IEC 10918-1 Digital Compression and Coding of Continuous-Tone Still Images (also known as JPEG).

3.2 Device Description

a. Summary of functions of the device and its major components:

An overall summary of the functions of the device and its indications for use should be provided. For devices comprised of more than one major component, the summary should list these components with a brief description of their individual functions. In cases where a major component is obtained from another manufacturer, the manufacturer and tradename should be given.

PACS devices which incorporate lossy compression will not be required to restrict indications for use. However, manufacturers may voluntarily restrict recommended use either in general or specific terms (e.g. not for primary diagnosis, not for use in conjunction with mammography images, etc.).

b. Diagram of layout and interconnections:

For devices comprised of more than one major component, an overall diagram illustrating their interconnection should be provided. Interfaces (e.g. ACR/NEMA, SCSI, etc.) should be labeled. Also, the physical means utilized for the interchange of data (e.g. twisted pair, coaxial cable, fiberoptic cable, etc.) should be identified. Interconnections which transmit compressed data should be specifically labeled along with the compression ratio.

c. Technical characteristics and means of operation:

The means utilized by each major component to perform its function should be described. A list of all operator controls with a brief description of their functions should be included. Any new technology or unique materials which are utilized should be identified. For devices which utilize new technology or materials, copies of related technical publications should be submitted.

The following information should be included for specific types of PACS-related devices. If the 510(k) is for a complete system, this information should be submitted for each device in the system.

i. Image digitizers -

All devices - The method used to digitize the image (e.g. video camera and ADC, solid state sensor or laser scanner) should be described. Also, a diagram illustrating the optical path indicating the positions of all major optical, mechanical and electronic components should be provided.

Film digitizers - The method and equipment used to scan the film should be discussed, and a diagram illustrating the major components of the scanning mechanism should be included.

ii. Communications and image storage devices -

Communications - In cases where standard, general purpose equipment is utilized it is only necessary to provide the manufacturer, tradename and a brief description. For new types of equipment the topology, access control methods and methods used for detecting transmission errors should be discussed.

Storage - In cases where standard, general purpose equipment is utilized, it is only necessary to provide the manufacturer, tradename, form of storage (analog or digital), and type of storage medium (e.g. solid state, floppy or hard disc, magnetic tape, optical disc). For new types of equipment, the new technology should be discussed in detail and copies of related technical literature provided.

Image formats - The manufacturer should identify any other manufacturers with whom he has or intends to make arrangements to obtain their image data formats.

Data compression - If standard data compression schemes (e.g. differential pulse code modulation (DPCM), Huffman encoding) are utilized in communications or storage, they may be identified by name. If non-standard or proprietary methods are employed, the algorithms utilized should be described in detail and copies of any related technical publications provided.

iii. Workstations -

Monitors - The monitor types (black and white or color, progressive or interlaced) and available image display formats (e.g. 2-on-1, 4-on-one) should be listed. Video monitor diagnostics provided by the software (e.g. SMPTE test pattern) should be identified or described.

Processors and storage - The image processing hardware should be listed along with the basic function of each device (e.g. host computer, additional processors and their functions). Image storage media provided with the workstation should be listed (e.g. floppy and hard discs, magnetic tape, optical disc, RAM, etc.).

Operator Interfaces - Keyboards and other controls (e.g. mouse, trackball) should be listed and any special purpose digitizers (e.g. 3D) should be described.

Software - All software image processing algorithms (e.g. filters and image enhancement techniques) should be listed along with their basic function. In cases where standard 3 dimensional reconstruction and display are provided, the algorithms (e.g. surface and volume rendering) should be identified. If new algorithms are used, copies of related technical references should be provided. In cases where quantitative algorithms are included in the software (e.g. cardiac function algorithms), the method of measurement should be described. Also, if new quantitative algorithms are used, the results of any clinical studies and copies of publications in the technical literature supporting the validity of the algorithms should be provided.

iv. Hardcopy devices -

All devices - For all types of hardcopy devices (film, paper, etc.), the form of input (i.e. video and/or digital input signals) should be listed. A diagram illustrating the optical path indicating the positions of all major optical, mechanical and electronic components should be provided. The means for adjusting the grey scale of the image (gamma corrections) should be described. Any internal calibration test patterns should be discussed. If an integral hardcopy medium processor is provided it should be described. The method for handling the hardcopy medium (e.g. cassette) should also be discussed.

Multiformat cameras - For multiformat cameras, the video monitor should be described, and the manufacturer should state if raster line suppression or image contrast inversion are provided. The number of lenses used and the mechanism (optical, mechanical or electronic) used to advance to the next position should be discussed.

