# News Briefs

## FDA Accepting Nominations for Advisory Committee Vacancies

The Food and Drug Administration (FDA) is accepting nominations for representatives to serve on advisory committees for its Center for Devices and Radiological Health. In particular, the Center is accepting nominations to fill four vacancies in the Radiologic Device Committee, one of which is available immediately, while the other three will open up January 31, 1991. The nominees for the radiologic device panel should be radiologists, radiation oncologists, or oncologists with expertise in hyperthermia. Nominations are handled by the FDA's office of health affairs.

Activities of the Center's advisory committees include: reviewing and evaluating available data on the safety and effectiveness of medical devices, recommending classification and changes in classification of devices, advising on possible health risks related to device use, and reviewing the Center's medical radiation programs and electronic product radiation standards activities.

According to Robert Gottesman, assistant director of health professional liaison at the office of health affairs, "Health professional members of a panel serve a three-year term. Essentially, [the FDA] is looking for well-rounded individuals with diverse experience in medical practice, teaching, and research." Mr. Gottesman notes that the agency encourages the nomination of minorities, women, and the disabled.

Nominations and other questions may be submitted to: Gordon C. Johnson, MD, Office of Health Affairs (HFZ-70), CDRH, 1390 Picard Drive, Rockville, Maryland 20850; (301) 427-1060. ■

## NIH Holds SPECT Conference

Researchers at the National Institutes of Health (NIH) in Bethesda, Maryland held a conference outlining the development and current applications of single photon emission computed tomography (SPECT) for the general medical community on April 25. NIH members from all fields of medicine were invited to attend the discussion, which was moderated by Theodore Simon, MD, deputy chief of the department of nuclear medicine, NIH; Robert Bonow, MD, chief of nuclear cardiology in the heart, lung, and blood section, NIH; and Walter E. Drane, MD, head of the division of nuclear medicine and professor of radiology, University of Florida College of Medicine in Gainesville.

"Basically, the conference had two main thrusts," Dr. Simon told *Newsline*. "First, we gave a review of the routine clinical uses of SPECT, with an emphasis on heart imaging and brain imaging, and how those representations can be used to depict and quantify neurological and psychiatric disorders. Second, we emphasized research opportunities provided by SPECT, with a focus on its quantitation ability and how it correlates with [positron emission tomography] PET," says Dr. Simon. He notes that the conference also addressed non-cardiac and non-neurological applications of SPECT, including bone imaging.

According to Dr. Drane, the NIH is a peculiar institution in that its members embraced PET enthusiastically 15 years ago and have since largely bypassed the SPECT modality. "Our discussion was geared towards emphasizing the fact that SPECT is the equal to and, in some cases, superior to PET," says Dr. Drane. "There are applications of bone imaging, tumor detections, hepatic resections that can only be performed by SPECT." As an additional example, Dr. Drane noted that there is no PET technique comparable to the SPECT method used for staging lymphoma.

Dr. Drane further pointed out that because NIH projects have concentrated around PET applications, there has been a tendency in the organization to downplay the clinical and research roles and potential of SPECT. "We wanted to make the audience aware that SPECT is at the cutting edge of imaging and provides high-quality service at a cost far less than PET," he says. "The assembly seemed to be quite receptive to our advocacy of SPECT."

Dr. Simon reports that the audience — which represented the broad spectrum of medical disciplines, consisting largely of clinicians unfamiliar with SPECT — gave an ardent response to the material presented. "This conference had a strong research angle to it, and the audience members were quite enthusiastic over learning how SPECT could be applied to their particular fields of interest." Dr. Simon adds that the NIH plans to hold future mini-conferences on monoclonal antibodies, SPECT, and other topics in nuclear medicine. ■

## SDIO to Fund Pet Projects

The Strategic Defense Initiative Organization (SDIO) has awarded contracts to develop radionuclide delivery systems to Science Research Laboratories, Incorporated (SRL) of Somerville, Massachusetts, which is working in conjunction with the Mallinckrodt Institute of Radiology at Washington University Medical Center in St. Louis and to Science Applications International Corporation (SAIC) of San Diego, which is

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working in conjunction with the University of Washington in Seattle. The Department of Defense's SDI program supported the development of a high-intensity ion source that will be used in the accelerators of the new delivery systems.

