The operating status of the airport will change from VFR to include IFR operations concurrent with publication of this SIAP.

DATES: Comments must be received on or before January 20, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Docket No. 96–ASO–36, Manager, Operations Branch, ASO–530, P.O. Box 20636, Atlanta, GA 30320.

The official docket may be examined in the Office of the Assistant Chief Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, telephone (404) 305–5586.

FOR FURTHER INFORMATION CONTACT: Benny L. McGlamery, Operations Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, GA 30320; telephone (404) 305–5570.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 96–ASO–36.'' The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. All comments submitted will be available for examination in the Office of the Assistant Chief Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, GA 30337, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Manager, Operations Branch, ASO–530, Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to establish Class E airspace at Hazard, KY. A VOR/DME RWY 14 and a GPS RWY 14 SIAP's have been developed for Wendell H. Ford Airport. Controlled airspace extending upward from 700 feet AGL is needed to accommodate these SIAP's and for IFR operations at Wendell H. Ford Airport. The operating status of the airport will change from VFR to include IFR operations concurrent with publication of this SIAP. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface are published in Paragraph 6005 of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR Part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet above the surface of the earth.

* * * * *

ASO FL E5 Hazard, KY [New]

Wendell H. Ford Airport, KY
(lat. 37°23′16″N, long. 83°15′43″W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Wendell H. Ford Airport.

* * * * *

Issued in College Park, Georgia, on November 21, 1996.

Benny L. McGlamery,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 96–30644 Filed 11–29–96; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. 96N–0320]

Radiology Devices; Proposed Classifications for Five Medical Image Management Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration is proposing to classify five generic types of radiology devices that provide functions related to medical image communication, storage, processing, and display. Under the proposal, the medical image storage device and the medical image communications device would be classified into class I (general controls),

and would be exempted from the requirement of premarket notification when they do not use irreversible compression. The medical image digitizer, the medical image hardcopy device, and the picture archiving and communications system would be classified into class II (special controls). The agency is publishing in this document the recommendations of the Radiology Devices Panel regarding the classification of these devices. After considering public comments on the proposed classifications, FDA will publish a final regulation classifying these devices. This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices.

DATES: Written comments must be submitted on or before March 3, 1997. FDA proposes that any final regulation that may issue based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Loren A. Zaremba, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1212.

SUPPLEMENTARY INFORMATION:

I. Background

A. Classification of Medical Devices

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295) and the Safe Medical Devices Act of 1990 (Pub. L. 101–629), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three classes of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (premarket approval). Procedures for the original classification of devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), are set forth in section 513 of the act and in 21 CFR 860.84. In accordance with these procedures, devices are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendations for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device.

A device that is first offered in commercial distribution after May 28, 1976, and that FDA determines to be substantially equivalent to a device classified under this scheme is classified into the same class as the device to which it is substantially equivalent. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807. A device that was not in commercial distribution prior to May 28, 1976, and that has not been found by FDA to be substantially equivalent to a legally marketed device is classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking proceedings.

Section 513(d)(2)(A) of the act authorizes FDA to exempt, by regulation, a generic type of class I device from, among other things, the requirement of premarket notification in section 510(k) of the act. Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting a premarket notification to FDA. If FDA has concerns only about certain types of changes to a particular class I device, the agency may grant a limited exemption from premarket notification for that generic type of device. A limited exemption will specify the types of changes to the device for which manufacturers are required to submit a premarket notification. For example, FDA may exempt a device from the requirement of premarket notification except when a manufacturer intends to use a different material.

To date, FDA has classified a total of 70 generic types of radiology devices (see 53 FR 1554, January 20, 1988; 54 FR 5077, February 1, 1989; and 55 FR 48436, November 20, 1990). With the exception of the magnetic resonance diagnostic device (21 CFR 892.1000), all of these 70 generic devices are of a type that were on the market before the enactment of the 1976 amendments. Of the 70 generic types of radiology devices, FDA exempted 8 from the requirement of premarket notification (54 FR 13826, April 5, 1989, and 59 FR 63005, December 7, 1994); of the 8 exempt devices, FDA exempted 7 with no limitations. The nuclear scanning bed (21 CFR 892.1350), however, is exempt only when the device is labeled with the weight limit, is used with planar scanning only, and is not intended for diagnostic x-ray use.

