evaluation of the safety and effectiveness had been provided by these review bodies. In addition, the safety and effectiveness of stents used for other indications has been the subject of four FDA advisory committee meetings.

On September 29, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b)(21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 16, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 21, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–18071 Filed 7–16–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Provider/Supplier Enrollment Application; *Form No.:* HCFA–855; *Use:* This information is needed to enroll providers/suppliers by identifying them, verifying their qualifications and eligibility to participate in Medicare, and to price and pay their claims; *Frequency:* Other (Initial Application/recertification); *Affected Public:* Business or other for profit, not for profit institutions, and federal government; *Number of Respondents:* 165,000; *Total Annual Responses:* 165,000; *Total Annual Hours:* 370,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov , or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: John Burke, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 9, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–18094 Filed 7–16–96; 8:45 am]

BILLING CODE 4120–03–P

Submitted for Collection of Public Comment: Submission for OMB Review

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Request:* Revision of a currently approved collection; *Title of Information Collection:* Statistical Report on Medical Care: Eligibles, Recipients, Payments and Services; *Form No.:* HCFA–2082; *Use:* The data reported in the HCFA–2082 are the basis of actuarial forecasts for Medicaid service utilization and costs; of analyses and cost savings estimates required for legislative initiatives relating to Medicaid and for responding to requests for information from HCFA components, the Department, Congress and other customers; *Frequency:* Annually; *Affected Public:* State, local,

or tribal government; *Number of Respondents:* 54; *Total Annual Responses:* 54; *Total Annual Hours:* 17,214.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: July 9, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–18093 Filed 7–16–96; 8:45 am]

BILLING CODE 4120–03–P

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health; HHS.

ACTION: Notice.

The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for U.S. companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications and issued patents listed below may be obtained by contacting John Fahner-Vihtelic at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7735 ext 285; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Broadband Transmit-Receive Switch

TJ Pohida (NCRR)
Filed 06 Nov 95
Serial No. 08/554,003

Transmit-receive (TR) switches are commonly used in complex electronic systems such as magnetic resonance imaging systems, radar systems, and a variety of communication systems. These switches are typically designed using quarter wavelength transmission lines in conjunction with solid state componentry. Although this type of TR switch performs well, the desirable properties of a quarter wavelength transmission lines are only exhibited over about a 10% variation in frequency. This type of TR switch is considered a narrowband switch. A significant need exists for a TR switch that uses the advantages of quarter wavelength impedance transformers and provides a broad bandwidth. The design of the present invention satisfies those needs by providing a TR switch which features a broadband frequency response. This invention can be implemented on any one of several transmission line media. Also, it can be manufactured according to any known manufacturing methods for similar devices. This technology has been implemented on a prototype imaging system. (portfolio: Devices/Instrumentation—Diagnostics, imaging apparatus)

System and Method for Performing In Vivo Imaging and Oxymetry by Pulsed Radiofrequency Electron Paramagnetic Resonance

R Murugesan, MK Cherukuri, JB Mitchell, S Subramanian, R Tschudin (NCI)
Filed 20 Jul 95
Serial No. 08/504,616

This invention provides a non-invasive system for *in vivo* imaging by fast-response pulsed radiofrequency (RF) electron paramagnetic resonance (EPR) spectroscopy. The imaging system can be used for measurement and 3-dimensional imaging of oxygen and free radicals in living systems, in conjunction with appropriate free radical probes. The system can be used to perform rapid 3-dimensional mapping of tissues and vasculature, for example cardiac and cerebral angiography, and also to distinguish normal and diseased tissues. The short relaxation time of the probes and the fast response associated with pulsed EPR techniques permit virtual real-time imaging. The system uses a magnetic field of only 10 mT-orders or magnitude smaller than the field used in conventional MRI techniques. The sensitivity, image resolution, and imaging speed of the pulsed RF EPR system are far superior to continuous wave RF EPR systems. (portfolio: Devices/Instrumentation—Diagnostics, imaging apparatus, electron paramagnetic resonance; Devices/Instrumentation—Diagnostics, imaging apparatus, spectroscopy)

System and Method for Simulating a Two-Dimensional Radiation Intensity Distribution of Photon or Electron Beams

J van de Geijn, H Xie (NCI)
Serial No. 08/368,589 filed 06 Jan 95
U.S. Patent No. 5,526,395 issued 11 Jun 96

The present invention provides a method for computer-assisted, interactive 3-dimensional radiation treatment planning and optimization. The computerized system is capable of processing and analyzing data obtained from x-ray, CT, MRI, PET, SPECT, and gammacamera devices. Hence, the system can be used as a training device, alleviating the need for training centers to purchase each of these devices. The computerized system comprises a fast, versatile, and user-friendly software package and computer components which are commercially available and which can be used without significant modification. Because the hardware costs of this system are much lower than the cost of systems of comparable ability, this invention ought to be particularly attractive to smaller radiation oncology facilities which seek a powerful treatment planning system. The low cost of the system is also particularly advantageous for medical training facilities, including medical schools. The invention also has potential use as a monitor for clinical quality assurance. (portfolio: Devices/Instrumentation—Therapeutics, methods of using devices)

Variable Axial Aperture Positron Emission Tomography Scanner

MV Green, J Seidel, WR Gandler (CC)
Filed 15 Dec 94
Serial No. 08/357,574

Development of a unique system that can operate as both a scintillation camera and a positron emission tomography (PET) scanner offers to significantly improve the visualization of physiological processes in the human body and other biological systems. Single photon emission computed tomography (SPECT) imaging—which utilizes one or more scintillation cameras rotated around a subject—is used in nuclear medicine worldwide. More recently, an alternative to SPECT imaging has involved the development and use of positron emission tomography (PET) imaging, in which the subject is surrounded by rings of detectors that detect the emission of a pair of annihilation photons from positron emitting racers in the body.