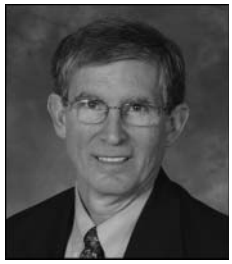
The State of Nuclear Medicine 2006

From the Newsline Editor

The year 2006 is off to a promising start for the nuclear medicine community. As I look at 2006 and reflect on 2005, I remain thankful that I am practicing nuclear medicine today and am able to experience the advances in medical technology, molecular medicine, and radioimmunotherapies. Patients are receiving more efficient and higher quality care as a result of these changes. Medical research and pharmaceutical developments are advancing with the use of novel radiopharmaceuticals and improved nuclear medicine techniques. In June of 2005, the National Cancer Institute (NCI) revamped its approach to clinical trials, prompted by advances in molecular imaging. In October 2005, the NCI created centers of cancer nanotechnology excellence in which nuclear medicine will play an integral part. The National Oncologic PET Registry is expected to begin accepting case studies in 2006, expanding data for PET use in oncology patients and holding the promise of improved patient care.

And yet, the challenges we all face to ensure the continued advancement of medicine through nuclear medicine remain daunting. On February 7, 2005, we learned that the U.S. Department of Energy would significantly cut the medical research budget for FY 2006. On February 22, 2005, the Nuclear Regulatory Commission announced a change in annual fees and fees for licensing and inspection, with hourly rates rising to $198 for Nuclear Materials and Waste Safety Programs. On March 17, 2005, the chair of the American College of Radiology Board of Chancellors, James Borgstede, told the U.S. House Ways and Means Subcommittee on Health that the overuse of medical imaging procedures by less qualified providers lowers the quality of patient care, undermines patient safety, threatens the status of Medicare, and drains the American health care system of billions of dollars each year. In October 2005 the Centers for Medicare & Medicaid Services released the 2006 Healthcare Common Procedure Coding System (HCPCS) Level II code set, containing 60 changes for nuclear medicine and drugs for 2006. On December 14, 2005 an article in the *Journal of the American Medical Association* (2005;294:2858–2865) indicated that despite tremendous input in time and funding, progress has been slow in improving patient safety in U.S. hospitals.



Conrad E. Nagle

This was also the year of Katrina. In a personal accounting by one of our nuclear medicine colleagues, we learned of events beyond the devastation witnessed on television, including a total disruption of medical care. "Patients and their attending physicians are unable to contact each other, although personal ads are beginning to appear in the local papers," wrote Terence Beven, MD, in his Newsline diary (*J Nucl Med.* 2005;46(11):11N–12N). More hurricanes, earthquakes, and tornadoes made the news, but medical news was topped by pandemic planning and fears associated with the avian flu. (Has anyone performed a nuclear medicine white cell scan yet?)

All these and more news items pertinent to nuclear medicine—the good, the bad, the encouraging, and the troubling—were included in the pages of Newsline this year. In our annual Newsline retrospective, we've asked colleagues from the SNM and various areas of nuclear medicine practice to give their valuable perspectives on the year past and their thoughts for the year to come. We're grateful to those who volunteered their valuable time over the holiday season to do so. At Newsline, we rely on our colleagues and readers to keep us apprised of news and information in the field throughout the year. We welcome contributions on practice-related issues of wide interest to the nuclear medicine community. Don't hesitate to contact me at cnagle@beaumont.edu if you have a suggestion for a feature story or other relevant news coverage.

I wish you all—and our exciting discipline—a good 2006.

Conrad E. Nagle, MD
Editor, Newsline

Enriching Professional Lives

The Society of Nuclear Medicine actively inaugurates and participates in programs and events to enrich its members' professional lives. SNM advances the highest standards in the practice of nuclear medicine and molecular imaging, addresses socioeconomic and governmental issues that significantly affect our profession, and promotes and maintains the highest standards of research and education. SNM has set out on a strategic course, with the aim to go as far as it can professionally—and then go even farther.

By Examining Health Care Policy and Practice

Members of our Committee on Health Care Policy and Practice are examining our profession's pressing issues. In examining pay-for-performance issues, committee members are developing procedure guidelines for myocardial perfusion, for general imaging, and for the use of radiopharmaceuticals. Committee members, headed by Robert Henkin, MD, are also studying same-day PET/CT, the American College of Radiology's designated physician imager program and our own physician-directed quality program, and supplying information regarding the credentialing of nuclear medicine physicians to interpret CT and PET/CT.

Entwined with this work will be the activities of the members of 2 other newly developed bodies: the Phase IV and Clinical Trials Committees. SNM is in the process of developing standards for using integrated PET/CT systems and addressing equipment specifications, image acquisition protocols, supervision, interpretation, professional qualifications, and safety. Work on PET/CT standards grew out of discussions with allies and resulted in publication of "Concurrent PET/CT with an Integrated Imaging System: Intersociety Dialogue from the Joint Working Group of the American College of Radiology, the Society of Nuclear Medicine, and the Society of Computed Body Tomography and Magnetic Resonance."

By Establishing a Molecular Imaging Focus

SNM's Nuclear Medicine Clinical Trials Group has been structured as a limited liability company, and its members now have the framework and infrastructure necessary to conduct multicenter clinical trials—with an emphasis on molecular imaging. Over time, these small trials are expected to encompass all the interests and possible applications of molecular imaging and diagnostic and therapeutic nuclear medicine. For example, clinical trials may be run to evaluate the effectiveness of new therapeutic radiopharmaceuticals or of using PET imaging as a surrogate marker for clinical outcomes when evaluating new therapeutic interventions.

Officially launched this past summer, the Molecular Imaging Center of Excellence (COE) is dedicated to all aspects of molecular imaging for the detection and management of disease. The center and its board members are responsible for developing all society-sponsored continuing education programs in molecular imaging. It focuses on significant issues important to the translation of new developments in molecular imaging to clinical practice and works closely with the Clinical Trials Group regarding the development of protocols for translational research. Molecular Imaging COE members will work with industry representatives to identify opportunities for cooperative programs in education and research in the field of molecular imaging.

Peter S. Conti

Our talks with allies about the field of molecular imaging continue. We recently cosponsored a meeting with the Radiological Society of North America and the participants from the first Molecular Imaging Summit in Chicago. We discussed the advantages of a group approach with members of Congress, the National Institutes of Health (NIH), and other federal agencies when it comes to seeking nuclear and molecular imaging research funding. SNM officers suggested that two subcommittees be developed: one to determine opportunities to network with government leaders and one to explore applying for institutional research training grants and providing feedback on NIH "roadmap" and "blueprint" initiatives in identifying major opportunities and gaps in biomedical research.

By Focusing on PET, Governmental Issues

SNM has joined allied organizations in supporting the Uniform Protocols for Imaging in Clinical Trials. A joint committee will establish widely acceptable standard protocols for PET, MR, and CT imaging in clinical trials; map out an annual strategy; and seek outside funding to support activities.

SNM officers have worked with representatives of the Food and Drug Administration (FDA) and have been informed in advance of that agency's proposed Current Good Manufacturing Practices regulation for the production of PET drugs. This regulation, along with a draft guidance document, will ensure that PET drug products meet safety, identity, strength, quality, and purity requirements. This is a major step forward in health care for patients, assuring that individuals are receiving high-quality drugs. SNM leaders have had consistently good dialogue with FDA officers on related issues and are encouraged to hear that progress is being made on the exploratory investigational new drug process. SNM's PET/CT coalition will continue to work on educating representatives of the Centers for Medicare & Medicaid on the benefits of PET/CT and advocate for its coverage.

Established more than 2 years ago, SNM's PET Center of Excellence is dedicated to all aspects of the development and utilization of PET and PET/CT in the detection and management of disease. The center focuses on educational programs and practical issues directly related to PET and PET/CT, including clinical practice, procedure guidelines, and reimbursement. The center, which has 1,800 members, will sponsor a continuing medical education track at the Annual Meeting in San Diego, CA, and a special workshop for the development of protocols for PET/CT dual-modality imaging. The center recently held its first election, selecting the following officers: James W. Fletcher, MD, president; Homer A. Macapinlac, MD, vice president; and Nancy M. Swanston, CNMT, RT(N), secretary/treasurer.

SNM met with representatives of the Nuclear Regulatory Commission (NRC) and discussed the Energy Policy Act of 2005, which grants NRC authority over naturally occurring and accelerator-produced materials. We will continue to support regulations that guard the public from unnecessary exposure to radiation while simultaneously protecting medical/scientific accessibility to these materials for nuclear medicine procedures and research.

By Promoting Education, Research

Our outstanding education program continues to grow to meet the needs of our members, as illustrated by the recent launching of Lifelong Learning and Self-Assessment Program modules to meet maintenance of certification requirements. Equally important is our responsibility to support and present research. For 6 straight years, the quality and influence of *The Journal of Nuclear Medicine* has continued to rise, moving from third to second place among nuclear medicine, radiology, and medical imaging journals, based on its impact factor, an estimate of the citation rate of the journal's papers. This growth in influence and prestige underscores the importance of the scientific and clinical research we publish each month.

Support for education and research continues to grow. For 2006, the Education and Research Foundation and the Professional Development and Education Fund are providing more than $240,000 for SNM- and SNMTS-sponsored scholarships, research grants, awards, and programs. This generous increase in support is made possible by corporate and individual donors committed to helping SNM and SNMTS extend opportunities to the molecular imaging community.

As SNM continues to enrich the profession this year, we will be able to live with greater vision and a finer spirit of achievement.

Peter S. Conti, MD, PhD, FACR, FACNP
President, SNM

Preparing for the Future

The Society of Nuclear Medicine Technologist Section is meeting the future head on: its officers have deliberated—and support—baccalaureate degree entry-level requirements for nuclear medicine technologists (NMTs) and the development of a master's degree–level nuclear medicine practitioner (NMP). These 2 initiatives will help us build our future, ensuring continued success for the nuclear medicine profession.

SNMTS leaders recently discussed these 2 initiatives at a 2005 education summit in Reston, VA, welcoming educators from certificate, associate, and baccalaureate programs as well as representatives from accrediting and professional organizations in the radiological sciences. Participating in the summit were 24 individuals representing the American College of Radiology, the American Registry of Radiologic Technologists, the American Society of Radiologic Technologists, the Joint Commission on Accreditation of Healthcare Organizations, the Joint Review Committee on Educational Programs in Nuclear Medicine Technology, the Nuclear Medicine Technology Certification Board, and the Section for Magnetic Resonance Technologists.

Summit participants examined education requirements and competencies needed for both the entry-level NMT and an advanced NMP. Our National Council of Representatives (NCOR), the SNMTS Executive Board, and SNM's board of directors approved position papers for both ideas at the society's Annual Meeting last summer. Summit participants realized the importance of developing a core curriculum and of bridging associate and certificate programs to a bachelor of science degree. It was also agreed that becoming an advanced NMP would involve earning a master's degree.

Valerie R. Cronin

SNMTS is especially grateful to the Professional Development and Education Fund, which has provided a $20,000 grant for the development of CT educational programs for technologists and 2 grants in the amount of $20,000 each for implementing the NMP program, which may be available as early as the 2007 fall term.

Entry-Level NMTs

SNMTS has observed that new advancements in multimodal imaging and therapy—and increasing demands for accountability—require increasing levels of skill and

knowledge not easily delivered within the current structure of entry-level educational programs. The summit allowed SNMTS officers to discuss the obstacles to implementing new recommendations about entry-level requirements and to brainstorm methods to implement such requirements.

Baccalaureate entry-level requirements will not affect current nuclear medicine technologists and will need to satisfy educational progression needs for those moving to the NMP level. This "2+2" model—2 years of general studies plus 2 years of professional curriculum—was identified as the most suitable baccalaureate model. Core curriculum and general education requirements to meet these needs were identified and discussed. Attendees produced a draft curriculum of 121–124 hours for an entry-level program that consists of prerequisites (general education), core curriculum (anatomy, chemistry, physics, algebra, statistics, etc.), professional technical courses (biomedical ethics, cross-sectional anatomy, instrumentation, radiation safety, patient care, emerging technologies, etc.), and electives (health care management, microbiology, genetics, cellular biology, etc.).

Summit attendees discussed the importance of NMTs achieving competence in the molecular sciences and of becoming technically competent, well-rounded, critical thinkers. It was voiced that to achieve professional status in the eyes of the federal government, the profession must require a bachelor's degree for entry level and that technologists need to be involved in lifelong learning.

SNMTS would like to have the new standards in place by 2010 and all NMT programs apply the baccalaureate degree by 2015. The priority of this process is to phase up—not phase out—existing programs. Another goal is to do a better job of communicating with members and stakeholders. To accomplish these goals, subgroups were appointed to focus on programmatic transition, core curriculum, collaborating with external stakeholders, and outreach to the nuclear medicine community.

Advanced Practice NMT

As part of its most recent strategic plan, SNMTS was charged with evaluating the need and the desire for an advanced level of clinical practice for NMTs. As the profession of nuclear medicine has matured and changes in health care have occurred over the past years, many NMTs have taken on roles in the clinical practice setting that are generally considered over and above the entry-level practice domain. Today, technologists may be asked (under the supervision of a physician) to administer interventional drugs, stress and monitor cardiac patients, and/or obtain an informed consent for specified procedures. NMTs must acquire new skills to keep up with technically complex SPECT and PET imaging in the new world of molecular imaging. Technologists and physicians have been surveyed about—and are supportive of—the development of an advanced nuclear medicine practitioner.

