



From the SNM

SNM Commends FDA Efforts

On January 12, the SNM issued a statement commending the Food and Drug Administration (FDA) Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Office of Regulatory Affairs for their commitment to facilitating safe and effective research with the release of 2 important documents on investigational new drugs. "Guidance for Industry and Reviewers: Exploratory Investigational New Drugs (EIND) Studies" provides new protections for patients as well as a pathway for investigators to more efficiently conduct life-saving studies. "Guidance for Industry: Approaches to Complying with Current Good Manufacturing Practice (CGMP) During Phase I Studies" will facilitate the production of investigational drugs for use in phase I studies, with the primary focus again on human safety. "These guidance documents took a significant amount of the FDA's time and dedication to ensure a secure process for researchers and developers of drugs and biological products," said SNM President Peter S. Conti, MD, PhD, professor of radiology, clinical pharmacy, and biomedical engineering at the University of Southern California, Los Angeles. "The nuclear medicine and molecular imaging community appreciates their hard work." An SNM task force compiled and submitted comments on EIND when the draft version was released to the public in spring 2005. Both documents can be accessed through the FDA Web site at www.fda.gov, where the CGMP guidance language remains available for public comment.

Society of Nuclear Medicine

Changes to Hospital Radiopharmaceutical Reimbursement

On January 1, the Centers for Medicare & Medicaid Services (CMS) implemented a temporary, 1-year policy for payment of radiopharmaceuticals in CY 2006. During this year, CMS will pay hospitals for outpatient radiopharmaceuticals with status indicator "H," based on the charge on the claim, times the overall hospital specific cost-to-charge ratio (CCR). CMS stated on New Year's Day in the *Federal Register* that "hospitals have the ability to set charges for items properly so that charges converted to costs can appropriately account fully for their acquisition and overhead costs. . . . Specifically, it is appropriate for hospitals to set charges for these agents in CY 2006 based on all costs associated with the acquisition, preparation, and handling of these products so that their payments under the OPPS can accurately reflect all of the actual costs associated with providing these products to hospital outpatients."

This new radiopharmaceutical payment policy was implemented by CMS in an effort to maintain consistency between the payment rates for these agents from CY 2005 to CY 2006. CMS also stated that the temporary policy was needed because there was insufficient data for radiopharmaceuticals and because CY 2004 mean and median costs from the hospital claims data were substantially lower than CY 2005 radiopharmaceutical payment rates.

The nuclear medicine community expressed concerns to CMS that hospitals might not have consistently and uniformly accounted for all acquisition, transportation, preparation, handling, and overhead costs of radiopharmaceuticals in their previous pricing on hospital charge masters. The preparation, distribution, administration, and safe disposal of radiopharmaceuticals,

along with labor costs and necessary patient and hospital staff protection costs, were not uniformly and accurately reflected in hospital charges. An analysis using 2004 hospital claims data provided by the Council on Radioisotopes and Radiopharmaceuticals estimated that 33% of hospitals might be underreporting the cost for at least 1 radiopharmaceutical product using the hospital overall CCR and that 13% might be overcharging. In response, the SNM created the "Hospital Analysis of Radiopharmaceutical Cost and Charge Spreadsheet." The spreadsheet includes formulas and data from 3 sample hospitals showing the new 2006 radiopharmaceutical payment methodology and potential impact on hospitals. Users can apply their own hospitals CCRs, charges, and costs to perform analyses and keep their facilities' 2006 radiopharmaceutical charges up-to-date.

SNM also presented 2 Coding Road Shows in January and February to "take the mystery out of HCPCS Level II coding and billing." For more information or to download a copy of the spreadsheet visit the SNM Web site at www.snm.org and click on PRACTICE MANAGEMENT.

Society of Nuclear Medicine

Additional Newsbriefs

NRC Recognizes ABSNM Certification

The Nuclear Regulatory Commission (NRC) announced in early 2006 that it would recognize American Board of Science in Nuclear Medicine (ABSNM) certification in 2 new categories: nuclear medicine physics and instrumentation, and radiation protection for radiation safety. Beginning in June 2006, ABSNM diplomats with these specialties can be approved as radiation safety officers by NRC.