Laser printers - For laser printers, the type of laser (e.g. HeNe, solid state) should be stated and the sensitivity of the hardcopy medium relative to the wavelength of the laser should be discussed. The methods of modulating the laser and scanning the beam over the hardcopy medium should be described.

d. Specifications:

The following specifications should be included for specific types of PACS-related devices. If the 510(k) is for a complete system, specifications should be submitted for each device in the system.

i. Image digitizers -

Video to digital - compatible video signals (lines/frame, frames/sec, progressive or interlaced), digital sampling rate and bit depth

Film digitizers - film size, matrix size and bit depth, spatial resolution, time to scan an image (specify matrix size). For laser digitizers, laser spot size and power.

ii. Communications and storage equipment -

Communications equipment - bits/sec and time to transmit an image (specify matrix size and bit depth)

Video recorders - compatible video signals (lines/frame, frames/sec, progressive or interlaced), bandwidth, tape size and speed, signal-to-noise ratio and total recording time

Digital storage devices - total number of bits, image matrix sizes, bit depth and number of images

iii. Workstations -

Video monitors - compatible video signals (lines/frame, frames/sec, progressive or interlaced), horizontal resolution or bandwidth, aspect ratio and screen size

Image processing hardware - clock rate and number of bits/word, time to perform major software operations such as tomographic image reconstruction, multiplanar reconstruction and 3 dimensional rendering

Digital storage devices - total number of bits, image matrix sizes, bit depth and number of images (specify matrix size)

iv. Hardcopy devices -

All types - compatible digital input (matrix size and bit depth), compatible video input (lines/frame, frames/sec,

progressive or interlaced), hardcopy image sizes and formats

Multiformat cameras - monitor vertical and horizontal resolution or bandwidth, aspect ratio and screen size

Laser printers - matrix size, bit depth, spatial resolution, laser spot size and power, time to produce an image (state matrix size)

3.3 Laboratory Tests

The following laboratory tests should be conducted for specific types of PACS-related devices. Manufacturers should include a brief description of their test methods and results in the 510(k). If the 510(k) is for a complete system, test methods and results should be submitted for each device in the system.

a. Image digitizers -

For devices which claim new or significantly improved digitizing hardware, the optical density (OD) to grey level tranfer curve, uniformity (local standard deviation of OD vs. OD) and spatial frequency response (modulation transfer function)

b. Communications and storage devices -

For devices which utilize compression techniques which result in a loss of image data, the normalized mean square error of the compressed image relative to the original.

When providing laboratory test data for a lossy compression scheme a manufacturer may substitute an alternative measure of information loss for normalized mean square error, if a description and justification are provided.

For devices which utilize standard lossy compression techniques, such as Discrete Cosine Transform (DCT) laboratory data is not required.

c. Hardcopy devices -

For devices which claim new or significantly improved hardware to produce the image, the grey level to OD tranfer curve, uniformity (local standard deviation of OD vs. OD) and spatial frequency response (modulation transfer function).

3.4 Substantially Equivalent (SE) Devices

a. Manufacturer and tradename of SE devices

All SE devices must have approved 510(k) notifications or be pre-amendments devices. Pre-Amendments devices should be identified. Document control numbers should be provided for post-Amendments devices if the control numbers are available.

b. Promotional material and specifications for SE devices (see section 2.2(e) above)

c. Tabular comparison of features and specifications of the device and SE devices

3.5 Labeling

a. Promotional material (drafts are acceptable)

Promotional material for devices which utilize lossy compression shall clearly state the compression ratios provided.

b. User's manual(s) (drafts are acceptable) including:

i. Any special intended uses (e.g. cardiac cath lab)

ii. Cautions and warnings (radiation, laser, electrical, etc.)

iii. Applicable specifications listed in section 2.2(e) above

iv. Operating instructions

These should describe any loss of information associated with image processing functions (filters) or image data compression operations.

Devices which utilize lossy compression shall be provided with instructions which explain the effects of lossy compression, and include examples of the effects of information loss on image quality.

v. Quality assurance procedures

Built-in component diagnostics, test patterns or recommended procedures

c. Images

Video and hardcopy images which have been subjected to lossy compression shall be provided with a printed message stating that lossy compression has been applied, and the approximate compression ratio.

3.6 Software Information

a. A list and brief description of the functions performed by the software

b. A description of the manufacturer's software development methods

This should include a list or diagram of the steps in the development of the software and the departments responsible for

each step. Procedures for controlling the software version during development and after release should be addressed.

c. A list of hazards related to the functions performed by the software, and means taken to mitigate these hazards

Such hazards may include loss or corruption of image data, patient ID, or information describing the examination.

d. A description of the software test procedures

e. A certification by a responsible company official that the software information provided in this notification is correct, and that the same procedures will be used to retest and revalidate the software when it is revised.

3.7 Safety and Effectiveness Information

The Safe Medical Devices Act of 1990 (SMDA) requires all persons submitting a premarket notification to include either:

(1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), or

(2) a statement that the safety and effectiveness information upon which an equivalence determination could be based will be made available to interested persons upon request (510(k) statement).

Safety and effectiveness information refers to information in the notification, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information.

Note:

The SMDA allows the manufacturer to submit a 510(k) summary with the premarket notification, or a 510(k) statement which affirms that the safety and effectiveness information will be submitted upon request.

If the 510(k) statement is submitted, the wording must follow that given above. A statement which reads "a summary of the safety and effectiveness information will be made available" is not acceptable.