Summit participants discussed the competencies and curricular requirements for developing a master's degree–level NMP program—a new level of opportunity for SNMTS members. It was agreed that the curriculum will be geared toward a general practitioner—rather than a specialist—and that the length of the program should be approximately 2 years. The proposed competencies will be presented to NCOR and Executive Board members for approval at this month's SNM's Mid-Winter Educational Symposium.

This year, SNMTS will continue to build the future of the nuclear medicine profession for our members and nonmembers alike.

Valerie R. Cronin, CNMT, FSNMTS
President, SNMTS

Delivering Quality

The quality of the Society of Nuclear Medicine's programs, courses, meetings, products, and services is the result of high intention, sincere effort, intelligent direction, and skillful execution. Guided by SNM leaders, it is the society's habit to provide the best for our members—and this year's balanced, fiscally sound budget continues to deliver crucial programs and services to 16,000 physician, technologist, and scientist members.

In Knowledge Power

The words *groundbreaking*, *improved*, and *powerful* aptly describe our diverse educational programs. We successfully launched our Lifelong Learning and Self-Assessment Program, allowing nuclear medicine health care professionals to fulfill maintenance of certification requirements. Self-assessment modules will be released throughout the year, providing online continuing education to all our members. In addition, the SNM Learning Center was reorganized, focusing on advanced programs with a wider range of topics rather than on basic PET workshops. Society officers will continue to monitor trends in educational offerings to provide the most current topics, keeping the center offerings relevant to members—

(Continued on page 19N)

Virginia Pappas

(Continued from page 14N)

for example, through online courses and articles, board reviews, and case studies. Every year, our Mid-Winter Educational Symposium and Annual Meeting, with its more than 1,000 scientific papers, posters, exhibits, and CE courses, deliver highly rated educational experiences. As part of maintaining our quality program, our staff is complying with new Accreditation Council for Continuing Medical Education guidelines for educational offerings.

We have instituted a Molecular Imaging Speakers Bureau with experts who can address nuclear cardiology, metabolic imaging, and general nuclear medicine. Funded through a GE Healthcare educational grant, this program allows an SNM member to make presentations that reach a wide variety of medical professionals, including referring physicians such as clinical oncologists, primary care physicians, neurologists, cardiologists, and pulmonologists.

To guide our specialty, we need to keep our eyes on key aspects of the nuclear medicine field. We're doing that with the "Nuclear Medicine Workforce in 2005." The first report of a larger, 3-year study of physicians and technologists—designed to provide information about personal demographics, employment, career paths, and workplace issues in this country—has been completed.

In Member Communications

As individual members and as members of committees, councils, or chapters, the society invites you to participate in its many professional, educational, and networking activities. Our 8 councils have been restructured and rejuvenated. Councils have planned and expanded educational offerings in their specialties with conference sessions, categorical sessions, continuing medical education courses, and workshops and have communicated research developments, professional news, case studies, and regulatory information to members via printed newsletters and e-letters, as well as through Web sites and communities. In addition, SNM's 13 state and regional chapters offer a unique way to network and share ideas with colleagues.

Opportunities are also available for those new to the profession. As a member of our Young Professionals Community—nuclear medicine residents, fellows, and young physicians and scientists—find a vital forum that gives you the opportunity to impact training and career development. And by adhering to recently drafted core values, SNM staff is emphasizing the importance of member and customer satisfaction with all interactions.

In Industry Relationships

Working with industry ensures that the research undertaken is relevant and can be practically applied. SNM collaborates with the commercial representatives of its Nuclear Medicine Industry Leaders Working Group on advocacy issues with the Food and Drug Administration and the Centers for Medicare & Medicaid Services and on support for physician outreach, educational initiatives, and international programs.

Our Industry Partnership Program is aimed at encouraging collaborative efforts with industry to promote rapid advance and innovation in medical care through molecular imaging. This year, industry and SNM leaders will discuss molecular imaging basic research, clinical issues, instrumentation, and drug discovery during an Industry Molecular Imaging Summit. Members of our Molecular Imaging Center of Excellence (COE) will use this input to create topical activities and educational programs.

In Public Impact

Your society worked tenaciously behind the scenes in Washington, DC, to counter cuts in basic and clinical nuclear medicine research from the Department of Energy's FY 2006 budget. Within hours of the budget's original release, SNM developed an action plan to counter the proposed budget cuts. Thousands of society members sent e-mails and letters to the chairs and members of key committees in the House and Senate. In addition, we contacted other associations and industry leaders to join our efforts and met with Capitol Hill health care champions. Unfortunately, in spite of all our actions, $23 million was cut from the Biological and Environmental Research Medical Applications and Measurement Science program. SNM will continue to work with congressional leaders to fully fund the program for FY 2007.

SNM continues its outreach efforts with members of numerous allied groups. For example, we recently participated in a meeting with the Health Professions Network, a premier group of health care practitioners—including educators, accreditors, and administrators—working to positively impact the delivery of high-quality patient care.

Millions of people have read or heard about SNM and its members over the past year through an increased emphasis on public relations, which brings more news about you and your work to professional and consumer publications. Also, our Annual Meeting was recently voted as one of the top 10 association/trade show/CME event/imaging-related educational programs in the first annual *Medical Imaging* Industry Top 10.

As you can see, these are but a few examples of how SNM remains committed to providing high-quality programs and services—and a future of value—for members and nonmembers.

Virginia Pappas, CAE
Chief Executive Officer, SNM

Education and Research Foundation for the SNM

The Education and Research Foundation (ERF) for the Society of Nuclear Medicine had a successful year in 2005 due to the generosity of the many members of SNM as well as industry. Its relationship with the SNM through the Strategic Alliance has continued and evolved to truly become a collaborative effort that has and will continue to benefit both organizations and nuclear medicine. Since the society assumed the responsibility of awarding the grants and awards that were previously the responsibility of the foundation, the ERF has been able to focus on its primary mission: raising funds to further the art and science of nuclear medicine.

At the 2006 SNM Annual Meeting in Toronto, Canada, the generosity of the nuclear medicine community was recognized by the foundation on the Honor Roll of Donors and was highlighted by the award of round-trip airline tickets for 3 winners in a drawing held at the ERF booth.

The ERF received more than 500 gifts in 2005, including a $25,000 grant from Mallinckrodt, which will support a new award in 2006. Digirad Corporation also provided $10,000 for a 2006 pilot research grant to be made in memory of Dr. William Ashburn. The Alavi family generously gave more than $80,000 to increase the Alavi Fund, which supports several awards made by the SNM. These generous donations enabled the ERF to provide more than $100,000 to support SNM grants and awards for 2005 and more than $136,000 in support for 2006. A great number of SNM members provided the ERF with gifts as well during this year. Most significantly, the leadership of the society generously supported the ERF fundraising campaign.

In 2005, the ERF supported 30 Paul Cole scholarships of $1,000 each and 5 Pilot Research Grants, one of which was the $10,000 Blahd Pilot Research grant. In addition, 7 student fellowships, each providing $3,000 for a medical or graduate student to spend a summer doing research in nuclear medicine, were supported by the foundation, as were several other awards, including the Tetalman Award. The Alavi Fund also provided for 62 subscriptions to *The Journal of Nuclear Medicine* (*JNM*) for institutions in developing countries, as well as a number of awards for articles written by nuclear medicine trainees and published in *JNM*.

Sue Weiss

After the tragic death of Dr. Robert Lull, the SNM, American College of Nuclear Physicians, American Board of Nuclear Medicine, and ERF together established a fund in his name. To date more than $25,000 has been given to the fund by members and friends of Dr. Lull. Because Dr. Lull was an outstanding educator and dedicated to teaching, the funds will be used to support young nuclear medicine professionals. The 4 organizations will determine the specific kind of awards that the fund will support.

At the fall retreat in November, the ERF board made plans for the 2006 fundraising campaign. The 2006 campaign year will again be a cooperative effort with the SNM. The foundation will focus on individual donations, and the SNM will focus on corporate contributions. To meet the needs of the molecular imaging and nuclear medicine community, the foundation looks forward to being able to increase its support of the SNM grants and awards program. The generosity of the members of the SNM will help to make this possible. Please remember the foundation as you consider your charitable giving in the coming year.

Sue Weiss
Executive Director
Educational and Research Foundation for the SNM

SNM Government Relations Report

Department of Energy

The administration's FY 2006 budget request for the Department of Energy (DOE) Office of Science cut approximately $23 million from the Medical Applications and Measurement Science program within the Office of Biological and Environmental Research (OBER)—a program that supported more than 80 basic nuclear medicine research projects in educational institutions, national laboratories, and private companies across the United States. SNM led a coalition of like-minded specialty societies and patient advocacy groups on a long government relations campaign to get the money reinstated through the Congressional Energy and Water Development Appropriations Subcommittees. After an uplifting victory in the House of Representatives,

(Continued on page 22N)

Hugh Cannon

(Continued from page 20N)
the Senate unfortunately remained silent on the issue. In the version of the bill that ultimately became law, the House and Senate appropriated the money but committed it to specific, "earmarked" projects rather than to basic nuclear medicine research.

Although the loss was devastating for basic research projects formerly funded through the DOE OBER, the campaign to restore the program ultimately caught the administration's attention, and, as a result, the DOE, National Institutes of Health, and National Academy of Sciences will collaborate on a study of the future of U.S.-funded nuclear medicine research in 2006. In the meantime, SNM will continue to fight for basic research and will focus future efforts on finding a permanent home for these projects.

Coding and Reimbursement

Led by Gary Dillehay, MD, the SNM Coding and Reimbursement Working Group compiled and submitted comments to the Centers for Medicare & Medicaid Services (CMS) regarding the 2006 Healthcare Common Procedure Code System (HCPCS). Due in part to the committee's comments, the 2006 file contains significant changes suggested by SNM for many of the radiopharmaceuticals—specifically, 32 new, 24 revised, and 44 deleted radiopharmaceutical HCPCS Level II codes took effect January 1. At the request of the nuclear medicine community, the CMS HCPCS Workgroup implemented a simplified and user-friendly new standard format for radiopharmaceuticals, effective 2006. Also, all codes were changed to "A" series HCPCS codes, which will break down site-of-services variations for 2006. For the long haul, these radiopharmaceutical HCPCS Level II changes are significant accomplishments for the SNM.

The SNM Coding and Reimbursement Working Group also compiled and submitted comments regarding the 2006 Hospital Outpatient Prospective Payment System (HOPPS) rule and the 2006 Physician Fee Schedule rule to the CMS. The SNM was successful in many of their comments and suggestions, as evidenced in both final rules. The SNM plans to meet with CMS on some outstanding issues in 2006 regarding 2007 payments for many nuclear medicine procedures.

Nuclear Regulatory Commission

As part of an ongoing effort to improve relations with the Nuclear Regulatory Commission (NRC), SNM members Terence Beven, MD, Alan Packard, PhD, Gary Dillehay, MD, and Roy Brown participated in meetings regarding Section 651(e) of the Energy Policy Act of 2005, which granted the NRC regulatory authority over naturally occurring and accelerator-produced radioactive materials (NARM).

SNM took the position of supporting regulations that would guard the public from unnecessary exposure to radiation while simultaneously protecting medical/scientific accessibility to accelerator-produced materials for nuclear medicine procedures and research. However, SNM warned the NRC against duplicative regulatory burden that would stifle the benefits of PET and SPECT through delays, double fees, etc. SNM requested that NRC staff carefully weigh the public benefit gained from future NARM regulations against the potential costs and burdens to scientific progress, and, more important, patient care.

Food and Drug Administration

Led by Henry VanBrocklin, PhD, a working group compiled and submitted SNM comments regarding exploratory investigational new drug studies and PET drug Current Good Manufacturing Practices rule/guidance. The Food and Drug Administration (FDA) continues to work with nuclear medicine experts on a wide variety of topics, and collaboration between the FDA, medical societies, and industry continues to be beneficial for everyone involved, particularly patients in need of nuclear medicine procedures.

USP

Led by Joseph Hung, PhD, the SNM Committee on Pharmacopeia (COP) compiled and submitted comments regarding proposed revisions to U.S. Pharmacopeia (USP) <797>. The SNM COP continues to be a premier source of USP knowledge within the nuclear medicine community and is actively involved with relevant USP expert committees.

Hugh Cannon
SNM Director of Public Affairs, SNM

Physics Applications in Nuclear Medicine: Organization and Progress

The year 2005 was again a year of significant progress in the area of physics applications in nuclear medicine. Significant developments were seen in detector development and reconstruction technology, and new tools became available. The dosimetry community organized several important compendia of literature resources. Electronic resources continued to be developed and disseminated, as is the trend in almost all areas of daily professional life.

(Continued on page 24N)

(Continued from page 22N)

Instrumentation and Analysis Innovations

The Annual Meeting of the SNM included papers chronicling promising technical developments in hardware and image reconstruction methods to improve the quality of clinical and research practice. The ability to identify depth of interaction achieved with Phoswich-type area detectors and multielement, multilevel block detectors with fast signal processing techniques promises improved PET and SPECT image resolution. A dual-ring system that uses both Compton coincidence and traditional 511-keV PET imaging was shown to produce spatial resolution better than 0.7 mm (*1*). A Medical Imaging Conference in the Institute of Electrical and Electronics Engineers Nuclear Sciences Symposium in October 2005 provided numerous examples of what is in the pipeline for clinical use. Improvements in scintillators and semiconductors for radiation detectors continue. Pixelated detectors can produce higher resolution than area detectors, and results obtained with silicon and with the higher stopping power of cadmium zinc telluride (CZT) are useful for direct imaging of the positron as well as PET applications in different embodiments (*2,3*). Silicon detector arrays are promising for low-energy SPECT imaging (*4*). The scintillator $LaBr_3$ is becoming available and being tested for use in gamma cameras sooner than had been predicted (*5*). Its high light output and fast decay time hold should lead to improved PET system performance, and the prospect of time-of-flight PET is being revisited (*6*). Improved arrays of avalanche photodiodes are now commercially available. Because they are unaffected by magnetic resonance fields, they hold real promise for concurrent small animal PET imaging in clinical MR imaging environments, and this could be as important as the addition of CT has been to PET and SPECT devices (*7,8*).

