

Service bulletin referenced and date	Page No.	Revision level shown on page	Date shown on page
Rolls Royce Service Bulletin RB.211-72-4666, Revision 3, October 14, 1977.	1	3	October 14, 1977.
	2-6, 6A, 7-10	2	August 26, 1977.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Lockheed Aeronautical Systems Support Company (LASSC), Field Support Department, Dept. 693, Zone 0755, 2251 Lake Park Drive, Smyrna, Georgia 30080. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Small Airplane Directorate, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, Suite 450, Atlanta, Georgia 30349; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment becomes effective on June 3, 1998.

Issued in Renton, Washington, on April 21, 1998.

Gary L. Killion,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98-11088 Filed 4-28-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. 96N-0320]

Radiology Devices; Classifications for Five Medical Image Management Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying five radiology devices that provide functions related to medical image communication, storage, processing, and display into class I (general controls) or class II (special controls). The medical image storage device and medical image communications device are classified into class I, and they are 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 are classified into class II. These actions

are being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990.

EFFECTIVE DATE: May 29, 1998.

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

In the **Federal Register** of December 2, 1996 (61 FR 63769), FDA issued a proposed rule to classify five medical image management devices into class I or class II. The medical image storage device and medical image communications device were proposed to be classified into class I, and exempted from the requirement of premarket notification when they do not use irreversible compression. The medical image digitizer, medical image hardcopy device, and picture archiving and communications system were proposed to be classified into class II. FDA provided for interested persons to submit written comments on the proposal by March 3, 1997.

II. Response to Comments

The agency received six comments responding to the proposed rule. These comments were submitted by a law firm, two manufacturers of medical image management devices, two medical professional organizations, and a medical device manufacturers' association.

1. One comment expressed concern that exempting medical image storage devices from the requirement of premarket notification would encourage less experienced manufacturers to use the marketplace as a testing ground for their new products. This comment stated that the medical image management industry needs guidance from FDA on material choices, labeling, and quality assurance issues. The comment also suggested that FDA consider adopting minimum standards relating to specifications, device compatibility, lifetime, and labeling.

FDA agrees that the integrity of medical image storage devices is important in health care. The agency does not believe, however, that premarket notification is necessary to ensure the safety and effectiveness of these products. The agency believes that other general controls, particularly the good manufacturing practices requirements (part 820) (21 CFR part 820)), which include controls on production, packaging, labeling, and recordkeeping, are sufficient to provide reasonable assurance of their safety and effectiveness. On November 21, 1997, the President signed into law the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115). Section 206(a)(2) of FDAMA added sections 510(l) and 510(m) to the act (21 U.S.C. 360(l) and (m)). Section 510(l) of the act 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. Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements if FDA determines that a premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that the medical image storage device and the medical image communications device do not require premarket notifications in accordance with the criteria in section 510(l) of the act. Also, FDA has determined that the medical image digitizer, the medical image hardcopy device, and the picture archiving and communication system require premarket notification in order to provide reasonable assurance of their safety and effectiveness. The class II devices in this rule will be subject to the design control requirements in part 820, while the class I devices will be exempt from the design control requirements in accordance with § 820.30. FDA believes that design controls are not necessary for class I devices in this rule. To provide guidance to the industry, FDA will continue to participate in the activities of voluntary standards organizations in the development of recommendations relating to materials

specifications, compatibility, labeling, and quality assurance issues associated with these devices.

2. One comment stated that an additional classification is needed for digital image capture devices, such as computed radiography, which do not have an integral x-ray source.

FDA agrees that a classification for digital image receptors, which would be applicable to computed radiography, as well as other technologies such as thin-film transistor arrays, is needed.

However, because a classification of this type of device was not included in the initial proposal, the agency believes it would be inappropriate to include such devices in this final rule. The agency intends to propose classification of these types of devices, and provide an opportunity for public comment, in a future rulemaking action.

3. One comment requested confirmation in the preamble of the final rule of their understanding that a "physician practice management system" is not a medical image management device, and is not subject to active regulation as a medical device if it does not possess any medical image management or processing functions.

FDA confirms that the classifications for medical image management devices include only devices which provide functions related to medical image communication, storage, processing, and display. Image capture programs, commonly called physician practice management systems or radiology information systems, which are restricted to the management of patient descriptive information, examination scheduling, billing, and other similar data, are not within the scope of these classifications.

4. One comment noted that it appears that the agency intends to place more stringent requirements on medical image management devices which utilize irreversible compression. The comment agreed that caution is advisable in evaluating such devices, and that images subjected to irreversible compression should be properly labeled. It was pointed out, however, that some degree of loss in data resulting from irreversible compression is acceptable in certain clinical applications.