B. Medical Image Management Devices

Developments in electronic data communications and storage technologies in recent years have led to the introduction of a number of radiological devices that are intended for use in the management of medical images after acquisition (Refs. 1 and 2). For digital modalities such as computed tomography (CT), magnetic resonance imaging (MRI), ultrasound, digital subtraction angiography, and computed radiography, the images are acquired in digital form and therefore lend themselves immediately to digital image management techniques. For analog devices such as conventional x-ray, devices have been developed to convert film images into a digital format.

A number of acronyms are used to describe medical image management devices, such as picture archiving and communications systems (PACS) and image management and communications systems (IMACS). The acronyms arise from the fact that the devices are principally utilized for the communication and storage of images. However, the digital format also facilitates the application of image processing and enhancement techniques, and these techniques are now available as features on many of these products.

The digital format utilized in medical image management devices provides a number of advantages, including the ability to transmit and receive images rapidly with high fidelity when used with digital communications technology. The devices, when utilized with electronic media such as random access memory (RAM), hard disks, and optical disks, also allow compact storage with rapid retrieval capability (Ref. 3).

However, image viewing is inherently an analog process. Presently, image display is performed using video monitors or hardcopy, and both are subject to limitations (Refs. 4, 5, and 6). Current video monitors do not provide brightness comparable to film/lightbox viewing, which limits the number of discernable grey levels. Also, the highest resolution video monitors presently available are 2048 x 2048 pixels, and the majority in clinical use are 1024 x 1024 pixels or less. Consequently, the number of addressable pixels on the video monitor can limit the available spatial resolution if that number is less than the matrix

size of the original image (which is always the case for an original x-ray film image). Laser and video printers are available for converting digital images to hardcopy, but this conversion process involves a sacrifice of the communication and storage advantages of the digital technology.

Many of the medical image management products included in this proposal did not exist when the radiological device classifications were first proposed in 1982. However, FDA has generally treated them as accessories to the imaging modalities (e.g., x-ray systems, CT scanners, and MRI systems) with which they are used, consistent with the identifications of these modalities. For example, the medical image digitizer and medical image hardcopy device (multiformat camera) have been considered to be accessories to the stationary x-ray system (21 CFR 892.1680) and computed tomography x-ray system (21 CFR 892.1750), respectively.

A significant expansion in the technical characteristics and functions of medical image management products has taken place in recent years so that the identification of many of these products as accessories to a specific radiological imaging modality is no longer entirely accurate. For example, medical image hardcopy devices, medical image storage devices, medical image communications devices, and picture archiving and communications systems are frequently intended for use with most or all imaging modalities. The classification action described in this proposal would establish independent classifications for medical image management products, consistent with their multimodality use.

FDA originally developed a guidance document for the submission of premarket notifications for PACS devices in 1991, which the agency updated in August 1993 (Ref. 7). This document outlines the suggested information for a premarket notification for PACS devices and related components. However, because no specific classifications have been established for these devices, uncertainty exists among manufacturers regarding whether medical image management products are medical devices and whether premarket notifications are required. The establishment of separate classifications for medical image management devices will help clarify the regulatory status of these devices. At the same time, the agency is proposing to exempt two of these devices from the requirement of premarket notification, with limitations. These exemptions will enable the agency to concentrate its resources on the evaluation of more critical products, and they will make it easier for manufacturers of the exempt devices to bring them to market.

It should be noted that the classifications will usually not apply to general purpose products, such as general purpose software, digital communications devices, and storage devices, that are not intended for medical use. These products are not considered to be medical devices. However, when they are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, or prevention of disease, or are intended to affect the structure or any function of the body, they are devices within the meaning of section 201(h) of the act (21 U.S.C. 321(h)). Intended use may be revealed by how the product is labeled, or if it is included as a component of a system labeled for medical use.