Dedicated breast-imaging systems for 3- and 4-dimensional PET, SPECT, and ultrasound imaging are in late stages of development, and initial clinical tests are anticipated in the coming year. Better geometry and increased spatial sampling are used and needed to achieve the high sensitivity and resolution needed for practical use in routine breast imaging. Multipinhole aperture systems pioneered by Barrett and the University of Arizona group for dynamic SPECT patient studies have moved a step closer to implementation on standard 2- and 3-headed clinical systems. The new systems are adapted primarily for small animal studies and provide the needed ultra-high resolution (0.2–0.5 mm). Clinical applications are expected based on systems developed and being tested by university research groups in Utrecht, The Netherlands (*9*), Philadelphia, PA, (*10*), and Jülich, Germany (*11*). Commercial companies are likely to market various systems and components in the coming year. One multipinhole aperture system is in the process of being marketed commercially for retrofitting clinical SPECT systems as high-resolution small animal imagers, based on technology from the Jülich group, and other companies are expected to market different models of collimator inserts.

Improved reconstruction algorithms continue to emerge. Cone beam reconstruction in the new generation of fast spiral multidetector CT systems has taken advantage of improvements in algorithms, and SPECT implementations have been reported (*12*) and reconstruction methods presented for use in nonuniform attenuating media (*13*).

A commercial camera was shown at the 2005 RSNA for nuclear cardiology applications which uses 10 CZT modules arrayed around a semicircle and was advertised to provide the same spatial resolution obtained with gamma cameras imaging ^{99m}Tc or ^{201}Tl in 1/10–1/20 the time currently used in clinical studies (*14*).

Much of the ongoing activity in universities, national laboratories, and industry is benefiting from close collaborations among groups with parallel goals. Great benefits are derived from these collaborations. A major problem that needs to be resolved relates to the availability of radioactive nuclides for use in the development and testing of new ideas and in the development of reliable, cost-effective means of disseminating them for widespread use. Most of the tracers available 20–30 years ago are no longer available. Even the best imaging device is not very effective without a strong signal from the targeting tracer that allows the production of a useful/meaningful image. The improved radiotracer availability problem has been recognized and addressed without success for at least 25 years, and we can only hope that this remaining roadblock can be removed.

Radiation Dosimetry and Radiobiology

The Journal of Nuclear Medicine (*JNM*) kicked off the year with a bang with the special supplement to the January issue entitled "Clinical Practice of Molecular Radiotherapy," organized by Steve Larson and Eric Krenning. In what was dubbed a "pragmatic perspective" by these editors, 25 superb articles on the practice of radionuclide therapy were penned by a "who's who" in this field (*15*). Overview articles and status reports on current technology in this area were given by contributors such as Kassis, Adelstein, deJong, Sgouros, Krenning, Pauwels, Sharkey, Goldenberg, Wahl, Zalutsky, and Buchsbaum, to name only a few. This supplement occupies a space on the bookshelf along with other authoritative references, separate from our normal collections of month-to-month journals. It is not possible in the space available here to spell out the important contributions from each of the 25 articles. Suffice it to say that this supplement is a landmark publication and necessary reading for anyone working in this field.

Similarly, Lassmann and Brans published the edited proceedings of the First International Symposium on Radionuclide Therapy and Radiopharmaceutical Dosimetry, held in Helsinki, Finland, in Sept 2004, in *Cancer Biotherapy and Radiopharmaceuticals* (*16*). Many important papers

(Continued on page 26N)

(Continued from page 24N)

discussing image quantification, dosimetric techniques, radiation biology, microdosimetry, and other topics were covered by highly qualified and experienced researchers. As with other dosimetry conference proceedings from the historical series dating back to 1970, these volumes should be within easy access for all dosimetry professionals.

The loss of Hal Anger this year was deeply mourned by those who knew and admired him, as well as by the many others whose work was made possible by his many contributions to nuclear medicine instrumentation. He was a modest man who worked alone, with the support of University of California Lab staff when needed. Without his invention of the gamma camera and its many embodiments, nuclear medicine's emergence as a medical specialty would have been much delayed. The long history of fundamental contributions from the Donner Laboratory at the University of California derive from the contributions he made as an electronic genius left to work alone in a well-endowed institution.

We noted also with deep sadness this year the passing of 2 important long-time contributors to the fields of radiation biology and dosimetry, Katherine Lathrop, a pioneer in the study of radiotracer use and radiobiology (*17*), and Jim Robertson, who contributed heavily to the understanding of radiotracer use and who gave considerable support to radionuclide production during his work with the Department of Energy (DOE) for many years (*18*). Both were longtime active members of the Medical Internal Radiation Dose (MIRD) Committee.

Cuts in DOE funding for the Office of Biological and Environmental Research (BER) caused a swift reaction by SNM leadership and others to attempt to minimize reductions in funded programs that have been important to progress in basic physics research in nuclear medicine activities for many years (*19*). Current funding levels are significantly reduced from previous levels, and many historically good and productive research programs are feeling the pinch.

A few other items of interest:

- Mike Welch (*20*) updated his "Potential and Pitfalls of Therapy with α–Particles," with reference to articles by Pozzi and Zalutsky (*21*), among others.
- Similarly, Brechbiel (*22*) provided an update on the use of Auger emitters for targeted therapy, noting a new contribution in *JNM* in this area (*23*).
- Dosimetry for ^{201}Tl-chloride should hardly be considered "news," but a new publication in 2005 by Thomas and colleagues (*24*) reestablished standard dosimetry for this agent, with the focus on correcting an important overestimate in testes dose that had been influencing published dose estimates for this compound for more than 2 decades.
- Brix and colleagues (*25*) performed an interesting investigation into combined effective dose from CT and radiopharmaceutical exposures in PET/CT studies and suggested that attention be paid to optimization of patient exposures where possible. Radiation dosimetry in diagnostic medical studies is frequently not considered with the same seriousness as those in therapeutic studies, for obvious reasons. Nonetheless, attention to cumulative patient dose from repeated studies (and from different modalities) and attempts to optimize and reduce dose where possible are always wise.
- A nice summary of available radionuclides and radiopharmaceuticals was given by Ed Silberstein in the May issue of *JNM* (*26*).

Electronic Resources

The RAdiation Dose Assessment Resource (RADAR) Web site (www.doseinfo-radar.com) continued to receive heavy traffic for the free dissemination of standardized dose estimates, decay data, absorbed fractions, dose conversion factors, information on radiobiology and dosimetry literature, and other material. Published articles support the scientific basis for the data on this site (*27–29*). In 2004, the OLINDA/EXM software, the purported successor to the MIRDOSE 3 code, was released, and an article in *JNM* in 2005 established its technical basis (*30–32*). Vanderbilt University continues distribution of the code since receiving Food and Drug Administration approval through a 510(K) mechanism in 2004.

A number of interesting e-mail lists (NucMed, RadPharm, PET-mail, Medical Imaging [Archive-Comm-L], Radsafe, Dose-Net, and others) exist for exchanging information actively with other interested parties daily by e-mail. Subscriptions are free, and digest versions (once-per-day summaries of all posts) are usually available. A large number of Yahoo groups also exist that have application to this area of science (but which are too numerous to mention) and use a bulletin-board approach to exchange information. See http://hps.org/resources.html for more details.

Michael Stabin, PhD
A. B. Brill, MD, PhD
Vanderbilt University
Nashville, TN

REFERENCES

1. Park S-J. First experimental results from the very high resolution PET concept. *J Nucl Med.* 2005;46(suppl 2):51P.
2. Huh SS, Burdette D, Chesi E, et al. A pixelated silicon positron sensitive imaging probe. In: *2005 Nuclear Science Symposium and Medical Imaging Conference: Abstracts.* Proceedings of the IEEE Nuclear Sciences Symposium and Medical Imaging Conference; Oct. 23–29, 2005; San Juan, Puerto Rico. Piscataway, NJ: IEEE; 2005:319.
3. Stickel JR, Shah Ks, Him H, Cirignano L, Cherry S. Pixelated cadmium zinc telluride (CZT) arrays: characterization and applications to positron emission tomography (PET). In: *2005 Nuclear Science Symposium and Medical Imaging Conference: Abstracts.* Proceedings of the IEEE Nuclear Sciences Symposium and Medical Imaging Conference; Oct. 23–29, 2005; San Juan, Puerto Rico. Piscataway, NJ: IEEE; 2005:219

4. Peterson TE, Furenlid LR, Wilson DW. Multi-pinhole SPECT imaging with silicon strip detectors. In: *2005 Nuclear Science Symposium and Medical Imaging Conference: Abstracts.* Proceedings of the IEEE Nuclear Sciences Symposium and Medical Imaging Conference; Oct. 23–29, 2005; San Juan, Puerto Rico. Piscataway, NJ: IEEE; 2005:108
5. Pani R, Cinti MN, Pellegrini R, et al. LaBr3:Ce scintillation camera. In: *2005 Nuclear Science Symposium and Medical Imaging Conference: Abstracts.* Proceedings of the IEEE Nuclear Sciences Symposium and Medical Imaging Conference; Oct. 23–29, 2005; San Juan, Puerto Rico. Piscataway, NJ: IEEE; 2005:267.
6. Karp JS, Kuhn A, Perkins AE, et al. Characterization of TOF PET scanner based on lanthanum bromide. In: *2005 Nuclear Science Symposium and Medical Imaging Conference: Abstracts.* Proceedings of the IEEE Nuclear Sciences Symposium and Medical Imaging Conference; Oct. 23–29, 2005; San Juan, Puerto Rico. Piscataway, NJ: IEEE; 2005:253.
7. Grazioso R, Zhang N, Corbeil A, et al. APD-based PET detector for simultaneous PET/MR imaging. In: *2005 Nuclear Science Symposium and Medical Imaging Conference: Abstracts.* Proceedings of the IEEE Nuclear Sciences Symposium and Medical Imaging Conference; Oct. 23–29, 2005; San Juan, Puerto Rico. Piscataway, NJ: IEEE; 2005:258.
8. Judenhofer MS, Siegel SB, Swann BK, et al. Development of an APD-based PET detector for a simultaneous PET and 7-Tesla MRI imaging. In: *2005 Nuclear Science Symposium and Medical Imaging Conference: Abstracts.* Proceedings of the IEEE Nuclear Sciences Symposium and Medical Imaging Conference; Oct. 23–29, 2005; San Juan, Puerto Rico. Piscataway, NJ: IEEE; 2005:237.
9. Beekman FJ, van der Have F, Vastenhouw B, van der Linden AJA, Burbach JPH, Smidt MP. U-SPECT-I shows molecular dynamics in the living mouse brain at sub-minute and sub-mm resolution. In: *2005 Nuclear Science Symposium and Medical Imaging Conference: Abstracts.* Proceedings of the IEEE Nuclear Sciences Symposium and Medical Imaging Conference; Oct. 23–29, 2005; San Juan, Puerto Rico. Piscataway, NJ: IEEE; 2005:297.
10. Cardi CA, Cao Z, Thakur ML, Karp JS, Acton PD. Pinhole PET (pPET): a multi-pinhole collimator insert for small animal SPECT imaging on PET cameras. In: *2005 Nuclear Science Symposium and Medical Imaging Conference: Abstracts.* Proceedings of the IEEE Nuclear Sciences Symposium and Medical Imaging Conference; Oct. 23–29, 2005; San Juan, Puerto Rico. Piscataway, NJ: IEEE; 2005:257.
11. Schramm NU, Hoppin JW, Lackas C, Wirrwar A, Behe M. Advanced applications in multi-pinhole SPECT. In: *2005 Nuclear Science Symposium and Medical Imaging Conference: Abstracts.* Proceedings of the IEEE Nuclear Sciences Symposium and Medical Imaging Conference; Oct. 23–29, 2005; San Juan, Puerto Rico. Piscataway, NJ: IEEE; 2005:240
12. Sun MA, Izaquirre EW, Funk T. Small-animal helical SPECT scanner. In: *2005 Nuclear Science Symposium and Medical Imaging Conference: Abstracts.* Proceedings of the IEEE Nuclear Sciences Symposium and Medical Imaging Conference; Oct. 23–29, 2005; San Juan, Puerto Rico. Piscataway, NJ: IEEE; 2005:268.
13. Huang Q, Zeng Gl, Gullberg GT. Analytical reconstruction for helical cone-beam SPECT with non-uniform attenuation correction. In: 2005 *Nuclear Science Symposium and Medical Imaging Conference: Abstracts.* Proceedings of the IEEE Nuclear Sciences Symposium and Medical Imaging Conference; Oct. 23–29, 2005; San Juan, Puerto Rico. Piscataway, NJ: IEEE; 2005:247.
14. Spectrum Dynamics, Ltd. Haifa, Israel. Available at: www.spectrum-dynamics.com. Accessed on January 1, 2006.
15. Larson SM, Krenning EP. **A pragmatic perspective on molecular targeted radionuclide therapy.** *J Nucl Med.* 2005;46(suppl):1S–3S.
16. Lassmann M, Brans B, Behr T. Introduction: 1st International Symposium on Radionuclide Therapy and Radiopharmaceutical Dosimetry. September 4–8, 2004, Helsinki, Finland. *Cancer Biother Radiopharm.* 2005:20:45–46. Full text of papers from the conference appeared in this and subsequent issues of *Cancer Biother Radiopharm.* (2005;20:47–118,181–237; 317–371).
17. Gottschalk A. In memoriam: Katherine Austin Lathrop, 1915–2005. *J Nucl Med.* 2005;46(5):18N.
18. Thomas SR. In memoriam: James Sydnor Robertson, MD, PhD, 1920–2005. *J Nucl Med.* 2005;46(9):30N.
19. [no author] DOE medical research funding cut in FY 2006 budget; SNM calls for nuclear medicine community action. *J Nucl Med.* 2005;46(3):13N–16N.
20. Welch MJ. Potential and pitfalls of therapy with α–particles. *J Nucl Med.* 2005;46: 1254–1255.
21. Pozzi OR, Zalutsky MR. Radiopharmaceutical chemistry of targeted radiotherapeutics, part 2: radiolytic effects of ^{211}At particles influence *N*-succinimidyl 3-^{211}At-astatobenzoate synthesis. *J Nucl Med.* 2005;46:1393–1400.
22. Boswell CA, Brechbiel MW. Auger electrons: lethal, low-energy, and coming soon to a tumor cell nucleus near you. *J Nucl Med.* 2005;46:1946–1947.
23. Ginj M, Hinni K, Tschumi S, Schulz S, Maecke HR. Trifunctional somatostatin-based derivatives designed for targeted radiotherapy using auger electron emitters. *J Nucl Med.* 2005;46:2097–2103.
24. Thomas SR, Stabin MG, Castronovo FP. Radiation-absorbed dose from ^{201}Tl-thallous chloride. *J Nucl Med.* 2005;46:502–508.
25. Brix G, Lechel U, Glatting G, Ziegler SI, Münzing W, Müller SP, Beyer T. Radiation exposure of patients undergoing whole-body dual-modality ^{18}F-FDG PET/CT examinations. *J Nucl Med.* 2005;46:608–613.
26. Silberstein E. Radionuclides and radiopharmaceuticals for 2005. *J Nucl Med.* 46;2005(5):13N–14N.
27. Stabin MG, Siegel JA. Physical models and dose factors for use in internal dose assessment. *Health Phys.* 2004;85:294–310.
28. Stabin MG, da Luz CQPL. New decay data for internal and external dose assessment. *Health Phys.* 2002;83:471–475.
29. Stabin MG, Stubbs JB, Toohey RE. *Radiation Dose Estimates for Radiopharmaceuticals.* NUREG/CR-6345, prepared for: U.S. Nuclear Regulatory Commission, U.S. Department of Energy, U.S. Department of Health & Human Services. April 1996.
30. Stabin MG. MIRDOSE: personal computer software for internal dose assessment in nuclear medicine. *J Nucl Med.* 1996;37:538–546.
31. [no author] New internal radiation dose and modeling software; FDA approves commercial MIRDOSE successor. *J Nucl Med.* 2004;45(11):26N–28N.
32. Stabin MG, Sparks RB, Crowe E. OLINDA/EXM: The second-generation personal computer software for internal dose assessment in nuclear medicine. *J Nucl Med.* 2005;46:1023–1027.

