

[The 21<sup>st</sup> Century Cures Act](#) (12/13/2016) amended the definition of “device” in the Food, Drug and Cosmetic Act to exclude certain software functions, including some described in this guidance document. FDA is assessing how to revise this guidance to represent our current thinking on this topic. For additional information, contact [digitalhealth@fda.hhs.gov](mailto:digitalhealth@fda.hhs.gov) or refer to <https://www.fda.gov/MedicalDevices/DigitalHealth/default.htm>.

Guidance for Industry

# **Guidance for the Submission Of Premarket Notifications for Medical Image Management Devices**

**Document issued on: July 27, 2000**

This document supersedes the Guidance for the Content and Review  
Of 510(k) Notifications for Picture Archiving and Communications Systems (PACS)  
and Related Devices dated September, 1983



**U.S. Department Of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health**

**Radiological Devices Branch  
Division of Reproductive, Abdominal, and Radiological Devices  
Office of Device Evaluation**

# Preface

## Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Loren A. Zaremba, Ph.D., Radiological Devices Branch, Office of Device Evaluation, FDA, 9200 Corporate Boulevard, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Loren A. Zaremba, Ph.D. at (240) 276-3666 or by electronic mail at [loren.zaremba@fda.hhs.gov](mailto:loren.zaremba@fda.hhs.gov).

## Additional Copies

World Wide Web/CDRH home page: <http://www.fda.gov/cdrh/ode/guidance/416.pdf> or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 416 when prompted for the document shelf number.

# Guidance<sup>1</sup> for the Submission of Premarket Notifications for Medical Image Management Devices

## **I. Scope**

This guidance is applicable to medical devices that provide functions related to the management of medical images after acquisition, including communication, storage, processing and display (generally known as Picture Archiving and Communications Systems (PACS)). Detailed definitions for the products that are considered to be within the scope of this guidance are contained in the classifications for these devices (see Section III. Below). Although the devices defined in these classifications are Class I and II, manufacturers are advised that not all medical image management devices are considered to be Class I or II. This guidance does not address image processing devices that utilize artificial intelligence or other techniques to identify abnormalities in medical images or assist in diagnosis.

This guidance is not applicable to manufacturers of general purpose image management products (e.g. software, communications devices, storage devices, TV monitors, scanners and frame grabbers) which are not labeled or promoted for medical use (21 CFR 807.65(c)). Such manufacturers are exempted from registration, listing and premarket notification. However, when integrated into a medical image management system by another manufacturer, a general-purpose image management product becomes a medical device. The original manufacturer is not responsible for the medical use of the device. This is the responsibility of the manufacturer of the medical image management system, and this guidance is applicable to such manufacturers.

This guidance is not applicable to physician practice management systems or medical information systems that are restricted to the management of patient descriptive information, examination scheduling, billing and other similar non-clinical data (FDA Policy for the Regulation of Computer Products, 11/13/89). It is also not applicable to video conferencing systems. FDA's device regulations and authorities do not apply to such products. Toolkits for developing medical imaging software are not considered medical devices because they are not a finished product.

The devices addressed by this guidance are primarily intended for use in conjunction with images obtained from radiological modalities. However, similar products have been introduced for the

---

<sup>1</sup> This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

management of visible light, and other types of images produced by non-radiological devices (e.g. surgical microscopes, laparoscopes, etc.). A manufacturer of an image management accessory for a non-radiological device should contact the branch of the Office of Device Evaluation (ODE) responsible for the review of that device for information regarding premarket notification requirements.

Formerly, medical image management devices were considered by the Agency to be limited to products intended for use with more than a single modality (e.g. x-ray system, CT scanner or MRI system). Products intended for use with a single modality (mini-pacs) were considered to be accessories to the radiological modalities for which they are specifically designed. However, the classifications for medical image management devices exempt some types of products from the premarket notification requirement. In order to apply uniform requirements to all types of medical image management devices, devices designated for use with a single modality are no longer treated as accessories to that modality. They are considered to be medical image management devices and subject to the applicable requirements and exemptions.