II. Panel Recommendations

The Radiological Devices Panel (the Panel), an FDA advisory committee, met on August 29, 1994, to review the proposed classifications. The Panel concluded that the proposed identifications are adequate, clear, and sufficiently inclusive.

The Panel recommended that medical image storage devices and medical image communications devices be placed in Class I and that devices that do not use irreversible compression be exempted from the requirement of premarket notification. As its reason for this recommendation, the Panel stated its belief that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommended that devices that do not use irreversible compression be exempted from the requirement of premarket notification because these products are transparent to the user and FDA review of premarket notifications are unnecessary for the protection of the public health.

The Panel recommended that medical image digitizers, medical image hardcopy devices, and picture archiving and communications systems be placed in Class II. The Panel stated as reasons for this recommendation the need for special controls, such as voluntary performance standards and testing guidelines, to ensure their safe and effective use. The Panel based its recommendations on its review of the studies cited in this document, premeeting briefing materials, and on the Panel members' personal knowledge of, and experience with, these devices. The Panel listed inadequate or inaccurate data leading to improper diagnosis as risks to health associated with the use of these devices. The Panel listed Digital Imaging and Communications in Medicine (DICOM), Joint Photographic Experts Group (JPEG), and Society of Motion Picture and Television Engineers (SMPTE) as relevant standards.

At the August 29, 1994, Panel meeting, representatives of the National Electrical Manufacturers Association (NEMA) stated opposition to the establishment of a separate classification for picture archiving and communications systems, recommending instead that FDA limit the classifications to components of such systems. However, the Panel dismissed this objection, noting that a manufacturer would have the option of obtaining marketing clearance for the entire system or for individual components. FDA believes that the establishment of a classification for PACS is needed because it is not feasible to establish separate classifications for all possible PACS components. The classification for PACS is intended to include those devices associated with medical image transmission, storage, processing, and display for which separate classifications have not been established. Also, the PACS classification will apply to the majority of premarket notifications for medical image management devices which are submitted for systems rather than for individual components. NEMA and other interested parties may submit alternative classification schemes in response to this proposal.

Summary minutes and a verbatim transcript of the Panel meeting have been placed in the Dockets Management Branch (address above).

III. Proposed Classifications

Based upon the types of equipment described in past and current premarket notifications, FDA has identified five generic types of radiology devices that provide functions relating to medical image management: The medical image communications device, the medical image storage device, the medical image digitizer, the medical image hardcopy device, and the picture archiving and communications system.

A. Medical Image Communications Devices and Medical Image Storage Devices

The two most basic types of medical image management devices are communications and storage products. A medical image communications device provides electronic transfer of

medical image data between medical devices. It includes the physical communications media (e.g., a twisted pair or fiber optic cable), modems, interfaces, and communications protocols that are marketed as part of the device. However, it does not include elements of the communications infrastructure, such as commercial telephone lines.

A medical image storage device is a device that provides electronic storage and retrieval functions for medical images. A medical image storage device may be comprised of microprocessors, interfaces, software, and one or more storage media. Examples of storage media include magnetic and optical discs, magnetic tape, and digital memory (e.g., RAM).

The safety and efficacy issues associated with these devices may be categorized as data integrity and device compatibility. An extremely high level of integrity has been achieved in electronic data transmission and storage through the use of modern error-checking methods, so that FDA does not consider data integrity to be a significant problem.

For a number of years device compatibility was a serious concern for image communications and storage devices because many manufacturers utilized proprietary image file formats. However, the American College of Radiology (ACR) and NEMA have developed a protocol for sharing digital images between medical devices called DICOM. This standard (Ref. 8) has been incorporated by a number of manufacturers into their new products and several companies are offering interfaces to convert the proprietary image formats utilized in older equipment to the DICOM format. Consequently, the compatibility issue is of decreasing concern.