The SNM Strategic Plan for Education

The SNM Committee on Education held a meeting on September 16, 2005, to review the society's educational program to ensure that it meets our strategic goals and the needs of SNM members and other health care professionals with an interest in nuclear medicine and molecular imaging. The committee considered 4 significant issues facing medical education:

1. Maintenance of certification (MOC);
2. Emerging technologies in nuclear medicine/molecular imaging;
3. The need for more online education; and
4. The fragmentation of nuclear medicine and molecular imaging.

These 4 issues will have a significant and long-term impact on the way health care professionals in nuclear medicine/molecular imaging choose to educate themselves and on how providers of education develop and implement educational activities.

The American Board of Medical Specialties (ABMS) MOC process is a major focus of the educational activities of the SNM. At the Mid-Winter Meeting in January 2004, the Board of Directors approved the business plan for

SNM's new Lifelong Learning and Self-Assessment Program (LLSAP), which has been developed to meet Part 2 of the new MOC requirements—continuous self-assessment. The first 4 modules were launched last December, with an additional 56 modules planned for introduction during 2006. Each module includes a syllabus with the latest information in the field, board-type multiple-choice questions with discussion of correct and incorrect answers, and interactive case studies with the opportunity for the participant to compare his or her report of the case with that of an expert. The cases utilizing PET/CT include images in Digital Imaging and Communication in Medicine format and software to create a virtual workstation for participants.

The SNM is also developing sets of interactive cases focusing on CT and PET/CT. These cases will help physicians meet the requirements for Part 4 of the ABMS MOC. The SNM will be working closely with the American Board of Nuclear Medicine to develop more tools for Part 4 over the next year.

Emerging technologies formed the second focus of discussion by the Committee on Education during its strategic planning meeting. Two years ago, the SNM began to make changes in its educational activities to accommodate the trend from PET to PET/CT fusion and other fusion imaging modalities. The Learning Center revamped its curriculum and offerings in January 2004, including the addition of more neurology PET/CT, cardiac PET/CT, and advanced oncology PET/CT workshops and symposia. In 2006, the Learning Center will add educational activities in CT and molecular imaging for physicians and in CT and cross-sectional anatomy for technologists.

Related to the issue of emerging technologies is the trend among health care professionals to rely increasingly on the Internet to access information and participate in educational activities. Data reviewed by the Committee on Education from a variety of sources, including the recent SNM Workforce Survey, confirmed this trend. As a result, many of the educational products offered in 2006 will be Web-based. The SNM Learning Center began to offer courses online in January, with plans to offer the advanced oncology PET/CT, neurology PET/CT, and cardiac PET/CT courses online during 2006. In addition, a new format with both online and live activities will be introduced this year for technologists. The Learning Center will offer a weekend CT workshop that includes online prerequisite courses. If this combination format is well received, more may be planned in the future. Additional future projects being planned by the SNM Education Program Development Committee include a case-based journal offering continuing education credit and online educational activities for SNM's scientist and pharmacist members.

Finally, there are many societies and organizations with an interest in nuclear medicine/molecular imaging, and within the SNM itself there are chapters, councils and centers of excellence. Many of these groups are vying to provide the nuclear medicine/molecular imaging professionals with educational programs. Among the action items targeted for this year as a result of the strategic planning meeting are efforts to collaborate with these organizations to share resources, expertise, and content to provide optimal educational activities for all members.

The Committee on Education has appointed a monitoring team to continually assess the needs of SNM members based on changes in technology and the marketplace and the success of current and new educational activities over the next year. The purpose of this team is to ensure that SNM's educational program continues to meet the needs of its members and to assist them in their ever-changing practices.

Tom R. Miller, MD, PhD
Chair, SNM Committee on Education

Alan H. Maurer, MD
Chair, SNM Education Programs Development Committee

N. Lynn Barnes, MEd
Director of Education, SNM

SNM Brain Imaging Council

The SNM Brain Imaging Council (BIC) has been active in the initial part of its 2005–2006 term. One of the goals for the council has been to draft procedure guidelines for ^{18}F-FDG PET brain imaging for SNM. Alan Waxman, MD, is heading a task force charged with drafting the guidelines. Work is ongoing at this point.

The BIC Board of Directors (BOD) will meet at the 2006 SNM Mid-Winter Meeting in Tempe, AZ, on February 11. At this meeting we will continue to pursue guideline development and also address the status of normal database compilation for ^{18}F-FDG PET brain images. Just as the normal database of ^{99m}Tc brain perfusion radiopharmaceutical SPECT was compiled and made available by the BIC, the goal for a normal database for ^{18}F-FDG PET brain scans will be to aid in the education and research missions of the BIC as the practice of brain imaging with PET becomes a major tool in clinical medicine. We have noted that the initial Centers for Medicare & Medicaid Services approval of ^{18}F-FDG PET in 2004 for differentiation of

David H. Lewis

(Continued on page 30N)

(Continued from page 28N)
Alzheimer's disease from frontotemporal dementia has led to more imaging studies for PET. With this emphasis, the BIC hopes to see even more expanded use in the future. In addition, the Kuhl–Lassen Award and potential recipients will be discussed at the BOD meeting in February.

Areas in which cutting-edge research continued in 2005 and into 2006 are exemplified by work being done at the University of Pittsburgh (PA), Washington University (St. Louis), the University of Pennsylvania (Philadelphia), and at the University of California at Los Angeles in the development of PET amyloid imaging in the brain. This technique is yielding insights into the pathophysiology of Alzheimer's disease and mild cognitive impairment. Frontiers of brain imaging research are also being expanded with small animal imaging of the brain with microPET and also optical imaging and MR imaging. It is also hoped that dopaminergic imaging will move from the research realm into clinical practice in North America, as it has in Europe.

For the SNM Annual Meeting in San Diego, CA, June 3–7, 2006, the BIC has planned and will sponsor a number of educational activities. First, on Saturday, June 3, will be a 1-day categorical seminar on "Biomarkers in Central Nervous System Diseases." In addition, continuing medical education sessions sponsored by the BIC will include 2 "Read with the Experts" sessions, a session on "Dopaminergic Imaging in Movement Disorders," the Kuhl–Lassen Award Lecture, and a session on "Practical Cerebrovascular Imaging with Nuclear Medicine." The BIC's mission is to enhance and support brain imaging education and to foster new investigators in brain imaging research. Thus, this year will see continuance of the Young Investigator's Award abstract session in the neurosciences presentations at the SNM Annual Meeting. We hope to see you in San Diego!

David H. Lewis, MD
Chair, SNM Brain Imaging Council

The Young Professionals Committee

The SNM Young Professionals Committee (YPC) has gained great momentum over the past year and a half, and I am delighted to provide this brief summary to update the nuclear medicine community on our ongoing and upcoming endeavors.

During the first half of the 2005–2006 year, the YPC's efforts focused on 2 major issues of interest to young professionals and the SNM: education and the current state of the nuclear medicine job market. The expanding use of fusion imaging with PET/CT and now SPECT/CT requires nuclear medicine physicians to become well versed in anatomic imaging for accurate functional image interpretation. There is concern that job availability has already or could become limited for those nuclear medicine physicians who are not formally trained or board certified in radiology. However, a paucity of data is available on the current state of the nuclear medicine job market to support this hypothesis.

As a first step, the YPC recently distributed a survey through the Nuclear Medicine Program Directors Association and our Web site to poll recent nuclear medicine graduates regarding their experience in finding a job in nuclear medicine. The overall objective of "The Nuclear Medicine Job Market Survey" is to gain a better understanding of the current state of the job market for nuclear medicine physicians. We anticipate that the data compiled from this survey will be used to help direct our efforts to those concerns that are most important to address.

In addition, the YPC is represented on the SNM Committee on Education. This committee has identified CT training for nuclear medicine physicians as an important educational issue.

At the 2005 Association of University Radiologists (AUR) meeting, YPC members had the opportunity to meet with an organization of chief radiology residents. As many readers are probably aware, the American Board of Radiology has decreased the amount of required training in nuclear medicine from 6 to 4 months, yet the number of topics radiology residents must master is increasing to include molecular imaging, therapy, and PET. The SNM is a logical organization to provide supplemental training in the areas in which radiology residents might not be receiving adequate instruction and experience during their general nuclear medicine training. Consequently, the YPC conducted a survey of radiology residents to gather data about which topics to cover and how to best present and distribute such educational materials. Approximately 140 radiology residents completed the survey, and the final data will be presented at the 2006 AUR Meeting in Texas.

A lot of work lies ahead for the YPC. In addition to completing the projects already described here, the YPC will sponsor online teaching files, and plans are underway for a workshop at the YPC luncheon at the 53rd SNM Annual Meeting in San Diego. The best "Young Professionals' Abstracts" will again be recognized at the

YPC luncheon. This year's awards will include both clinical and basic science categories.

A strong, enthusiastic core leadership has been assembled and our membership continues to grow. I am looking forward to an exciting year and, on behalf of the YPC, look forward to working with all of you.

Heather A. Jacene, MD
Chair, SNM Young Professionals Committee

From the Computer and Instrumentation Council

The year 2005 was busy for the SNM Computer and Instrumentation Council (CaIC), with much of the activity revolving around the Annual Meeting of the SNM, held last June in Toronto, Canada. Through the efforts of Tim Turkington, PhD, and David Cooke, MSEE, the council organized a categorical seminar on PET instrumentation that literally had standing room only. A continuing education session on PET/CT acceptance testing and quality control, along with an update on the Integrating the Healthcare Enterprise (IHE) initiative activities, was organized by George Zubal, PhD. As in the past, the CaIC sponsored the Young Investigator Symposium, with the award for the best presentation going to Brendan Vastenhouw of the Department of Nuclear Medicine, Image Sciences Institute, University Medical Center, Utrecht, The Netherlands, for his work: "Submillimeter Total-Body Mouse Imaging with U-SPECT I." At the Toronto meeting, the CaIC also inaugurated the Edward Hoffman Memorial award to honor Hoffman's outstanding scientific and service contributions to our field. The first recipient of the award was Simon Cherry, PhD, who gave an excellent talk and highlighted Hoffman's substantial influence on his own career.

The 2006 SNM Mid-Winter Meeting will be held in Tempe, AZ, on February 11–12, and the CaIC is organizing 2 of the sessions. The first will be "Clinical Implementation of Advanced Image Processing and Reconstruction Algorithms" and will feature presentations on commercially available software from both developers and users. Presentations in this session will include:

"Flash 3D, CT Attenuation Compensation and Scatter Correction," Hans Vija, PhD, Siemens Medical Solutions, Molecular Imaging.