The Mallinckrodt research team will develop a fully automated radiopharmaceutical synthesis unit that will be used with a new compact accelerator, designed by Ruth Shefer, PhD, and Robert Klinkowstein, PhD, principal researchers at SRL. The accelerator and the synthesis unit will be connected with a PC-based programmable logic controller and tested in a clinical PET center.

Michael J. Welch, PhD, professor of radiation chemistry at the Mallinckrodt Institute, who will lead the research effort at his institution, sees the emergence of the new accelerator/radionuclide system as a breakthrough for positron emission tomography (PET) technology. "In conventional cyclotron-based PET centers, short-lived isotopes are produced using medium-energy particle beams," says Dr. Welch. "We can simplify PET technology by producing these isotopes with low-energy beams." Dr. Welch also notes that because the new accelerator is lighter and less expensive than a conventional cyclotron, it will encourage wider dissemination of PET technology. While a cyclotron can weigh up to forty tons and cost $2 million, SRL's accelerator will weigh ten tons, cost $500,000, and require only one-sixth of the electrical power used in conventional cyclotrons. The Mallinckrodt research team expects to test the new accelerator production system within two years.

The University of Washington research team, led by Kenneth Krohn, PhD, professor of radiology and radiation oncology, adjunct professor of chemistry, and Jean Link, a radiochemist, will develop positron-emitting radionuclides while SAIC's team, led by William Hagan, PhD, will build an accelerator. ■

## Labs Must Submit Funding Plan for Decommissioning to NRC

Nuclear Regulatory Commission (NRC) regulations require medical research and pharmaceutical laboratories licensed to use radioactive isotopes to have decommissioning funding plans in place by July 27, 1990. The regulations apply to license holders who possess and use unsealed by-product material of half-life greater than 120 days and in quantities exceeding 100,000 times the applicable quantities set forth in Appendix C to 10 CFR Part 20. These facilities need to submit plans to the NRC that address timing, funding methods, record keeping, and environmental review. Each decommissioning funding plan must contain, at a minimum, a cost estimate for decommissioning and a description of the assuring funds. Laboratories that do not comply face fines as high as $50,000 per day. ■

## Waste Board Reports on Yucca Mountain HLRW Site

The Nuclear Waste Technical Review Board (NWTRB) issued its first report on the Department of Energy's (DOE) scientific and technical work to qualify Nevada's Yucca Mountain site as suitable for the nation's first high-level radioactive waste (HLRW) repository. The Board's report lists 24 recommendations that are intended to improve the DOE's site study. The recommendations are grouped into three categories: technical and scientific; strategic and non-technical; and science policy. The report includes suggestions that deal with mechanical excavation, early exploratory drifting, fracture flow, $^{14}C$ release mechanisms, system safety, and interactions between the DOE and Nevada.

Interactions between the DOE and Nevada have been so hostile that they are suing each other. The state of Nevada filed suit against the Federal Government on December 27, 1989, claiming that Nevada has a right to veto use of the Yucca Mountain site as a HLRW repository. The state is adamantly opposed to a HLRW site within its borders and has passed legislation barring any such site. The DOE filed suit against the state of Nevada on January 25, 1990, claiming that Nevada does not have the right to deny the DOE access permits to study the site. It is the DOE's contention that Nevada can only veto the site as a repository after the DOE has completed its scientific studies and has recommended to Congress that the Yucca Mountain site be used as a HLRW repository.

The Yucca Mountain site became embroiled in this controversy when the Nuclear Waste Policy Amendments Act (NWPAA) of 1987 named Yucca Mountain as a potential permanent repository for disposal of spent nuclear fuel and other high-level radioactive waste. The Act directed the DOE to perform scientific and technical studies to determine if Yucca Mountain was a suitable HLRW site. The NWPAA also created the NWTRB to review the DOE's studies and report on them to Congress at least twice a year. In making its final decision on the site, Congress will rely heavily on the DOE studies and the NWTRB reports. ■