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Established in 1976, the ABSNM is sponsored by the American College of Nuclear Medicine, the American College of Nuclear Physicians, and the SNM. Its primary objective is to certify scientists practicing in nuclear medicine. The certification process requires passing a 2-part comprehensive examination administered by the Board. Certification by the ABSNM indicates successful completion of certain requirements of study and professional experience that the Board considers necessary to constitute an adequate foundation in nuclear medicine science, which includes nuclear medicine physics and instrumentation, radiopharmaceutical science, and radiation protection.

This year's examination is in June. The deadline for receipt of applications to qualify for the examination was March 1. For more information and access to applications, see www.snm.org/absnm.

*American Board of Science
in Nuclear Medicine*

Study Assesses U.S. Market for Radiopharmaceuticals

A report issued on January 19 by Bio-Tech Systems, Inc., a market research and analysis firm based in Las Vegas, NV, points to the strength and diversity of radiopharmaceuticals in the United States market. The report notes that U.S. sales of diagnostic radiopharmaceuticals reached \$1.53 billion in 2004 and are expected to rise to \$3.20 billion by 2010. Radiopharmaceutical sales grew by 14.3% in 2004 and should continue growth in the range of 13%–16% through 2008. This growth will be based on the introduction of new products, strong demand for cardiology procedures, and increased sales of oncology products, particularly ^{18}F -FDG. Sales of nuclear cardiology products will continue to drive the radiopharmaceutical market, with high utilization of nuclear perfusion studies coupled with advanced pharmacologic stress agents. Nuclear cardiology sales of \$1.06 billion in

2004 will increase to \$1.89 billion by 2010. ^{18}F -FDG sales will increase from \$249 million in 2004 to \$522 million by 2010. ^{18}F -FDG distribution will continue to improve, allowing more widespread use of PET in community hospitals. With reimbursement stabilizing and procedure volume increasing, PET should become more profitable for providers as well as suppliers of ^{18}F -FDG. In addition, new PET radiopharmaceuticals in the pipeline for specialized applications should add to these sales estimates. Market growth should also benefit from higher prices for many of the new products. More biopharmaceutical products for SPECT imaging will incorporate monoclonal antibody- and peptide-based targeted agents, expanding the range of nuclear procedures.

In a press release summarizing the report, Bio-Tech Systems noted that recent approval of 2 therapeutic radiopharmaceuticals has overlapped into the diagnostic market, creating a stronger link between targeted imaging and complementary therapeutic products. This has helped nuclear medicine, which is required in all cases to assess biodistribution and dosing of therapeutic radiopharmaceuticals as well as evaluate patient response to therapy. The report has a strong focus on new products and technology and emerging market opportunities. Many of the new diagnostic agents have a therapeutic counterpart. The prospects for growth of PET and PET/CT procedures are also covered, as well as SPECT/CT. The report can be ordered through www.bio-tech.com.

Bio-Tech Systems, Inc.

Unauthorized Self- Injection Cited by NRC

In an article published in the February supplement to *Health Physics* (2006;90[suppl 2]:S24–28), Miller et al. from the Penn State College of Medicine Hershey Medical Center reported on findings by the Office of Investigation of the U.S. Nuclear Regulatory Commission (NRC) which determined that, on at least 3 occasions

over the past decade, technologists in the Hershey nuclear medicine program were injected with radiopharmaceuticals without appropriate approval. The findings were originally summarized in an October 14, 2005, letter from Samuel Collins, NRC regional administrator, to Hershey administrators. The investigation began when a single incident was discovered by Hershey and promptly reported to the NRC. The other 2 incidents were discovered by the NRC during the follow-up investigation. The 3 incidents were described as: (1) an authorized user deliberately administered byproduct material to an individual, with no medical reason, for the sole purpose of comparing images from 2 cameras (contrary to 10 CFR 35.11); (2) an employee deliberately used byproduct material to perform an unauthorized bone scan on himself (contrary to 10 CFR 35.27a); and (3) an employee deliberately used byproduct material to perform an unauthorized brain scan on herself. In an alternative dispute resolution involving the licensee, an independent mediator, and representatives of the NRC, an agreement was worked out whereby the licensee admitted to the violations and worked with the NRC to inform other licensees about the dangers of unauthorized administration of byproduct material and to remind them of additional precautions to minimize the possibility of such incidents. In addition, the licensee was required to add in-service training and precautions.