"Wide-Beam Reconstruction Method for Shortening Scan Time of Gated Cardiac SPECT Perfusion Studies: A Preliminary Clinical Evaluation," Salvador Borges-Neto, MD, Duke University Medical Center, and Shuli Schwartz, UltraSPECT.

"Evolution: A Framework for Advanced SPECT Reconstruction with Compensation for Image Degrading Factors," Eric Frey, PhD, Johns Hopkins Medical Institutions.

"Fast, High-Quality Cardiac SPECT Using Astonish Reconstruction," Richard Meyers, MD, Radiological Associates of Sacramento, and Ling Shao, Philips Medical Systems.

The second session will focus on the new realm of SPECT/CT and will feature presentations by clinical users of each of the products. The program will include:

"Initial Clinical Experience with Siemens Symbia SPECT-CT," by Manuel D. Cerqueira, MD, and Frank DiFlippo, PhD, Cleveland Clinic Foundation.

"Specifications and Applications of an Integrated SPECT/Low-Output CT System: The GE Hawkeye," James A. Patton, PhD, Vanderbilt University Medical Center.

"Initial Clinical Experience with the Philips Precedence SPECT/CT System," Jack A. Ziffer, MD, PhD, Miami Baptist Cardiac and Vascular Institute.

The material presented in these sessions shares the common characteristics of being new, exciting, and ready for prime-time routine implementation in the clinic.

The CaIC remains active in the Digital Imaging and Communication in Medicine (DICOM) and IHE arenas through the tireless efforts of Jerry Wallis, MD. These activities include providing standards for presenting nuclear cardiology results on PACs and for reliable connectivity between different DICOM-compliant systems. This work promises to have both immediate and long-range significance for the nuclear medicine community.

The future plans of the CaIC include the 2006 SNM Annual meeting in San Diego, CA, in June, where we will be offering another categorical seminar and 2 continuing education sessions. The council is also working with Fred Fahey, DSc, to explore the possibility of including an information technology component to the Annual Meeting. Finally, the CaIC is putting together a syllabus summarizing the relevant information on nuclear medicine instrumentation and software with which a qualified expert should be familiar.

Mark T. Madsen, PhD
President, SNM Computer and Instrumentation Council

From the Correlative Imaging Council

The SNM Correlative Imaging Council (CIC) had a very productive year, with educational activities continuing to be our main function. At the 2005 SNM Mid-Winter Meeting, the CIC organized an educational track in PET/CT. Topics included PET/CT instrumentation, CT protocols and techniques, protocols and dose reduction techniques in children, and PET/CT evaluation in head/neck cancer, thorax, and abdomen. At the 2005 SNM Annual Meeting in Toronto, Canada, the CIC again presented a very timely categorical course titled, "Nuts and Bolts of PET/CT and Beyond." The course was well attended and covered a wide range of topics, including PET/CT in oncology, PET/CT in cardiology, and state-of-the-art pulmonary embolism evaluation using ventilation/perfusion lung imaging and spiral CT. At the conclusion of the session, the CIC held its annual business meeting.

One of the highlights of CIC activities in 2005 was a retreat held on August 6 in conjunction with a CT training course for nuclear medicine physicians, organized by our incoming president George Segall, MD. The Stanford University faculty gave the CT course, which was very helpful in continuing progress toward a potential and much-anticipated CT certification for nuclear medicine physicians. Useful resources for CT learning will also be compiled by the CIC and made available for ready reference.

The educational program was followed on the next day by a stimulating retreat for the board of directors (BOD) of the CIC at the lovely Thomas Fogarty Winery. Thanks are due to Dr. Segall for his excellent organizational efforts on both the educational CT course and the retreat. In the lovely surroundings of the winery, the BOD not only relaxed but also had a very fruitful brainstorming and strategy-planning session for CIC activities and future direction. Walter Wolf, PhD, our outgoing president, gave an excellent historical perspective of the council, to which he continues to be an invaluable resource.

The key outcomes of the discussions included a consensus that the CIC should continue to provide CT training courses for nuclear medicine physicians and future program content for the categorical seminar at SNM annual meetings. The BOD discussed and approved the motion that an organ- or system-based categorical course be presented in the future, as this would be the most helpful and appropriate for optimal patient management. Toward this goal, the first organ-based seminar is being planned to cover breast cancer and will be offered during the 2006 SNM Annual Meeting in San Diego, CA. The seminar will cover all aspects of breast cancer, including diagnosis, oncologic and surgical management, and future trends. The program is emerging as an exciting state-of-the-art session and should be well attended.

Lalitha Ramanna, MD
President, SNM Correlative Imaging Council

International Atomic Energy Agency Highlights

It was a very good year for the International Atomic Energy Agency (IAEA). Any year in which you win the Nobel Peace Prize can be counted as good, but this hard-working group saw a number of long-term plans come to fruition in 2005 and achieved significant milestones in other projects, some with important implications for the future of nuclear medicine.

Noting that "Since 1957, the IAEA has worked tirelessly and expertly to stem the proliferation of nuclear weapons and to promote the safe and peaceful uses of nuclear technology," the Norwegian Nobel Committee awarded the 2005 Nobel Peace price to Dr. Mohamed ElBaradei, director general, and the IAEA in equal shares. The IAEA announced that its share of the prize will be spent to use nuclear technology to solve some of the most basic problems in the developing world. Nuclear techniques to expand food resources and evaluate child development will target childhood nutrition problems, and, through the PACT program, training in radiation oncology will be expanded into areas of the developing world where the need is greatest. Dr. ElBaradei has

Mathew L. Thakur

From the Correlative Imaging Council

The SNM Correlative Imaging Council (CIC) had a very productive year, with educational activities continuing to be our main function. At the 2005 SNM Mid-Winter Meeting, the CIC organized an educational track in PET/CT. Topics included PET/CT instrumentation, CT protocols and techniques, protocols and dose reduction techniques in children, and PET/CT evaluation in head/neck cancer, thorax, and abdomen. At the 2005 SNM Annual Meeting in Toronto, Canada, the CIC again presented a very timely categorical course titled, "Nuts and Bolts of PET/CT and Beyond." The course was well attended and covered a wide range of topics, including PET/CT in oncology, PET/CT in cardiology, and state-of-the-art pulmonary embolism evaluation using ventilation/perfusion lung imaging and spiral CT. At the conclusion of the session, the CIC held its annual business meeting.

One of the highlights of CIC activities in 2005 was a retreat held on August 6 in conjunction with a CT training course for nuclear medicine physicians, organized by our incoming president George Segall, MD. The Stanford University faculty gave the CT course, which was very helpful in continuing progress toward a potential and much-anticipated CT certification for nuclear medicine physicians. Useful resources for CT learning will also be compiled by the CIC and made available for ready reference.

The educational program was followed on the next day by a stimulating retreat for the board of directors (BOD) of the CIC at the lovely Thomas Fogarty Winery. Thanks are due to Dr. Segall for his excellent organizational efforts on both the educational CT course and the retreat. In the lovely surroundings of the winery, the BOD not only relaxed but also had a very fruitful brainstorming and strategy-planning session for CIC activities and future direction. Walter Wolf, PhD, our outgoing president, gave an excellent historical perspective of the council, to which he continues to be an invaluable resource.

The key outcomes of the discussions included a consensus that the CIC should continue to provide CT training courses for nuclear medicine physicians and future program content for the categorical seminar at SNM annual meetings. The BOD discussed and approved the motion that an organ- or system-based categorical course be presented in the future, as this would be the most helpful and appropriate for optimal patient management. Toward this goal, the first organ-based seminar is being planned to cover breast cancer and will be offered during the 2006 SNM Annual Meeting in San Diego, CA. The seminar will cover all aspects of breast cancer, including diagnosis, oncologic and surgical management, and future trends. The program is emerging as an exciting state-of-the-art session and should be well attended.

Lalitha Ramanna, MD
President, SNM Correlative Imaging Council

International Atomic Energy Agency Highlights

It was a very good year for the International Atomic Energy Agency (IAEA). Any year in which you win the Nobel Peace Prize can be counted as good, but this hard-working group saw a number of long-term plans come to fruition in 2005 and achieved significant milestones in other projects, some with important implications for the future of nuclear medicine.

Noting that "Since 1957, the IAEA has worked tirelessly and expertly to stem the proliferation of nuclear weapons and to promote the safe and peaceful uses of nuclear technology," the Norwegian Nobel Committee awarded the 2005 Nobel Peace price to Dr. Mohamed ElBaradei, director general, and the IAEA in equal shares. The IAEA announced that its share of the prize will be spent to use nuclear technology to solve some of the most basic problems in the developing world. Nuclear techniques to expand food resources and evaluate child development will target childhood nutrition problems, and, through the PACT program, training in radiation oncology will be expanded into areas of the developing world where the need is greatest. Dr. ElBaradei has

Mathew L. Thakur

also announced plans to use his share of the prize for charitable purposes.

The Vienna symposium on radiopharmaceuticals was the nuclear medicine highlight of the IAEA year. It was attended by more than 220 basic scientists and clinicians from 70 countries, including North America, many countries in Europe, and more than 50 developing countries. Invited to speak at the opening ceremony were the representatives from the European Association of Nuclear Medicine (EANM; Dr. Ignasi Carrio), the Singapore Radiological Society, the World Federation of Nuclear Medicine and Biology (WFNMB; Dr. C. Lee), and the SNM (myself). I was glad to represent SNM as its immediate past president, not only because I was able to share with leading world radiopharmaceutical scientists and physicians some of the SNM activities to promote nuclear medicine in developing countries, but also because in my absence there would have been a void for SNM on the podium at the traditional European-type of formal opening ceremony in which other prominent biomedical organizations, such as EANM and WFNMB participated. Thanks to SNM for partially covering my travel expenses.

Scientifically, the symposium was a very good one. The topics ranged from novel diagnostic agents in oncology, neurology, and cardiology to therapeutic applications in oncology to rheumatoid arthritis. The topics also included production of radionuclides using cyclotrons and using low-, medium-, and high-neutron flux reactors. In issues related to federal regulations, restrictions associated with highly enriched uranium targets were discussed, and it was noted that certain developing countries with access to high-flux reactors are planning to use low-energy uranium targets, with some even going back to bombarding ^{98}Mo and developing ^{99}Mo/^{99m}Tc generators using "gel" columns onto which a relatively large quantity of molybdenum can be loaded.

It was also interesting to note that developing countries are eager to have cyclotrons, PET, and PET/CT scanners installed in rapidly increasing numbers. One speaker from Europe stated in his presentation that the fate of ^{99m}Tc may be "short lived" when cyclotrons and PET scanners are increasing in numbers so rapidly.

I was also impressed by the ways in which radiopharmacists and nuclear medicine experts who hail from different parts of the world work at IAEA throughout the year to promote nuclear medicine and the peaceful applications of nuclear energy in developing countries. Their creative ways of utilizing the relatively small amount of funds for education and research to promote capacity building in local production and utilization of radiopharmaceuticals for nuclear medicine applications in developing countries is inspiring. This not only properly serves the IAEA mission but also helps enormously the many deserving investigators in developing countries.

In brief, for me it was a scientifically rich, socially enjoyable, and professionally beneficial gathering. I am glad that, on behalf of SNM, I was able to participate in the meeting, which conveyed successfully SNM's contribution in promoting nuclear medicine in developing countries and our symbolic support for IAEA activities. These efforts may lead SNM to a closer partnership with the IAEA.

Mathew L. Thakur, PhD
Immediate Past President, SNM
Director, Radiopharmaceutical Research
Professor of Radiology & Radiation Oncology
Thomas Jefferson University
Philadelphia, PA

Council on Radionuclides and Radiopharmaceuticals

The Energy Policy Act of 2005

Congress passed the Energy Policy Act of 2005, and President Bush signed it into law on August 8, 2005. The bill contained 2 important sections for nuclear medicine. First, the bill assured a continued supply of high-enriched uranium (HEU) that is used to produce the isotopes ^{99}Mo and ^{131}I that are so important to nuclear medicine. The Council on Radionuclides and Radiopharmaceuticals (CORAR) supported this language with tremendous help from SNM and many people in the nuclear medicine community through letters to their congressmen and senators. The language in the bill will assure a continued supply of HEU until low-enriched uranium (LEU) technology is fully developed and commercially viable. The industry is currently developing LEU targets and alternate reactor technologies utilizing LEU. The act also gave the Nuclear Regulatory Commission (NRC) authority over specific nuclear materials.

NRC Jurisdiction Over ARM

The Energy Policy Act of 2005 broadened the definition of byproduct material to include accelerator-produced

radioactive materials (ARM). Before passage of the act, ARM was regulated by the individual states. The NRC will now have jurisdiction over all radioactive material produced in accelerators, including but not limited to ^{201}Tl, ^{111}In, ^{67}Ga, ^{123}I, and ^{82}Sr/^{82}Rb, as well as all PET radionuclides. The NRC has been seeking input from CORAR, SNM, and the entire nuclear medicine community in their development of implementing regulations. CORAR and SNM also participated in an NRC-sponsored public meeting on this topic. NRC has already sent a draft rulemaking to the states for their review, and is expected to publish the proposed rulemaking on this subject in early 2006. This rulemaking process will need the continued involvement of the nuclear medicine community in 2006.

Food and Drug Administration Current Good Manufacturing Practices

On September 20, 2005, the U.S. Food and Drug Administration (FDA) published a Proposed Rule in the *Federal Register* on Current Good Manufacturing Practices (CGMPs) for PET drugs. On the same day, the FDA announced the availability of draft guidance on PET drug CGMPs. CORAR and SNM have been providing FDA feedback on their PET CGMP rulemaking and guidance for the last few years, and CORAR again submitted comments on the most recent proposed rule and guidance. As a general matter, the proposed PET drug CGMP requirements are a more simplified version of the CGMP requirements set forth in 21 CFR Part 211. However, the FDA has afforded smaller PET centers some flexibility in the application of CGMP.