However, in recent years there has been a marked increase in the number of devices that utilize data compression techniques to reduce image transmission time and data storage requirements (Ref. 9). The utilization of data compression has been accelerated by the development of the JPEG standard and the commercial availability of microprocessors for performing JPEG compression (Ref. 10). Data compression methods are of two types, reversible or irreversible. Reversible data compression methods are such that the original image data may be retrieved following the compression process. With irreversible data compression methods, portions of the original data are irretrievably lost. Irreversible data compression is generally done so as to sacrifice information that is least likely to be useful to the reader, e.g., higher spatial frequencies (fine detail).

The current version of the guidance document for the submission of premarket notifications for PACS devices suggests specific labeling for devices that use irreversible data compression. The guidance document suggests that video image displays and hardcopy images that have been subjected to irreversible compression should display a message stating that irreversible compression has been applied and should state the approximate compression ratio. This message is consistent with the *ACR Standard for Teleradiology* (Ref. 11), which requires that transmitting stations must have annotation capabilities that include the degree of compression.

FDA currently receives and evaluates a large number of premarket notifications for medical image communications and storage devices each year. Many of these devices are transparent to the user, i.e., the input and output data are identical. Consequently, FDA is proposing that they be placed in Class I and be exempted from the requirement of premarket notification. Granting these exemptions will allow the agency to make better use of its resources and thus better serve the public.

FDA is not proposing to exempt devices that perform irreversible compression from the requirement of premarket notification. At present there is a great deal of activity in the development and clinical evaluation of algorithms for the irreversible compression of medical image data. Review of premarket notifications for devices that use irreversible compression will provide FDA with the opportunity to evaluate these algorithms on an individual basis to ensure that their suitability for use in the medical application has been demonstrated.

B. Medical Image Digitizers and Hardcopy Devices

The medical image digitizer is a device that converts an analog medical image into a digital format. Most radiological examinations are still conducted with x-ray film as the image receptor and digitizers provide a means for converting the film information to digital form. Medical image hardcopy devices provide the opposite function, i.e., they convert an image from an electronic form to a visual printed record.

The principal types of digitizers currently in use are frame grabbers, charge coupled devices (CCD's), and laser scanners. Frame grabbers may be coupled to the video output of the imaging device, or to the output of a video camera placed over the film. CCD's may be linear scanners or arrays. The various types of digitizers differ in spatial resolution, range of film density that can be digitized, and grey level discrimination capability. A discussion of performance differences and appropriate testing and quality control procedures for various types of digitizers is in Ref. 12.

The most common examples of hardcopy devices are multiformat cameras and laser printers. Multiformat cameras produce copies by exposing film to an image on a video monitor. Laser printers produce copies by modulating a laser beam that is scanned over the film. Recently, FDA has granted marketing clearance to devices that produce reflective paper hardcopy by means of inkjet, laser/dry silver, and thermal processes. As with digitizers, the quality of the hardcopy that can be obtained depends on the design of the device. However, most of the standard measures of image quality are applicable to hardcopy devices, and recommendations have been made regarding appropriate testing and quality control procedures. A description of such procedures using the SMPTE test pattern is in Ref. 5. The use of this pattern is also recommended in the *ACR Standard for Teleradiology*.

The performance characteristics of both digitizers and hardcopy devices can have a significant influence on diagnostic capability and patient care. Also, adequate quality control procedures are needed to ensure their continued performance. FDA is working with voluntary standards groups to develop standardized specifications, test methods, and quality control procedures for digitizers and hardcopy devices. The attention that has been given to the problems associated with performance and quality control in the literature and by standards groups indicates that special controls (e.g., voluntary standards) are needed to ensure the safety and efficacy of these devices. Consequently, FDA is proposing that they be placed in Class II.