Health Physics

Nuclear Regulatory Commission

Sabri Receives KFAS Prize

In a ceremony held on December 5, the prime minister of Kuwait presented Dr. Osama Sabri with the Kuwait Foundation for the Advancement of Science (KFAS) award for applied sciences. The award is one of 5 annual prizes that are widely known as the “Nobel prizes of the Arab world.” The award went to Sabri for his scientific achievements in evaluating the role of

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nuclear medicine (including PET and SPECT) in functional neuroimaging of dementia and schizophrenia. The prize committee cited numerous publications, presentations, and research through which Sabri has contributed significantly to the functional imaging of psychopathologic processes in the human brain.

Sabri is currently the director and chair of the Department of Nuclear Medicine of the University of Leipzig, Germany, where he runs a PET center (including a PET scanner, cyclotron, 6 hot cells, and several radiochemical laboratories) dedicated to neurologic research. His main research foci have been in PET and SPECT studies on neuroreceptors and neurotransmitters in dementia and disorders with cognitive impairments.

The KFAS was founded in 1976 by the Amir of Kuwait, Sheikh Jaber Al-Ahmad Al-Jaber Al-Sabah. Press releases indicate that it is the oldest scientific organization in the Arab world. Its annual prizes are in basic sciences, applied sciences, economic and social sciences, arts and literature, and Arabic and Islamic scientific heritage, although not all prizes are awarded every year. Recipients of the awards receive US\$105,000, a gold medal, commemorative shield, and certificate of recognition.

*Kuwait Foundation for the
Advancement of Science*

Lawrence Nominations Extended

The Office of Science of the Department of Energy (DOE) announced on January 23 that it would extend the deadline for nominations for the E.O. Lawrence Award until May 1. In issuing the extension Dr. James L. Decker, principal deputy director of the Office of Science, called attention to a nomination criterion that is new this year: the requirement that recipients must be in their midcareers (defined as within 20 years after receiving a PhD). Thus, only nominees who received their doctorates after 1985 will be eligible

for this year's award. A brochure describing the award and nomination process, with contact information, is available at [www.science.doe.gov/lawrence/lawrence_brocure\(oct2005\).pdf](http://www.science.doe.gov/lawrence/lawrence_brocure(oct2005).pdf).

U.S. Department of Energy

Blaufox Laboratory for Molecular Imaging Dedicated

A dedication ceremony for a new imaging laboratory at the Albert Einstein College of Medicine of Yeshiva University (New York, NY) was held on January 10. The new facility, the M. Donald Blaufox Laboratory for Molecular Imaging, will house state-of-the-art microPET imaging equipment for the study of animal models. The laboratory was established with a major gift from Ronald Lissak, president and chief executive officer of Integral PET Associates, and his wife, Marcia, chief operating officer of the company. The company named the facility in honor of Blaufox, university chair and professor of nuclear medicine at Einstein and its affiliated university hospital, Montefiore Medical Center. "This is a wonderful gift. It will play a key role in our investigations of a wide range of diseases, from cancer to epilepsy, from rheumatoid arthritis to diabetes," said Dr. Dominick P. Purpura, the Marilyn and Stanley M. Katz Dean of the Albert Einstein College of Medicine. "Marcia and I are very pleased to make this gift in honor of our good friend, Don Blaufox," said Ron Lissak. "I met Don almost 11 years ago when we began planning for the installation of the first PET scanner at Einstein/Montefiore. One of the leading nuclear medicine physicians in the nation, Don has been, and has remained through the years, a wonderful friend and mentor." Blaufox has served as editor of numerous professional publications and has published more than 260 articles and book chapters. A collector of antique medical instruments and artifacts, he is the author of several books, including *An Ear to the Chest: An Illustrated History of the Evolution of the Stethoscope*, published in 2002. "MicroPET

has the potential to revolutionize animal studies of disease models by providing more efficient and accurate data on growth, response to therapy, and systemic effects in all types of animal models," said Blaufox.