FDA Critical Path Initiative

In 2004, the FDA introduced its Critical Path Initiative designed to reduce barriers to the development of new drug therapies. The agency is encouraging the development, qualification, and use of biomarkers, including imaging biomarkers, for a variety of functions, including screening promising drug candidates, enriching investigational study populations, evaluating the effectiveness of therapies during development, and serving as surrogate endpoints for approval purposes. During 2005, CORAR met with the FDA to discuss imaging biomarkers and the possible sharing of data between imaging and therapeutic drug manufacturers. In 2006, CORAR intends to work more closely with SNM, the American College of Radiology, and the National Electrical Manufacturers Association on the Critical Path Initiative and to continue to communicate with FDA on imaging biomarkers.

Reestablishment of the Medical Imaging Drugs Advisory Committee

The FDA terminated the Medical Imaging Drugs Advisory Committee (MIDAC) in November 2002. Since then, in letters and discussions with the FDA, CORAR has advocated the reestablishment of the committee. CORAR has also communicated with FDA to seek improvements in the agency's current procedures for obtaining expert advice on imaging products and issues, which is to appoint medical imaging experts as ad hoc voting members to existing standing advisory committees.

Hospital Outpatient Prospective Payment System (HOPPS)

The Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) requires the Center for Medicare & Medicaid Services (CMS) to determine payment for specified covered outpatient drugs in 2006 based on average acquisition costs. In the 2006 HOPPS proposed rule, CMS indicated that they would use average sales price data as a proxy for the average acquisition cost rather than rely on data from a study compiled by the Government Accountability Office. CORAR provided detailed comments to CMS regarding cost-to-charge ratio (CCR) payment methodology and drug handling costs for radiopharmaceuticals. CMS adopted many CORAR recommendations in the November 10, 2005, final HOPPS rule for 2006, including CORAR's recommendations to use the overall hospital (not department-specific) CCR as the basis for determining radiopharmaceutical payment. Also, over the past 5 years, CORAR and its manufacturer members have submitted numerous requests for additional and more accurate Healthcare Common Procedure Coding System (HCPCS) codes for various radiopharmaceutical products. Throughout this period, the HCPCS National Panel has established a wide variety of new HCPCS billing codes including temporary C-codes, Q-codes, and permanent A-codes to describe radiopharmaceuticals.

CORAR appreciates the continued support from SNM staff, SNM members, and SNM leadership.

Roy W. Brown
Senior Director, Federal Affairs
Council on Radionuclides and Radiopharmaceuticals, Inc.

Committee on Pharmacopeia: Most Recent Proposed Revisions to USP <797>

Throughout the year, the Committee on Pharmacopeia (COP) of the SNM Radiopharmaceutical Sciences Council keeps members of the nuclear medicine community apprised of important news through the SNM Web site, periodic announcements, educational offerings at professional meetings, and articles in the pages of Newsline. This article reviews the most recent proposed revisions to the *United States Pharmacopeia* (USP) General Chapter <797>, titled "Pharmaceutical Compounding—Sterile Preparations." The entire text of these revisions is available at www.usp.org/healthcareInfo/pharmInfo/revisions797.html.

A public meeting hosted by the USP Expert Committee on Sterile Compounding was held at the USP Headquarters on November 15–16, 2005, in Rockville, MD, to discuss various issues related to these proposed revisions. Before this meeting, comments on proposed revisions to <797> were compiled and reviewed by the SNM COP, and the final version of comments was submitted to the USP on behalf SNM. A summary of our comments follows:

- The new definition for term "preparation" suggests that the "preparation" (or "compounded sterile preparation, CSP") may contain sterile "product(s)," which is (are) defined as commercially manufactured sterile drug(s) or nutrient(s) as per the proposed revisions to <797>. In order to ensure that <797> is consistent in its verbiage, COP suggested that the proposed definition for "preparation" be revised as follows:

  A preparation, or compounded sterile preparation, CSP, is a sterile drug or nutrient ~~prepared~~ **compounded** in a licensed pharmacy or other health care related facility pursuant to the order of a licensed prescriber, which may or may not contain sterile products.
- A radiopharmaceutical prepared with the use of a reagent kit ("cold kit") should not be considered as a "preparation" (i.e., "compounded sterile preparation, CSP"), as it is a commercially available drug, nor would it be considered a "product," since it is a commercially manufactured drug to be reconstituted using another commercially manufactured drug(s), rather than a single commercially manufactured drug. As such, COP would like to suggest that the definition of "product" be modified as follows:

  A product is a commercially manufactured sterile drug or nutrient **or a commercially manufactured sterile drug or nutrient that is to be reconstituted or combined with another (other) commercially manufactured sterile drug(s) in accordance with the manufacturer's labeling. Products have** ~~that has~~ been evaluated for safety and efficacy by the U.S. Food and Drug Administration, FDA. Products are accompanied by full prescribing information~~,~~ **and, when applicable, preparation information,** which is commonly known as the FDA-approved manufacturer's labeling or product package insert.
- One of the revised standards and clarifications pertaining to "product" as per the proposed revisions is the "use of sterile products is not subject to <797> unless their preparation, packaging, and storage deviates from their product package inserts, or their preparation requires sterilization (i.e., involves a high-risk level component)." This statement suggests that if there is any deviation from the package insert with regard to the preparation, packaging, and storage of a "product," then adherence to <797> would be required even if the aforementioned deviation (e.g., exceeding the recommended radioactivity limit, using an alternative heating or quality control method, etc.) does not affect the sterility status of the finished "product." Therefore, COP would like to recommend an alternative statement as follows:

  Use **and preparation** of ~~sterile~~ products is not subject to <797> unless their preparation, packaging, and storage deviates from their product package inserts **in such a manner that sterility of the final product could be potentially compromised,** or their preparation requires sterilization (i.e., involves a high-risk level component).

Joseph C. Hung, PhD
*Chair, SNM Committee on Pharmacopeia**

* Members: Marc S. Berridge, PhD; Ronald J. Callahan, PhD; Jeffrey A. Clanton, MS; Henry H. Kramer, PhD; Carol S. Marcus, PhD, MD; Steve Mattmuller, MS; James A. Ponto, MS, BS; Timothy M. Quinton, PharmD; Sally W. Schwarz, BS, MS; Edward B. Silberstein, MD; Suresh C. Srivastava, PhD; Dennis P. Swanson, MS; and Ronald E. Weiner, PhD.

NeutroSpec Withdrawn from Market

The Food and Drug Administration (FDA) issued a Public Health Advisory on December 19 to alert health care providers that the agency had requested market withdrawal of the diagnostic imaging agent NeutroSpec (^{99m}Tc-fanolesomab) pending additional review of reported deaths and serious and life-threatening adverse events associated with use of the product. The manufacturer, Palatin Technologies, Inc. (Cranberry, NJ), and marketing partner, Tyco Healthcare Mallinckrodt, agreed to implement an immediate voluntary market suspension making the product unavailable for approved or investigational uses.

Postmarketing adverse events reported to the FDA from patients receiving NeutroSpec included shortness of breath and sudden drops in blood pressure that led to death from cardiopulmonary failure in 2 patients and required cardiopulmonary resuscitation, oxygen, and/or intravenous fluids in 15 other patients. The FDA noted that these events occurred within minutes after NeutroSpec administration. Most, but not all, of the patients who experienced these events had existing cardiac and/or pulmonary conditions that may have placed them at higher risk. A review of all post-marketing reports showed an additional 46 patients who experienced adverse events that were similar but less severe. All of the reactions also occurred immediately after NeutroSpec was administered.

According to the advisory, the decision to suspend marketing was based on the life-threatening nature of the associated adverse events, the unpredictability of the reaction, and availability of other means of diagnosing appendicitis that do not carry these risks. In a statement issued on the same day as the advisory, Palatin Technologies, Inc., confirmed immediate voluntary suspension of NeutroSpec sales and announced a recall of all existing customer inventories of the product. After initial reports of serious adverse events earlier in the fall, including the 2 deaths, which involved patients with severe underlying cardiopulmonary compromise who received NeutroSpec for off-label uses, Palatin had issued a provider letter about safe use on November 30.

NeutroSpec, the only diagnostic agent approved for imaging equivocal appendicitis, was approved for marketing by the FDA on July 6, 2004. In premarket studies submitted to the FDA as part of the drug's application for approval, NeutroSpec was administered to 523 patients. These studies revealed relatively few safety concerns. Most of the adverse events reported since marketing occurred in patients who were given the drug on an off-label basis. Off-label indications have included osteomyelitis and other infections. No evidence suggests that patients who received the drug face any long-term risks.

The FDA advisory suggested the use of alternative ways to diagnosis appendicitis, including helical CT and ultrasound. In early January, the agency was conducting additional investigations into the deaths and adverse events associated with NeutroSpec and was working closely with the manufacturers to evaluate the risks and benefits associated with its use. An FDA advisory committee meeting was to be scheduled for early 2006 to discuss existing data about the risks and benefits of NeutroSpec, what additional safety measures should be taken with its use, and what indications may exist where benefits of the product are outweighed by the known risks.

For more information, see the FDA advisory at www.fda.gov/cder/drug/advisory/technetium99.htm, and see the latest news on the sales withdrawal and recall at www.palatin.com. The FDA urges health care providers to report adverse event information associated with this or any medical product to the FDA via the MedWatch program by phone (800-FDA-1088), by fax (800-FDA-0178), or at www.fda.gov/medwatch/index.html.

U.S. Food and Drug Administration
Palatin Technologies, Inc.

NRC and States Issue Controls Requirements

The Nuclear Regulatory Commission (NRC) and state regulators announced on December 5 the issuance of legally binding requirements to licensees to implement increased controls over radioactive materials in certain "quantities of concern." The requirements are the first part of a cooperative effort, announced in September, between the NRC and the 33 Agreement States to enhance controls of radioactive materials that could potentially be of use to terrorists. The effort is consistent with the International Atomic Energy Agency's Code of Conduct for the Safety and Security of Radioactive Materials, which is the internationally recognized standard for categorizing and protecting radioactive materials. The NRC's order to its licensees was published December 1 in the *Federal Register.* As of December 2, approximately 2,200 licensees nationwide had received the requirements. "This effort demonstrates close cooperation between federal and state agencies toward the common goal of protecting public health and safety in the productive use of radioactive materials," said Jack Strosnider Jr., director of the NRC Office of Nuclear Materials Safety and Safeguards.

"The 33 Agreement States have done a tremendous job in rapidly issuing increased controls that were essentially identical to NRC's requirements," said Janet Schlueter, director of the NRC

(Continued on page 40N)

(Continued from page 36N)

Office of State and Tribal Programs. Licensees must complete implementation of the required measures within 180 days of receiving them. Although the radionuclides of concern are not used in routine nuclear medicine practice, several have been used in connection with research and still others are used in radiation oncology and treatment devices. Among the radionuclides of concern are ^{241}Am, ^{252}Cf, ^{244}Cm, ^{60}Co, ^{137}Cs, ^{153}Gd, ^{192}Ir, ^{147}Pm, ^{238}Pu, ^{239}Pu, ^{75}Se, ^{90}Sr, ^{170}Tm, ^{169}Yb, combinations of these materials, and any of these materials in combinations of certain quantities with other radionuclides. Additional information about the increased controls, including guidance to licensees, is available from the NRC's electronic document database, ADAMS, by entering ML053130241 in the search box at www.nrc.gov/reading-rm/adams/web-based.html.

U.S. Department of Energy

DOE Off-Site Source Recovery Project

On December 12 the U.S. Department of Energy (DOE) issued a special announcement about its program to recover excess and unwanted radioactive sealed sources presenting disposal difficulties. The DOE conducts the program with reduced or no costs to licensees. When initiated in the 1970s, the program dealt largely with ^{241}Am and plutonium sources but more recently has moved aggressively to include other isotopes of concern. Medical licensees are encouraged to register other sealed sources for potential inclusion in this program. The DOE is currently emphasizing larger excess sources containing ^{60}Co and ^{137}Cs, such as medical irradiators. The DOE is also considering a campaign to manage large numbers of small obsolete sources, examples of which are ^{137}Cs brachytherapy sources and others. To be considered, institutions must register their material with Los Alamos National Laboratory. To learn more and register online, visit http://osrp.lanl.gov.

Department of Energy

Nuclear Medicine an Imaging Utilization Driver

In an article appearing in the January issue of the *American Journal of Roentgenology* (2006;186:7–11), Matin and colleagues from the Brigham and Women's Hospital of the Harvard Medical School (Boston, MA) assessed the use of imaging services at their institution from 1993 to 2002 to determine whether a downward trend in utilization observed in the previous decade had continued or whether expanding modalities and applications had resulted in increased use. The authors analyzed 10-year trends in diagnostic imaging services for inpatients, focusing on annual utilization rates of conventional studies, ultrasound, nuclear medicine, CT, and MR imaging. Trends in relative value units (RVUs) were used as one of several metrics of change in the study. Utilization of conventional studies was found to have decreased significantly over the study period. The rate of use of nuclear medicine studies increased incrementally in the first half of the study period but increased by 37% in the second half with the introduction of clinical PET. This represented a 2-fold increase in the number of nuclear medicine studies over the decade, from 2,400 in 1993 to approximately 5,000 in 2002. The increase was also marked in CT and MR imaging, which increased from 8,402 and 1,728 studies, respectively, in 1993 to 20,715 and 6,902, respectively, in 2002. These changes were accompanied by an increase of 49% in total professional RVUs, 78% in technical RVUs, and 72% in global RVUs, reflecting the growing complexity of the technology associated with the newer modalities. The authors concluded that "the rising complexity and severity of illness among patients, combined with the increasing clinical utility of newer imaging techniques, may explain the progressive substitution of these newer studies for conventional studies."