## **II. Background**

The medical image management products addressed in this guidance were not included when the radiological device classifications were first proposed in 1982. However, the FDA generally treated them as accessories to the imaging modalities with which they were used. For example, the medical image digitizer and medical image hardcopy device (multiformat camera) had been considered to be accessories to stationary x-ray and computed tomography systems, respectively. However, a significant expansion in the functionality of medical image management products has taken place, so that identification of many of these products as accessories to a specific radiological imaging modality is no longer appropriate.

FDA originally developed a guidance document for the submission of premarket notifications for medical image management devices in 1991 that the Agency updated in August 1993. However, because no specific classifications had been established for these devices, uncertainty still existed among manufacturers regarding whether they were medical devices and whether premarket notifications were required.

On December 2, 1996, FDA published proposed classifications for five types of medical image management devices in the Federal Register (61 FR 63769). Under this proposal, the medical image storage device and medical image communications device would be Class I, and would be exempt from premarket notification requirements if they did not utilize irreversible (lossy) compression. The medical image digitizer, medical image hardcopy device, and picture archiving and communications system would be Class II, requiring premarket notification.

No significant objections were received regarding the proposed classifications, and the Agency issued these same classifications in a final rule, on April 29, 1998 (63 FR 23385) with an effective date 30 days following publication (May 29, 1998). Several errors appeared in this publication and a correction

notice was published in the Federal Register on August 24, 1998 (63 FR 44998). However, this correction notice did not affect the effective date of the classifications.

During the period between the publication of the proposal and final rule, the Food and Drug Administration Modernization Act of 1997 (FDAMA) was enacted. FDAMA provides that a premarket notification is not required for a Class I device, unless the device is intended for a use that is of substantial importance in preventing impairment of human health, or the device presents a potential unreasonable risk of illness or injury.

Medical image storage devices and medical image communications devices were classified as Class I devices, thus are subject to this provision of FDAMA. After reviewing the intended uses and risks associated with these devices, the Agency concluded that medical image storage and medical image communications devices that utilize irreversible compression do not meet the FDAMA criteria for premarket notification. Consequently, these devices were included in a list of Class I devices which were proposed for exemption from premarket notification in a Federal Register of November 12, 1998 (63 FR 63222). No negative comments were received and the final rule was published in the Federal Register on January 14, 2000 (65 FR 2296). The final rule removed the restriction relating to irreversible compression and extends the exemption from premarket notification to all medical image storage and medical image communications devices.

In the last few years, a number of legislative changes relating to the authority of the agency have occurred. These changes have resulted in the adoption of new regulations and administrative procedures by CDRH, which affect the 510(k) process. The Safe Medical Devices Act of 1990 (SMDA) has resulted in new Good Manufacturing Practice (GMP) regulations requiring pre-production design controls and several administrative requirements (Truthful and Accurate statements, Summaries of Safety and Effectiveness, and Statements of Indications for Use) have been added. The Food and Drug Administration Modernization Act (FDAMA) of 1997 and a re-engineering effort have resulted in the development of a new 510(k) paradigm that incorporates alternative approaches to demonstrating substantial equivalence in premarket notifications. These approaches are intended to facilitate the marketing clearance of devices for which recognized standards exist, and for cases in which the new device is a modification of a previously cleared product.

On March 20, 1998 CDRH issued a document entitled “The New 510(k) Paradigm - Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications”. This document is available on the CDRH web site (<http://www.fda.gov/cdrh/ode/parad510.html>). In addition to the traditional 510(k), this document describes two alternatives, the “Special 510(k): Device Modification” and the “Abbreviated 510(k)”.

