SUMMARY MINUTES

OF THE

RADIOLOGICAL DEVICES PANEL

August 29, 1994

OPEN SESSION

Parklawn Building
Rockville, MD

Picture Archiving and Communications Systems (PACS)

The open session was dedicated to a discussion of PACS. Dr. Zaremba began the session with a briefing. Many PACS did not exist when the original radiological device classifications were established, but were found to be equivalent to their analog counterparts or other related devices. CDRH has been receiving a large number of PMA submissions for PACS for years. Although they often use new technology, they generally do not have new indications for use or raise new safety or effectiveness issues. Therefore, they have not required premarket approval, and the Agency has been classifying them as accessories to the imaging modalities with which they are used. All of these modalities are in Class II.

Definition. Dr. Zaremba proposed the following definition of PACS:

> 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; telecommunications devices; computers; video monitors; magnetic, optical disk, or other storage devices; and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression, or quantification.

The safety and effectiveness issues related to PACS concern data integrity, device connectivity/compatibility, and image data compression. Industry standards are such that the integrity of data transmission and storage is no longer a significant problem. Connectivity and compatibility has been addressed by the ACR/NEMA standard. In recent years, PACS have begun to use irreversible image data compression. The Agency updated the PACS

guidance last year to include labeling requirements for this technology.

Classification categories. Because PACS are not formally classified, manufacturers are not sure whether PACS are medical devices and whether premarket notifications are required. To clarify this situation, CDRH is considering establishing the following five new classifications for radiological devices:

- Picture archiving and communications system--Class II. Includes products that combine several functions and are packaged as PACS systems as well as devices for which there are no other specific classifications, such as workstations, image processing software, and special monitors. FDA is encouraging manufacturers, through NEMA, to develop standard specifications and measurement techniques for products such as monitors, digitizers, and hardcopy devices.
- Medical image digitizer--Class II.
- Medical image storage device--Class I.
- Medical image hardcopy device--Class II.
- Medical image communications device--Class I.

These classifications will not apply to general purpose products, which are not considered to be medical devices. Devices that can affect diagnostic accuracy are in Class II.

S. Ted Treves, M.D., chief of the Division of Nuclear Medicine in the Department of Radiology at Childrens Hospital of Boston, asked Dr. Zaremba why the Agency limited the description of PACS software to programs that enhance images and excluded the management aspects of imaging. Dr. Zaremba replied that the state-of-the-art in telecommunications is acceptable.

NEMA's point of view. The panel then invited representatives from NEMA to speak. Bob Britain, vice president for medical products, explained that NEMA represents manufacturers of diagnostic imaging and therapy systems. In cooperation with ACR, NEMA established the Digital Imaging Communications (DICOM) standard in the early eighties when PACS began to be manufactured. Britain noted that it is unusual for a trade association and a medical group to establish a standard so early.

Dr. Joe Gitlin, who is associated with Eastman Kodak, is a professor of radiology at The Johns Hopkins University, and chairs NEMA's medical PACS section. He spoke as NEMA's expert. Gitlin's first point was that **there are no such things as PACS.** He said the term PACS covers such a wide range of systems that it is impossible to regulate them together. He suggested that FDA regulate the components of these systems instead. Dr. Treves said that he agreed with Dr. Gitlin that PACS do not exist and that FDA should regulate the components. He also said that it may be premature to regulate the entire process. Dr. Zaremba responded that the Agency is regulating PACS instead of components because that is the form in which manufacturers are submitting 75 percent of the 510(k) applications. Dr. Treves questioned whether the Agency should take this opportunity to educate manufacturers in this regard.

Dr. Gitlin then questioned the classification of PACS in Class II. He allowed that digitizers pose a problem related to performance issues. Performance standards are critical to the patient, he said, when the device is 1) sophisticated and 2) has a number of functions, or 3) users have a choice of what to select and need to be assured they are getting the level or reading they wanted.