American Journal of Roentgenology

Fire Sale on NM Equipment?

A story in the December 9 issue of the *Nashville Business Journal* suggested that an "impending glut" in the PET imaging market will make used nuclear medicine equipment "a real bargain" during 2006. Attorney William Wright, Jr., wrote that the effects of the November 2 Centers for Medicare & Medicaid Services (CMS) final rule to include nuclear medicine as a designated health service under the Ethics in Patient Referrals Act will lead to a "fire sale on nuclear imaging equipment." Although CMS delayed implementation until January 1, 2007, Wright believes that rather than restructure current ownership of physician-invested imaging centers, many physicians will simply choose to sell.

The news story was framed not as a cautionary tale but as an opportunity for new investors. Wright noted that few physicians will choose to embrace the risks inherent in the 2 options that would allow them to maintain ownership or interest in imaging facilities. The first is to avoid referring any Medicare & Medicaid patients to their facilities—an impractical solution and one hedged by significant and punitive consequences should any lapses occur. The second is to restructure ownership of centers to conform to equipment-leasing arrangements as spelled out by CMS, a strategy that has already been criticized on ethical grounds by industry observers. Given these options, many nuclear medicine physicians may choose to simply sell their imaging centers to new investors.

Wright noted that one result may be a consolidation within the industry, with less profitable centers closing. He concluded, however, that nuclear imaging will remain a "highly profitable business," and that the coming year "will provide a window of opportunity for new investors to redefine the nuclear imaging industry and possibly snap up some bargains in the process."

Nashville Business Journal

NIH Launches Cancer Genomics Project

The National Cancer Institute (NCI) and the National Human Genome Research Institute (NHGRI) announced on December 13 the launch of a comprehensive effort to accelerate understanding of the molecular basis of cancer through the application of genome analysis technologies, especially large-scale genome sequencing. The Cancer Genome Atlas (TCGA) will begin with a pilot project to determine the feasibility of a full-scale effort to systematically explore the universe of genomic changes involved in all types of human cancer. "Thanks to the tools and technologies developed by the Human Genome Project and recent advances in using genetic information to improve cancer diagnosis and treatment, it is now possible to envision a systematic effort to map the changes in the human genetic blueprint associated with all known forms of cancer," said National Institutes of Health (NIH) Director Elias A. Zerhouni, MD. "This atlas of genomic changes will provide new insights into the biological basis of cancer, which in turn will lead to new tests to detect cancer in its early, most treatable stages; new therapies to target cancer at its most vulnerable points; and, ultimately, new strategies to prevent cancer."

NCI and NHGRI have each committed $50 million over 3 years to the TCGA Pilot Project. The project will develop and test the science and technology framework needed to systematically identify and characterize the genetic mutations and other genomic changes associated with cancer. The pilot will involve a few types of cancer that will be chosen for their value in helping to determine the feasibility of a possible larger scale project. The process for determining the types of cancers to be studied is currently underway. Data collected by designated TCGA Centers will be deposited in public databases supported by NCI's cancer Biomedical Informatics Grid (caBIG) and the National Library of Medicine's National Center for Biotechnology Information. As in the Human Genome Project, TCGA data will be made available to the worldwide research community. For more information on the project, see www.nih.gov/news/pr/dec2005/nci-13a.htm.

National Cancer Institute

NIBIB Workshop on Point-of-Care Tech

The National Institute of Biomedical Imaging and Bioengineering (NIBIB), in partnership with the National Science Foundation (NSF), has announced a workshop to address the topic of "Improving Health Care Accessibility through Point-of-Care Technologies." The meeting, which will be held April 11 and 12 in Washington, DC, will bring together a diverse group of technology developers, clinicians, and clinical researchers to assess the technological developments required for advances in point-of-care testing and to identify high-priority clinical applications that can benefit from a point-of-care approach. Specifically, advances in several technology areas will be considered, including sensors and lab-on-a-chip devices, noninvasive patient monitoring, low-cost imaging, health informatics, and telehealth. Clinical needs will be addressed in the areas of primary care, emergency medical services, home and community-based health care, and health care in developing countries. In addition, representatives from the in vitro diagnostics, patient monitoring, imaging, and telehealth industries will provide their perspectives on commercializing technologies for point-of-care use. The impact of regulatory and reimbursement issues will be addressed, as will various topics relevant to the manufacturing of low-cost devices. The meeting will highlight successful collaborations and provide opportunities to network with clinicians and technology developers to begin building interdisciplinary teams and will present an opportunity to inform representatives from NIBIB, NSF, and the National Institutes of Health about the role these agencies can play in bridging the technology/clinical gap in the development of point-of-care technologies. To learn more about the meeting, visit www.capconcorp.com/nibib-pointofcare.

National Institute of Biomedical Imaging and Bioengineering

U.S. Progress Slow in Improving Patient Safety

A study published in the December 14 issue of the *Journal of the American Medical Association* (2005;294:2858-2865) and authored by Longo et al. from the University of Missouri–Columbia reported slow progress in improving patient safety in U.S. hospitals. In response to concerns originally raised by the Institute of Medicine in 1996 about medical errors and quality of care, new patient safety systems have been created in many institutions. The authors conducted a survey to assess the status of hospital patient safety systems at 2 points in time, 2002 and 2004, and to identify changes over time in hospitals in 2 states. The survey instrument was a 91-item questionnaire that included information on 7 main variables identified as important for patient safety: computerized physician order entry (CPOE) systems, computerized test results, and assessments of adverse events; specific patient safety policies; use of data in patient safety programs; drug storage, administration, and safety procedures; manner of handling adverse event/error reporting; prevention policies; and root cause analyses. The results indicated that "development and implementation of patient safety systems is at best modest" and that "self-reported regression in patient safety systems was also found." Among the surprises noted was that although a substantial percentage of hospitals have medication safety systems, only 3% reported full implementation of CPOE systems, a step considered essential to improving safety measures.

Journal of the American Medical Association

Each month the editor of Newsline selects articles on therapeutic, diagnostic, research, and practice issues from a range of international publications. Although we have divided these into sections on diagnosis and on therapy and adjunct imaging, the increasing molecular focus of functional imaging continues to blur such traditional distinctions in the field. Most selections come from outside the standard canon of nuclear medicine and radiology journals. These briefs are offered as a monthly window on the broad arena of medical and scientific endeavor in which nuclear medicine now plays an essential role.

Therapy and Adjunct Imaging

Tolerance of Therapy After ^{131}I-Tositumomab RIT

In an article e-published on December 16 ahead of print in *Cancer*, Dosik et al. from the Weill Medical College of Cornell University and New York Presbyterian Hospital (New York, NY) reported on a study designed to determine whether patients with progressive disease after radioimmunotherapy (RIT) could tolerate subsequent therapy regimens. The study included 68 patients with non-Hodgkin's lymphoma who had progressive disease after ^{131}I-tositumomab RIT. These patients had received a median of 2 treatment regimens before RIT (66%, anthracyclines; 19%, platinum; 50% fludarabine). At the time of recurrent disease (median, 168 days after RIT), hematologic values were assessed. At that time no significant differences were found between pre-RIT and time-of-recurrence values, except for platelet counts, which were lower at progression (median, 130K cells/μL). All patients had white blood cell counts >1.0K cells/μL. Forty-four patients (65%) went on to receive additional chemotherapy regimens (median, 2 regimens; 43%, anthracyclines; 39%, platinum; 23%, fludarabine; 30%, stem cell transplantation). The remaining 24 patients received no additional chemotherapy. Most of the subsequently treated patients experienced disease improvement, although 18 (40%) died as a result of refractory disease after additional chemotherapy. The authors concluded that most patients with progressive disease after ^{131}I-tositumomab therapy were able to receive and benefit from subsequent therapy.

Cancer

^{90}Y Microsphere Treatment Response Measured by PET and CT

Lewandowski et al. from Northwestern Memorial Hospital (Chicago, IL), DataMedix Corp. (Newtown Square, PA), and the Johns Hopkins Hospital (Baltimore, MD) reported in the December issue of the *Journal of Vascular and Interventional Radiology* (2005;16:1641–1651) on a phase II study to determine the safety and efficacy of ^{90}Y microsphere treatment in patients with liver-dominant colorectal metastases in whom standard therapies had failed or were inappropriate. The study included 27 patients with unresectable hepatic colorectal metastases who were treated with the microspheres at a targeted absorbed dose of 135–150 Gy. Safety and toxicity were assessed using National Cancer Institute criteria, and response was assessed by the results of CT and ^{18}F-FDG PET imaging. PET indicators of tumor response consistently exceeded those measured by CT for both the first (88% and 35%, respectively) and second (73% and 36%, respectively) treated lobes. The authors reviewed side effects, treatment-related toxicities, and other sequelae and concluded that the microsphere administration provides "stabilization of liver disease with minimal toxicity in patients in whom standard systemic chemotherapy regimens have failed." They also noted the utility of PET in assessing disease progression and effectiveness of treatment.

Journal of Vascular and Interventional Radiology

^{131}I Therapy and Juvenile Differentiated Thyroid Carcinoma

In an article published in the December issue of *Endocrine-Related Cancer* (2005;12:773–803), Jarzab et al. from the Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology (Glidice, Poland) reviewed the current status and management of juvenile differentiated thyroid carcinoma (DTC), with special attention to the role of ^{131}I therapy in children. In addition to characterizing juvenile DTC and noting clinical differences with adult DTC, the authors detailed the most common therapeutic approaches. These usually include a combination of surgery, ^{131}I ablation, and thyroid hormone therapy. Most current therapeutic designs rely on adult data and on treatment strategies based on adult outcomes, but the authors recommended distinct treatment strategies for children. An intensive approach, consisting of total thyroidectomy and central lymphadenectomy in all cases, completed by modified lateral lymphadenectomy when necessary and followed by ^{131}I administration, was preferred by the authors. They noted that many institutions choose more conservative approaches, but that most European centers employ radioiodine ablation as an essential element in

juvenile DTC treatment. The effectiveness, side effects, risks, and precautions for such therapy were reviewed. The authors concluded their comprehensive review by noting that "different therapeutic combinations should be prospectively compared using recurrence-free survival as the primary endpoint" and that "efforts also should be made to identify molecular signatures predicting recurrence, metastasis, and mortality."

Endocrine-Related Cancer

^{99m}Tc-Labeled mAb Detection of Ganglioside Expression in Breast Cancer

In an article e-published on December 2 ahead of print in *Breast Cancer Research and Treatment*, Oliva et al. from the National Institute of Oncology and Radiobiology (Havana, Cuba) described the use of ^{99m}Tc-labeled monoclonal antibody scintigraphy for in vivo detection of GM3(NeuGc) gangliosides in human breast tumors. Gangliosides are considered promising targets for cancer immunotherapy, and the GM3(NeuGc) ganglioside of is special interest because of previous research suggesting its low expression in normal tissues and overexpression in human breast tumor. The authors applied a radioimmunoscintigraphic technique with 3 different doses of technetium-labeled 14F7, a highly specific anti-GM3(NeuGc) monoclonal antibody, in a phase I/II clinical trial, including 14 women with stage 2 breast cancer. Imaging indicated tumor antibody accumulation in 100% of patients who received a 1-mg dose of the radioimmunoconjugate but in only 60% and 33% of those receiving 0.3- or 3-mg doses, respectively. Although it is difficult to draw conclusions from these dose results based on the small number of participants, the authors succeeded in providing evidence of in vivo immune recognition of GM3(NeuGc) in breast tumors. They concluded that these findings reinforce the value of this target for cancer immunotherapy.

Breast Cancer Research and Treatment

^{18}F-FDG PET Radioguided Surgery in Thyroid Cancer

Kraeber-Bodere et al. from the Hôtel Dieu Hospital and the René Gauducheau Cancer Center (Nantes, France) and the Claude Huriez Hospital (Lille, France) reported in the December issue of *Surgery* (2005;138: 1176–1182) on the feasibility of ^{18}F-FDG PET radioguided surgery in patients with radioiodine-negative differentiated thyroid cancer. The study included 10 patients with 1–5 foci of uptake on PET who were administered a mean activity of 265 MBq ^{18}F-FDG 30 minutes before scheduled surgery. Radioactivity uptake in tumor and normal tissues was measured before and after resection. Six patients were injected with recombinant human thyroid-stimulating hormone preoperatively. The authors found complete correlation between abnormal findings detected by preoperative PET imaging and those detected with the gamma probe. All positive tissues detected with the probe were confirmed to be differentiated thyroid cancer. The surgeon's hands were exposed to 90–270 μSv of radiation, and radiation levels to patients were minimized, with complete resection of tumor contributing significantly to lessening cumulative radiation. The authors concluded that these results "show the feasibility and benefit of ^{18}F-FDG radioguided surgery with a gamma probe in the management of differentiated thyroid cancer patients with radioiodine-negative recurrence."