The Special 510(k) is based on the requirement that manufacturers establish design controls in accordance with the SMDA and 21 CFR 820.30. A manufacturer uses the FDA guidance document entitled “[Deciding When to Submit a 510\(k\) for a Change to an Existing Device](#)” to decide if a device modification could be implemented without submission of a new 510(k). If a new 510(k) is needed, and if the modification does not affect the intended use of the device or the basic fundamental scientific

technology, conformance with design controls may form the basis for clearing the application. Under this option, a manufacturer who is intending to modify a legally marketed Class II device would conduct the necessary verification and validation activities to demonstrate that the design output of the modified device meets the design requirements. Once the company has ensured the satisfactory completion of this process through a design review, a Special 510(k) may be submitted. While the basic content requirements for the submission are the same, this type of submission should also reference the cleared 510(k) and contain a “Declaration of Conformity” with design control requirements. In the Special 510(k) the manufacturer has the option of using a third party to assess conformance with design controls (refer to the paradigm document for details). Special 510(k)s are processed by the Office of Device Evaluation within 30 days of receipt.

The Abbreviated 510(k) is based on the use of conformance to voluntary standards in place of data review as the means by which the safety and effectiveness of Class II devices can be assured. A guidance document on the use of standards, “Use of Standards in Substantial Equivalence Determinations” ([www.fda.gov/cdrh/ode/guidance/1131.pdf](http://www.fda.gov/cdrh/ode/guidance/1131.pdf)) was issued in March of 2000. This guidance established three methods for using voluntary standards in place of data in a 510(k). These were: the submission of a Declaration of Conformity to an FDA-recognized standard, a statement that a device conforms (or will conform prior to marketing) to an FDA-recognized standard (to be used where statements have been previously used), and a statement that the device conforms (or will conform) to a standard that is not yet recognized by FDA. In the last case there is less assurance that the non-recognized standard will be acceptable in meeting 510(k) requirements and the sponsor is responsible for providing sufficient justification that the non-recognized standard is suitable for its purpose. In addition to the required elements of a 510(k) as described in 21 CFR 808.87, Abbreviated 510(k) submissions should include information that describes how conformance to one or several voluntary standards, have been used to address risks associated with the device. A third party may be used to assess conformance with these standards (refer to the paradigm document for details). The review of abbreviated 510(k)s is intended to be more efficient since they are not required to contain the experimental (test) data from which conformance is determined.

### **III. Classifications for Medical Image Management Devices**

The following five classifications for medical image management devices are currently provided in 21 CFR Part 892:

#### **Sec. 892.2010 Medical image storage device.**

- (a) *Identification.* A medical image storage device is a device that provides electronic storage and retrieval functions for medical images. Examples include devices employing magnetic and optical discs, magnetic tape, and digital memory.
- (b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to Sec. 892.9.

Sec. 892.2020 Medical image communications device.

- (a) *Identification.* A medical image communications device provides electronic transfer of medical image data between medical devices. It may include a physical communications medium, modems, interfaces, and a communications protocol.
- (b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to Sec. 892.9.

Sec. 892.2030 Medical image digitizer.

- (a) *Identification.* A medical image digitizer is a device intended to convert an analog medical image into a digital format. Examples include systems employing video frame grabbers, and scanners which use lasers or charge-coupled devices.
- (b) *Classification.* Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Standard, Joint Photographic Experts Group (JPEG) Standard).

Sec. 892.2040 Medical image hardcopy device.

- (a) *Identification.* A medical image hardcopy device is a device that produces a visible printed record of a medical image and associated identification information. Examples include multifunction cameras and laser printers.
- (b) *Classification.* Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Standard, Joint Photographic Experts Group (JPEG) Standard, Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).

Sec. 892.2050 Picture archiving and communications system.

- (a) *Identification.* A picture archiving and communications system is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. Its hardware components may include workstations, digitizers, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices, and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression, or quantification.
- (b) *Classification.* Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Standard, Joint Photographic Experts Group (JPEG) Standard, Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).