Dr. Zaremba responded that the Agency is specifically concerned about digitizers because there are large differences in their measurement methodologies and their methods of specifying their optical density ranges. This is the main reason the Agency is proposing that they be in Class II. If there were methods of measuring optical density performance, these methods could be passed along in the specifications, so users could make their own judgments. Ivan A. Brezovich, Ph.D., of the Radiation Oncology Department of the University of Alabama at Birmingham, suggested that users of digitizers receive a test pattern showing them what an image will look like going in and coming out of the device. This test pattern could be in the literature that comes with the device. Sridhar B. Seshadri, MSEE, MBA, director of both Information Systems and Capital Projects as well as Medical Informatics Research in the Department of Radiology at Hospital of the University of Pennsylvania, spoke to the panel on behalf of NEMA. Seshadri told the panel that as a user of film digitizers, he would like these devices to come with a tag that says they meet the signal to noise ratio, and specifies their spatial resolution and contrast resolution. He said he thought setting standards for different medical disciplines would be premature. He also said he thought the next revolution would be in computer radiography. Dr. Zaremba agreed that FDA should not define, for example, which compression rate is suitable. That, he added, is why the Agency was asking for a labeling requirement. He said the Agency would address computer radiography separately. Dr. Hackney asked why this device would be treated separately when it performed the same function as the devices discussed that day. Dr. Zaremba replied that it would be discussed separately because it used different technology.

Dr. Phillips explained that placement in Class II does not necessarily mean there are

performance standards, only special controls. Dr. Gitlin said he would go along with proposals that ensure that users can maintain high levels of quality. Dr. Hackney asked the NEMA representatives why they were concerned about these devices being in Class II. Britain responded that Class I controls are quite formidable and that Class II is not for devices for which it would be nice to have a standard. Melpi Jeffries, an FDA classification specialist, explained that if a device needs a special standard unlike, say, UL standards, to make it safe and effective, it should be placed in Class II. Britain responded that the DICOM standard was not established to ensure safety and effectiveness, but so the equipment made by different manufacturers would be compatible. Dr. Phillips countered that such compatibility is a safety and effectiveness issue and would be a problem for patients if data could not be transferred from one institution to another. Dr. Zaremba added that it would also be a problem if the quality of the image was not suitable for a diagnosis because a patient could be mistreated. Dr. Marcus polled the panel, and the panelists agreed that the standards do relate to safety and effectiveness. Dr. Brezovich stressed, however, that this depends on the nature of the component.

Regarding hardcopy devices, Dr. Gitlin said he would distinguish between conventional printers and computers. On the subject of irreversible compression, he said that his research shows there is a difference in accuracy and particularly confidence in interpretation when users look at highly compressed images. He said there is a need for studies in clinical environments that will enable the determination of where this technology is and is not appropriate. He further noted that the DICOM standard is coming up for international adoption; he does not think it should be subject to FDA regulation.

Deliberations. Dr. Phillips asked the panel two questions: Are the classification definitions adequate and clear? And, are the classification categories proposed sufficiently inclusive? He also asked them to complete the general device classification questionnaire for each category they find appropriate.

The panel voted to accept the five categories Dr. Zaremba defined as appropriate. They then began to fill out the classification questionnaire for PACS. They said PACS should be in Class II, that there be voluntary performance standards and testing guidelines for their use, and that they should be used only by those with specific training or experience. They listed "inadequate/inaccurate data leading to improper diagnosis" under risks to health presented by the device, and DICOM, the SMPTE test, and the JPEG standard of compression under related standards.

Dr. Gitlin remained disappointed with the general PACS classification. Seshadri told the panel that he thought they should exercise their authority to tell vendors to submit their applications at the subsystem level. Dr. Marcus responded that the panel was trying to cover all of the options. If manufacturers are savvy, she said, they will submit their applications as Seshadri suggested. If not, FDA will still be able to proceed. After some discussion the panel invited NEMA to submit an alternative scheme in writing. Dr. Phillips reminded everyone that the panel is only advising the Agency. The Agency must respond to their comments and all responses to the ruling the Agency will publish in the Federal Register.

The panel placed the other four categories into two groups--digitizers and hardcopy machines in a Class II group, and image storage and communications devices in a Class I group--and filled out the questionnaire two more times. They recommended that FDA

exempt the Class I devices from premarket notification unless the devices use lossy compression.

The next panel meeting is tentatively scheduled for December 12, 1994. Next year's meetings were scheduled for March 6, June 19, September 11, and December 11.