Albert Einstein College of Medicine

NRC Looks at New Regulations

The Nuclear Regulatory Commission (NRC) announced on January 4 its plans to consider amending regulations to improve, update, and clarify requirements for the possession and use of products containing radioactive material. The NRC has authority to issue general and specific licenses for the use of byproduct material and to grant exemptions from licensing for beneficial uses of licensed material where the exemption will not constitute an unreasonable risk. Commission regulations currently have 15 exemptions from licensing for byproduct material. Examples include watches and smoke detectors containing certain amounts and types of radioactive material. The proposed improvements and updates to the exemptions include the following changes: (1) Transfers of products and materials to persons exempt from licensing would have to be reported by the next January 31 date. Currently, such reports are required only once every 5 years. (2) Exempt amounts of radioactive material could not be bundled together into a single product if it would create a radiation level above what was anticipated in authorizing the exempt use. (3) Extraneous provisions of the regulations would be removed by deleting exemptions for products that are no longer being distributed. (4) A specific exemption from licensing requirements would be granted to smoke detectors containing only specified small amounts of ^{241}Am . In addition, the NRC proposes to clarify the steps general licensees must take if they wish to transfer a product to a specifically licensed status. The proposed rule was published January 4 in the *Federal Register*, and comments will be accepted until March 20. Comments

should be submitted through the NRC rulemaking Web site at: <http://ruleforum.llnl.gov/>.

The NRC also announced on January 12 the opening of a narrow window during which it sought public comment on several issues concerning the protection and security of radiation sources, as part of requirements under the Energy Policy Act of 2005. This legislation established the Radiation Source Protection and Security Task Force, with the NRC as its chair, to evaluate and provide recommendations relating to the security of radiation sources in the United States from potential criminal or terrorist threats, including acts of sabotage, theft, or use of a radiation source in a radiation dispersal device. The task force is comprised of representatives from more than a dozen federal agencies and departments. The task force's efforts have focused for the most part on category 1 and 2 sources as defined by the International Atomic Energy Agency's Code of Conduct on the Safety and Security of Radioactive Sources.

The topics on which the NRC sought comment included: (1) the list of sources requiring security because of their public health risk or potential attractiveness to terrorists; (2) the national system for recovery of lost or stolen radiation sources; (3) safe and

secure storage of radiation sources when not in use; (4) the national source tracking system for radiation sources; (5) a national system for proper disposal of radiation sources; (6) import and export controls; (7) procedures for improving security and control for use and storage of radiation sources; (8) procedures for improving the security of transportation of sources; (9) background checks for individuals with access to sources; and (10) alternative technologies that could perform all or some of the functions that use radiation sources. The comment period closed on February 10, but the topics addressed are informative in that they suggest areas in which changes to current rules may be considered.

Nuclear Regulatory Commission

Michigan Physician Receives iBOT System

Ben Dwamena, MD, a nuclear medicine physician at the Ann Arbor (MI) Veterans Affairs (VA) Hospital and clinical assistant professor of radiology at the University of Michigan, made national news in November when he received an Independence iBOT 4000 mobility system. Dean Kamen, inventor of the Segway transporter, designed the iBOT in partnership with Johnson & Johnson. It uses a combination of elec-

tronics, sensors, and software components to provide new levels of freedom and accessibility for individuals with disabilities. A 1998 traffic accident left Dwamena with a quad-3 disability and some remaining upper mobility. He learned about the iBOT system from a report on the ABC newsmagazine "20/20." With the push of a button, the chair elevates users to move at eye level and to reach high places independently. The front wheels rotate up and over the back wheels while users remain seated at an elevated position. Stair functions and 4-wheel functions enable users to safely climb up and down stairs, climb curbs, and travel over uneven terrain, such as grass, gravel, and sand. "The iBOT will provide me with greater freedom and accessibility, both on the job and at home," said Dwamena. Interviewed by Ann Arbor reporters in late December after more than a month's experience with the new device, he noted that his range of personal mobility, both in and outside the workplace, had increased significantly. Face-to-face conversations, once impossible without asking colleagues and patients to be seated, are now possible as well. "The eye-to-eye contact is very nice," said Dwamena.

*Mary Free Bed Hospital
Grand Rapids, MI*

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including the SNM, are expected to respond to the ATA document in the coming months. In addition, increasing numbers of innovative studies, such as the remnant ablation research by Pacini et al. and reports of highly

accurate predictive nuclear medicine imaging techniques, may spur frequent revisions by the ATA and other groups.

The complete guidelines are available online from the ATA at www.thyroid.org/professionals/publications/guidelines.html. ☼