C. Picture Archiving and Communications System

A picture archiving and communications system is defined in this proposal as a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and processing of medical images. This classification is intended to include products that combine several functions and that are marketed as PACS systems. It would include systems ranging in

complexity from teleradiology products (small, portable devices that transmit images over phone lines and enable an on-call radiologist to review images in his/her home) to large fixed systems that utilize fiber optic networks and are capable of transmitting and storing images for an entire hospital or group of hospitals.

Another common example of this device is the medical image workstation, which is generally comprised of a computer, video monitor, and storage device. The computer generally utilizes software related to data communications, file management, and image processing. The classification is also intended to include devices which provide image-related capabilities, and for which there are no other specific classifications, such as image processing software and video monitors.

Software is an important component of a PACS device. It is generally responsible for data file organization and also may provide image processing functions such as filtering (e.g., edge enhancement), measurement (e.g., distance, area, and volume determinations), and special image displays (three dimensional surface and volume rendering). Stand-alone software marketed for use in PACS devices would be included in this classification unless it is general purpose software that is not intended for a medical use.

Video monitors are also an important component of PACS devices. Manufacturers have generally not submitted separate premarket notifications for monitors, but rather have included them in submissions for devices such as workstations. Some video monitors are general purpose consumer products. However, most monitors used in medical imaging are specialized devices with high brightness and spatial resolution (1,000 lines or greater). These monitors can take the place of film and their characteristics can have a significant effect on the ability of health professionals to make a diagnosis.

A discussion of the important performance characteristics of video monitors (e.g., luminance, dynamic range, distortion, resolution, and noise) and the need for standards is in Ref. 4. The National Information Display Laboratory is currently working with Committee JT–20 of the Electronic Industries Association (EIA) to develop standardized procedures for measuring the performance of cathode ray tube (video monitor) displays (Ref. 13). Also, Working Group XI of the ACR/NEMA Committee is currently developing a standard display function for video monitors (Ref. 14).

FDA is proposing to classify picture archiving and communication systems into Class II. FDA believes that special controls such as standardized performance specifications, measurement methods, and quality control procedures are necessary to assure the safety and efficacy of these devices. Documents addressing these subjects have been or are currently being developed by the ACR, NEMA, and EIA.

If a PACS device includes components that would otherwise be exempt from the requirement of premarket notification (e.g., general purpose, communication, or storage devices), the premarket notification for the system would not be required to include a demonstration of substantial equivalence for the exempt components.

IV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. ''PACS, A NEMA Primer,'' published by the National Electrical Manufacturer's Association, compiled by the members of the MEDPACS Section of the Diagnostic Imaging and Therapy Systems Division, November 1988.

2. Choplin, R. H., J. M. Boehme, and C. D. Maynard, ''Picture Archiving and Communications Systems: An Overview,'' *Radiographics*, vol. 12, No. 1, 1992.

3. Frost, M. M., J. C. Honeyman, and E. V. Staab, ''Image Archival Technologies,'' *Radiographics*, vol. 12, No. 2, 1992.

4. Dwyer, S. J. et al., ''Performance Characteristics and Image Fidelity of Gray-Scale Monitors,'' *Radiographics*, vol. 12, No. 4, 1992.

5. Gray, J. E. 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, Part 1, March/April 1993.

6. Kato, H., ''Hard- and Soft-Copy Image Quality,'' in ''Syllabus: A Categorical Course in Physics—Physical and Technical Aspects of Angiography and Interventional Radiology,'' edited by Stephen Balter and Thomas B. Shope, presented at the 81st Scientific Assembly and Annual Meeting of the Radiological Society of North America, November 26–December 1, 1995, RSNA Publications, Oak Brook, IL.

7. ''Guidance for Content and Review of 510(k) Notifications for Picture Archiving and Communications Systems (PACS) and Related Devices,'' Office of Device Evaluation, Center for Devices and Radiological Health, August 1993.

8. Bidgood, W. D., and S. C. Horii, ''Introduction to the ACR–NEMA DICOM Standard,'' *Radiographics*, vol. 12, No. 2, 1992.