The new classifications relate directly to the product codes that have been used for some time within the Agency for these devices. These product codes and the related classifications are:

LMA - Image Digitizer (Sec. 892.2030)

LMB - Digital Image Storage Device (Sec. 892.2010)



LMC - Multi-format Camera (Sec. 892.2040)

LMD - Digital Image Communications System (Sec. 892.2020)

LLZ - Image Processing System (Sec. 892.2050)

Classifications 892.2010 and 892.2020 are intended to include all medical image management devices whose principal functions are communications or storage. Classification 892.2050 is intended to cover devices that have not been included in the other medical image management device classifications (i.e. 892.2010-2040). There has been some confusion regarding the applicability of 892.2050 because the term “PACS” has commonly been used to refer to all types of medical image management devices. The classification 892.2050 – Picture Archiving and Communications System is not intended to include products whose principal function is medical image communications and/or storage. These devices are classified under 892.2010 and 892.2020

In many cases it is difficult to decide if a device should be classified as a Medical Image Communications Device, a Medical Image Storage Device, or as a Picture Archiving and Communications System. In such cases the classification is determined by the additional functions performed by the device. Simple manipulations which do not alter the image data, such as window and level, pan and zoom, and image annotation are considered to be within the scope of the communications and storage functions, and do not preclude a system from these classifications. However, image processing functions which are intended to alter the image data (e.g. filtering, multiplanar reconstruction, and 3D reconstruction), are considered to be outside the scope of the storage and communications functions. Also, complex quantitative functions (e.g. arterial stenosis evaluation, ventricular volume calculations, and calcium scoring) are not considered to be communications and storage functions. Devices which incorporate such functions are treated as picture archiving and communications systems, which are Class II devices, and premarket notification is required. In questionable cases manufacturers are advised to obtain an opinion from the Agency.

#### **IV. Format and Content of 510(k) Notification**

The following illustrates the suggested format and content for a 510(k) notification for medical image management devices. The format is optional, and companies may utilize a format which most clearly and concisely presents the relevant information for their product. Content will vary depending upon the type of device. Guidance is provided regarding appropriate information for specific types of devices (e.g. laser digitizers, printers, monitors, etc.).

##### **A. General Information**

1. Name and address of manufacturer
2. Establishment registration number
3. Name, title and phone number of contact

4. Tradename and common name of the device
5. Classification(s) of the device
7. Intended use
8. Substantially Equivalent (predicate) device(s)  
(manufacturer, tradename and 510(k) number if known)
9. Applicable mandatory and voluntary standards including Declaration of Conformity or certification statement to applicable voluntary standards that are cited for the device. Additional information on the CDRH standards program is available on the CDRH website at <http://www.fda.gov/cdrh/stdsprog.html>.

a. 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

b. CDRH - Recognized Voluntary Standards -

- i. DICOM (Digital Imaging and Communications in Medicine) - Developed by the American College of Radiology and the National Electrical Manufacturers Association. Specifies the format for the communication of digital images between individual devices and over networks.

Note: Sponsors who claim DICOM compliance should provide a DICOM Conformance Statement.

- ii. JPEG (Joint Photographic Experts Group) Standard - Specifies methods for the compression (reversible and irreversible) of digital medical images. References – ISO/IEC 10918-1 (1994-02) Digital Compression and Coding of Continuous-Tone Still Images (JPEG), G.K. Wallace, “The JPEG Still Picture Compression Standard”, Communications of the ACM, Vol. 34, No. 4, April 1991
- iii. SMPTE (Society of Motion Picture and Television Engineers) Test Pattern - Intended to test CRT monitors and printers used to display medical images for acceptance and quality control purposes. Reference - J.E. Gray et al., “Multiformat Video and Laser Cameras: History, Design Considerations, Acceptance Testing and Quality Control,

Report of AAPM Diagnostic X-ray Imaging Committee Task Group No. 1, Medical Physics, vol. 20, No. 2, Pt. 1, March/April, 1993.

## **B. Administrative Information**

1. 510(k) Summary of Safety and Effectiveness or 510(k) Statement. Submit one or the other, not both. The content and format of these documents are described in 21 CFR 807.92 and 807.93.

A 510(k) Summary should be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence.

Required wording for the 510(k) Statement is:

“I certify that, in my capacity as (the position held in company by person required to submit the premarket notification, preferably the official correspondent in the firm), of (company name), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential information, as defined in 21 CFR 20.61.”

2. FDA Indication for Use Form
3. Truthful and Accurate Statement (21 CFR 807.87(k)). Suggested wording is:

“I certify that in my capacity as (position held in company by person required to submit the premarket notification, preferably the official correspondent of the firm) of (company name), I believe to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.”