The agency has concluded that devices that do not utilize irreversible compression should be exempt from the requirement of premarket notification. Because such products do not alter image content, FDA believes that premarket evaluation is not necessary for such devices, if good manufacturing practices are employed to ensure storage and communications fidelity. FDA

believes that devices that do utilize irreversible compression should be evaluated prior to marketing because such devices induce a loss of information that can affect the suitability of the image for use in diagnosis. This evaluation will include an examination of the compression algorithm, the amount of information loss over the range of compression levels utilized as compared to established algorithm, and the labeling employed to inform users that irreversible compression has been applied.

5. The agency is also taking this opportunity to address the issue of the applicability of these classifications to devices that are intended for use in the management of visible light images.

The medical image storage device, the medical image communications device, the medical image digitizer, the medical image hardcopy device, and the picture archiving and communications system, which are classified by this final rule, are listed in 21 CFR part 892, which is a listing of radiology devices. The identifications of these devices, however, refer to medical images, and are not restricted to radiology images. Consequently, sponsors of devices intended for use in the management of visible light images or images obtained from other nonradiological imaging modalities may in general use these radiology classifications, for purposes of seeking to establish substantial equivalence, if there does not exist a classification for a similar product that is more specifically applicable to the images. However, decisions regarding the substantial equivalence of nonradiological devices to the medical image management device classifications being finalized here will be made on a case-by-case basis.

III. Final Classifications

After reviewing the public comments, the agency has determined that it is appropriate to classify the devices as proposed. Accordingly, the medical image storage device and medical image communications device when they do not use irreversible compression are classified into class I.

The medical image digitizer, the medical image hardcopy device, and the picture archiving and communications system are classified into class II. The following voluntary standards will serve as special controls to ensure the safe and effective use of these devices:

1. The Digital Imaging and Communications in Medicine standard, developed by the American College of Radiology and the National Electrical Manufacturers Association (NEMA),

which specifies the format for the communication of digital images between individual devices as well as over networks. This standard has solved many of the problems of incompatibility between medical image management devices caused by the use of proprietary image file formats. A copy of the standard may be obtained from NEMA, 1300 North 17th St., Rosslyn, VA 22209.

2. The Joint Photographic Experts Group (JPEG) standard, which specifies methods for the compression (reversible and irreversible) of digital medical images (see Ref. 1).

3. The Society of Motion Picture and Television Engineers test pattern, which is used to test CRT monitors and printers used to display medical images for acceptance and quality control purposes (see Ref. 2).

IV. References

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

V. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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 impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354) (as amended by subtitle D of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so 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 this final rule does not impose any new requirements, the Commissioner of Food and Drugs certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate and, therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

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, 21 CFR part 892 is amended as follows:

PART 892—RADIOLOGY DEVICES

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

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Sections 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 without irreversible data compression. 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.

§ 892.2020 Medical image communications device.

(a) *Identification.* A medical image communications device provides electronic transfer of medical image data between medical devices without irreversible data compression. 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.

§ 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) Std., Joint Photographic Experts Group (JPEG) Std.).

§ 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) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).

§ 892.2050 Picture archiving and communications system.

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) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).

Dated: April 13, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98-11317 Filed 4-28-98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[GA-035-9807a; FRL-6004-8]

Approval and Promulgation of Implementation Plans; Georgia: Approval of Revisions for Transportation Control Measures

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving revisions to the Georgia State Implementation Plan (SIP) submitted by the Department of Natural Resources on August 29, 1997, requesting the incorporation of several transportation control measures (TCMs) and the deletion of two TCMs from the existing SIP. This action will only address the incorporation of four of the five TCMs requested for incorporation. The other TCM actions will be handled under separate rulemaking action. The four TCMs, subject to this action include: The addition of a high occupancy vehicle (HOV) lane, an employer-based program, a university ridershare program, development of transportation management associations. This action does not address the alternative fuel station vanpool project, the five express bus routes on Cobb Community Transportation (CCT) and two park and ride lots on CCT routes.

DATES: This final rule is effective June 15, 1998 unless adverse or critical comments are received by May 29, 1998. If adverse comments are received EPA will publish a timely withdrawal of this rule.

ADDRESSES: Written comments on this action should be addressed to Kelly A. Sheckler at the Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303. Copies of documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day. Reference file GA35-9807. The Region 4 office may have additional background documents not available at the other locations. Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460 Environmental Protection Agency, Region 4 Air Planning Branch, 61