9. Zaremba, L. A., and R. A. Phillips, ''Image Compression—Regulatory Issues and Policies,'' presented at the 35th Annual Meeting of the American Association of Physicists in Medicine, Washington, DC, August 8–12, 1993.

10. Wallace, G. K., ''The JPEG Still Picture Compression Standard,'' *Communications of the ACM*, vol. 34, No. 4, April 1991.

11. ''ACR Standard for Teleradiology,'' available from the American College of Radiology, Reston, VA.

12. Trueblood, J. H., S. E. Burch, K. Kearfott, and K. W. Brooks, ''Radiographic Film Digitization,'' in ''Digital Imaging, Medical Physics Monograph 22,'' edited by W. R. Hendee and J. H. Trueblood, Medical Physics Publishing, Madison, WI, 1993.

13. ''Display Monitor Measurement Methods Under Discussion by EIA (Electronic Industries Association) Committee JT–20,'' National Information Display Laboratory, Princeton, NJ.

14. Blume, H., S. Daly, and E. Juka, ''Presentation of Medical Images on CRT Displays: A Renewed Proposal for a Display Function Standard,'' Proceedings of the SPIE, vol. 1987, pp. 215–231, 1993.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impact of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and therefore is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the agency believes only a small number of firms will be affected by this rule when finalized, and because the burdens associated with the

classification of these devices into Class I and Class II, as proposed, is significantly less than those associated with the alternative classification into Class III, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. Request for Comments

Interested persons may, on or before March 3, 1997, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 892 be amended as follows:

PART 892—RADIOLOGY DEVICES

1. The authority citation for 21 CFR part 892 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New §§ 892.2010, 892.2020, 892.2030, 892.2040, and 892.2050 are added to subpart B to read as follows:

§ 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 only when the device stores images without performing irreversible data compression.

§ 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 only when the device transfers images without performing irreversible data compression.

§ 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.

§ 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 multiformat cameras and laser printers.

(b) *Classification*. Class II.

§ 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.

Dated: November 17, 1996.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 96–30650 Filed 11–29–96; 8:45 am]

BILLING CODE 4160–01–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Chapter I

[CC Docket 96–237; FCC 96–456]

Implementation of Infrastructure Sharing Provisions in the Telecommunications Act of 1996

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: On November 22, 1996, the Commission adopted a *Notice of Proposed Rulemaking*, as part of the Commission's implementation of the Telecommunications Act of 1996 (the 1996 Act), to initiate a rulemaking proceeding to implement new Section 259 (Infrastructure Sharing) of the Communications Act of 1934 (the Act), as amended. Section 259 generally requires an incumbent local exchange carrier (incumbent LEC) to make available to a defined ''qualifying carrier,'' such ''public switched network infrastructure, technology, information, and telecommunications facilities and functions'' as the qualifying carrier may request, in service areas where the qualifying carrier has requested and obtained designation as an eligible carrier under Section 214(e). Section 259(a) directs the Commission to prescribe regulations that implement this requirement within one year after the date of enactment of the 1996 Act, *i.e.*, by February 8, 1997.

DATES: Comments are due on or before December 20, 1996. Reply comments are due on or before January 3, 1997. Written comments by the public on the proposed and/or modified information collections are due on or before December 20, 1996. Written comments must be submitted by the Office of Management and Budget (OMB) on the proposed and/or modified information collections on or before January 31, 1997.

ADDRESSES: Comments and reply comments should be sent to the Office of the Secretary, Federal Communications Commission, 1919 M Street, N.W., Suite 222, Washington, D.C. 20554, with a copy to Scott Bergmann of the Common Carrier Bureau, Federal Communications Commission, 2033 M Street, N.W., Suite 500, Washington, D.C. 20554. Parties should also file one copy of any documents filed in this docket with the Commission's copy contractor, International Transcription Services, Inc., 2100 M Street, N.W., Suite 140, Washington, D.C. 20037. In addition to