## **C. Device Description**

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

Provide an overall summary of the functions of the device and its intended use. 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, provide the name of the manufacturer, tradename of the component and 510(k) number if appropriate.

2. Diagram of layout and interconnections:

For devices comprised of more than one major component, provide a diagram illustrating their interconnection. Any 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, fiber optic cable, etc.) should be identified. Interconnections which transmit compressed data should be labeled along with the compression ratio(s).

### 3. Technical characteristics and principles of operation:

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

The following information should be included for specific types of medical image management devices. If the 510(k) is for a complete system, this information should be submitted for each device in the system as appropriate.

#### a. Image digitizers -

All types - 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 and 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.

#### b. Image communications and 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 should 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. In either case the compression ratios to be employed should be specifically stated.

c. 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-1) 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 disks, magnetic tape, optical disc, RAM, etc.)

Operator interfaces - Keyboards and other control (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 functions. In cases where standard 3 dimensional reconstruction and display are provided, the algorithms (e.g. surface and volume rendering) should be identified. If new rendering 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.

d. 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 and indicating the positions of all major optical, mechanical and electronic components should be provided. The means for adjusting the gray 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. The means employed for compensating for laser output fluctuations should also be discussed.

#### 4. Specifications:

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

##### a. Image digitizers -

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

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

##### b. 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

##### c. 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 three dimensional rendering

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

d. 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 (FWHM) and power, time to produce an image (state matrix size)

## **D. Laboratory and Clinical Testing**

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

1. Image digitizers -

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

2. Communications and storage devices -

For devices which utilize compression techniques which result in the loss of image data, the normalized mean square error of the compressed image relative to the original should be measured and reported for each level of compression utilized by the device.

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

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

3. Hardcopy devices -

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

## **E. Comparison to Legally Marketed (Predicate) Devices**

1. Manufacturer and tradename of predicate device(s)

All predicate devices should have cleared 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.

2. Promotional material and specifications for SE devices.
3. Tabular comparison of features and specifications of the device and SE device(s).
4. Discussion of similarities and differences and an explanation of important differences.

## **F. Labeling**

1. Labeling and promotional material.

Labeling and promotional material for devices which utilize irreversible compression should clearly state the compression ratios provided.

If no promotional material is available, provide a list of statements that will be made for the product that are indicative of the intended use.

A medical image management device may be claimed to be useful for diagnostic, referral or archival purposes at the discretion of the manufacturer. Due to the wide variety of potential clinical applications for these devices, FDA has not attempted to formulate criteria to distinguish devices intended for diagnosis from those intended for referral or archival purposes.

2. User's Manuals (drafts are acceptable) including:
  - a. Indications for use of product and any applicable contraindications
  - b. Cautions and warnings (radiation, laser, electrical, etc.)
  - c. Product specifications



If the product does not conform to the DICOM standard, the manufacturer should identify the models of products marketed by other manufacturers with compatible image formats.

d. Operating instructions

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

Devices that utilize irreversible compression should be provided with instructions that explain the effects of such compression, and include examples of the effects of information loss on image quality.

e. Quality assurance procedures (e.g. built-in component diagnostics, test patterns or recommended procedures, recommended testing schedules).

### 3. Images

A message stating that irreversible compression has been applied, and the approximate compression ratio should accompany images that have been subjected to irreversible compression.

Manufacturers are also encouraged to appropriately label images which have been subjected to any processing, including matrix and bit depth reduction, which reduces the information content of the original image.

## G. Software Information

Software for most medical image management devices is considered to be of minor concern. The following information should be included in the submission. For further information refer to the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices available on the FDA website at <http://www.fda.gov/cdrh/ode/57.html>.

1. A list and a brief description of the functions performed by the software.
2. A description of the manufacturer's software development methods.

Include a list or diagram of the steps in the development of the software and the departments responsible for each step. Procedures for configuration management of the software during development and after release should be addressed. Methods for testing after changes or upgrades should be indicated.

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

4. A description of the software test procedures.
5. 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.