Surgery

Radionuclide Therapy as Palliation

Liepe et al. from University Hospital Dresden (Radeberg, Germany) reported in the November/December issue of the *American Journal of Hospice and Palliative Care* (2005; 22:457–464) on a study investigating the efficacy and toxicity of several radiopharmaceuticals in the palliation of painful bone metastases. The study included 64 patients with breast or prostate cancer. Of these, 31 were treated with ^{188}Re-hydroxyethylidene diphosphonate (^{188}Re-HEDP), 15 with ^{186}Re-HEDP, and 18 with ^{89}Sr, and data on pain symptoms, quality of life, and bone-marrow function were recorded. Blood counts were made weekly for 6 weeks and at 12 weeks. In a questionnaire format, the majority of patients reported pain relief after radiopharmaceutical treatment (77% after ^{188}Re-HEDP, 67% after ^{186}Re-HEDP, and 72% after ^{89}Sr). A smaller percentage of patients reported that they were able to discontinue analgesics and were pain free at 12 weeks (16% after ^{188}Re-HEDP, 13% after ^{186}Re-HEDP, and 17% after ^{89}Sr). Thrombocytopenia (platelet count $<100 \times 10^3/\mu L$) was noted in 3 patients during ^{188}Re-HEDP therapy, 1 during ^{186}Re-HEDP therapy, and 3 during ^{89}Sr therapy, with nadirs of platelet and leukocyte counts observed between weeks 2 and 5 after treatment. These effects were reversible by week 12. The authors concluded that these results indicate "that all evaluated radiopharmaceuticals were effective in pain palliation without induction of severe side effects."

American Journal of Hospice and Palliative Care

Early ^{18}F-FLT PET and Response to Breast Cancer Therapy

In an article e-published on December 14 ahead of print in the *Journal of Molecular Imaging and Biology*, Pio et al. from the David Geffen School of Medicine at the University of California Los Angeles compared the utility of ^{18}F-FDG and 3'-^{18}F-fluoro-3'-deoxythymidine (^{18}F-FLT) PET imaging in predicting the long-term effects of chemotherapy in tumor viability in breast cancer. The study included 14 patients newly diagnosed with primary or metastatic

breast cancer who were scheduled to begin a chemotherapeutic regimen. Each patient was scanned with both tracers on 2 separate days within a 1-week period before beginning treatment. These studies were repeated 2 weeks after the end of the first cycle of chemotherapy and after the final cycle or 1 year after the initial PET scan (whichever was first). The authors found that mean change in ^{18}F-FLT (but not ^{18}F-FDG) uptake in primary and metastatic tumors after the first course of chemotherapy showed a significant correlation with late (average, 5.8 months) changes in CA27.29 tumor marker levels. ^{18}F-FLT tracer uptake after a first course of chemotherapy also correlated with late changes in tumor size as assessed by CT. The authors concluded that "a 10-minute FLT PET scan acquired 2 weeks after the end of the first course of chemotherapy is useful for predicting longer term efficacy of chemotherapy regimens for women with breast cancer."

Journal of Molecular Imaging and Biology

PET Targeting of HSV Oncolytic Gene Therapy in Prostate Cancer

In an article e-published on December 16 ahead of print in the *Journal of Molecular Imaging and Biology,* Mullerad et al. from the Memorial Sloan–Kettering Cancer Center (New York, NY) reported on a proof of concept study of the ability of ^{18}F-FDG PET to predict tumor response to oncolytic herpes simplex virus (HSV) therapy in both in vitro and in vivo prostate cancer models. The authors found that after HSV therapy, androgen increased cell kill by 74% in vitro and enhanced viral yield by 2.4-fold in an animal model. They found that this enhanced efficacy was predicted by high ^{18}F-FDG accumulation in intact animals, compared with low uptake in animals after orchiectomy. They concluded that these results provide "the mechanistic basis for selecting patients for targeted oncolytic viral therapy by means of a noninvasive molecular imaging method in the treatment of prostate cancer."

Journal of Molecular Imaging and Biology

Diagnosis

^{131}I-MIBG Imaging and Pheochromocytoma

Guller et al. from University Hospital Basel (Basel, Switzerland), Durham Veterans Affairs Medical Center and Duke University (Durham, NC), and the University of Missouri (Columbia) reported in the January issue of *Annals of Surgery* (2006;243: 102–107) on a study designed to define the most sensitive biochemical test for diagnosis of pheochromocytoma and to assess the utility of ^{131}I-labeled metaiodobenzylguanidine scintigraphy (^{131}I-MIBG) in such diagnoses. The study included 152 patients (12.5% with bilateral disease, 29.6% with malignant pheocromocytoma, and 23.0% with hereditary forms of the disease). Each patient underwent ^{131}I-MIBG scintigraphy. The authors found that the most sensitive test was total urinary normetanephrine (96.9%), with the second and third most sensitive being platelet norepinephrine (93.8%) and ^{131}I-MIBG scintigraphy (83.7%). ^{131}I-MIBG scintigraphy in combination with tests for platelet norepinephrine, plasma norepinephrine, total urine normetanephrine, and urine norepinephrine yielded sensitivities of 100%, 97.1%, 96.6%, and 95.3%, respectively. The authors concluded that although the laboratory tests of choice to establish the diagnosis of pheochromocytoma are urinary normetanephrine and platelet norepinephrine, the addition of ^{131}I-MIBG further improves sensitivity. They advocated performing a ^{131}I-MIBG scan "if the diagnosis of pheochromocytoma is clinically suspected and catecholamine measurements are within the normal range."

Annals of Surgery

SLN Biopsy and Oral Cancer Staging

In the December issue of *Laryngoscope* (2005;115:2217–2220), Rigual et al. from the Roswell Park Cancer Institute (Buffalo, NY) and St. Paul's Hospital (Vancouver, Canada) reported on a study to determine the feasibility and accuracy of sentinel lymph node (SLN) biopsy in the staging of patients with T2N0 oral carcinoma. The study included 20 patients with previously untreated N0 oral cavity squamous cell carcinoma. All patients underwent SLN biopsy after preoperative technetium sulfur colloid lymphoscintigraphy with intraoperative gamma probe guidance and peritumoral injection of 1% isosulfan blue. SLNs and non-SLNs were examined for histology after neck dissection in all patients. The authors found that SLNs were identified in all patients (100%) and accurately predicted the pathologic nodal status in 18 (90%). In 6 of these patients, tumor was found exclusively in the SLNs. Occult nodal metastases were present in 60% of patients. The authors concluded that SLN biopsy is a "technically feasible and accurate procedure for staging the neck in oral carcinoma patients." They noted that the rate of occult metastases in this study group was higher than in previously reported studies with other techniques, suggesting that multiinstitutional studies of SLN biopsy could yield important data for the management of patients with oral carcinoma.

Laryngoscope

PET/CT vs CT in Adrenocortical Carcinoma

In an article e-published on December 20 ahead of print in the *Journal of Clinical Endocrinology and Metabolism*, Leboulleux et al. from the Institut Gustave Roussy (Villejuif, France) reported on a study comparing PET/CT and CT in diagnosis and prognosis of adrenocortical carcinoma. The study included 28 patients with adrenocortical cancer.

Each underwent ^{18}F-FDG PET and thoraco-abdomino-pelvic CT (TAP-CT) imaging. A gold standard of progression on follow-up TAP-CT or as identified at pathology revealed a total of 269 lesions in 57 organs in 22 patients. The sensitivities for the detection of lesions and identification of metastatic organs were 90% and 93%, respectively, for PET/CT and 88% and 82%, respectively, for TAP-CT, with 12% of lesions and 18% of metastatic organs identified only with PET/CT and 10% of lesions and 7% of metastatic organs identified with TAP-CT only. Thirty-eight percent of local relapses were seen only with PET/CT. PET/CT findings modified treatment in 5 cases, 1 of which was found to have been false-positive on PET. ^{18}F-FDG uptake was a significant prognostic factor for survival. The authors concluded that ^{18}F-FDG PET/CT is "complementary to TAP-CT and of special interest in the diagnosis of local relapses."

Journal of Clinical Endocrinology and Metabolism

PET/CT and Thyroid Nodules Before Surgery

Mitchell et al. from Harvard Medical School (Boston, MA) reported in the December issue of *Surgery* (2005;138:1166–1175) on a study assessing the utility of ^{18}F-FDG PET/CT in the preoperative evaluation of thyroid nodules. The study included 31 patients with a total of 48 lesions who underwent fine-needle aspiration and ^{18}F-FDG PET/CT imaging before surgery. Pathologic results indicated that 15 of 48 lesions were malignant and 33 were benign. ^{18}F-FDG PET/CT had a 60% sensitivity (9 of 15 malignant lesions) and 91% specificity (30 of 33 benign lesions). The combined-modality PET/CT imaging had positive and negative predictive values of 75% and 83%, respectively. The authors concluded that PET/CT "provides a high negative predictive value for malignancy, making this a potentially useful tool in the evaluation of thyroid nodules with indeterminate fine-needle aspiration" and called for additional studies to determine the true accuracy of this approach.

Surgery

PET Assessment Before Radical Hysterectomy

Unger et al. from the Louisiana State University Health Sciences Center (Shreveport) reported in the November/December issue of the *International Journal of Gynecological Cancer* (2005;15:1060–1064) on a retrospective study to evaluate the ability of whole-body ^{18}F-FDG PET imaging to select appropriate candidates for radical hysterectomy and pelvic lymphadenectomy. The study included 14 women undergoing planned radical hysterectomy and pelvic lymphadenectomy with clinically localized cervical cancer and either negative or inconclusive metastatic nodal disease as assessed by PET. Pelvic lymph nodes were clearly negative on PET in 12 of the women. The remaining 2 had focal tracer uptake that was deemed suspicious although not definitive for nodal metastasis. These pelvic nodes were positive at surgery in both women, in each of whom CT had failed to detect nodal disease. Neither PET nor CT could detect parametrial disease, and each also failed to detect primary tumor in some cases. The results led the authors to conclude that ^{18}F-FDG PET findings that are clearly negative for nodal disease indicate good candidates for radical hysterectomy who are at low risk for subsequent chemoradiation.

International Journal of Gynecological Cancer

PET, CT, and Size of Lymph Nodes in NSCLC

In an article e-published on December 5 ahead of print in the *European Journal of Cardiothoracic Surgery*, de Langen et al. reported on the results of a meta-analysis of published studies on metastatic involvement for different size categories of enlarged lymph nodes in patients with non–small cell lung cancer (NSCLC). Although a number of studies have suggested that ^{18}F-FDG PET is superior to CT in staging the mediastinum in patients with the disease, other findings indicate that PET performance may vary with nodal size as seen on CT. The authors noted that the association between size and probability of malignancy should be clearly elucidated if PET is to be used to successfully predict outcomes and if both PET and CT are to be used to stratify patients for mediastinoscopy or thoracotomy. Fourteen multi-institutional analyses were included in the meta-analysis. The prevalence of metastatic involvement and related test performance of CT and ^{18}F-FDG PET in these studies were calculated for lymph nodes measuring 10–15, 16–20, and $>$20 mm. In patients with a negative PET scan and lymph nodes measuring 10–15 cm, the post-test probability of N2 disease was 5%, suggesting that these patients should be planned for thoracotomy, because the yield of mediastinoscopy would be quite low. In patients with a negative PET and lymph nodes measuring $\geq$16 mm, the post-test probability for N2 disease was 21%. The authors concluded that these patients should proceed to mediastinoscopy before possible thoracotomy to lower the numbers of unnecessary thoracotomies in this subset.

European Journal of Cardiothoracic Surgery

^{99m}Tc-Sestamibi Scans and ^{18}F-FDG PET in Multiple Myeloma

Hung et al. from the Changhua Christian Hospital (Taiwan) reported in the November/December issue of *Anticancer Research* (2005;25:4737–4741) on a comparison of ^{99m}Tc-sestamibi scans and ^{18}F-FDG PET imaging in the assessment of multiple myeloma. The study included 12 patients with multiple myeloma. Each underwent a conventional radiologic skeletal survey, ^{99m}Tc-sestamibi scan, and ^{18}F-FDG-PET imaging. The 3 approaches detected 34 lesions and

5 cases of bone marrow involvement. The skeletal X-ray survey detected 4 soft tissue lesions (21.1%), 12 skeletal lesions (80%), but no bone marrow involvement (0%). The ^{99m}Tc-sestamibi scan found 4 cases of bone marrow involvement (80%), 13 soft tissue lesions (68.4%), and 12 skeletal lesions (80%). The PET scan detected 5 cases of bone marrow involvement (100%), 17 soft tissue lesions (89.5%), and 14 skeletal lesions (93.3%). The authors concluded that although both ^{99m}Tc-sestamibi and ^{18}F-FDG PET have value in patients with multiple myeloma, PET imaging can detect more lesions than the ^{99m}Tc-sestamibi scan.

Anticancer Research

PET and Brain Ammonia in Cirrhosis

In an article e-published in the December issue of *Hepatology* (2005; 43:42–50), Keiding et al. from the Aarhus University Hospital (Denmark) reported on the methodology and implications of PET imaging of brain metabolism of ^{13}N-ammonia during acute hepatic encephalopathy (HE) in patients with cirrhosis. Previous studies have suggested that disturbances in brain ammonia metabolism are key actors in the pathogenesis of HE. The authors used ^{13}N-ammonia PET to study brain ammonia kinetics (in cerebral cortex, basal ganglia, and cerebellum) in 8 patients with cirrhosis and an acute episode of clinically overt HE, 7 patients with cirrhosis without HE, and 5 healthy volunteers. Arterial ^{13}N-ammonia, ^{13}N-urea, and ^{13}N-glutamine concentrations levels were measured in blood samples. Differences were noted in permeability/surface area product of ^{13}N-ammonia transfer across the blood–brain barrier in the 3 groups of patients. Metabolic trapping of blood ^{13}N-ammonia in the brain, however, did not correlate to specific regions or patient groups. Mean net metabolic flux of ammonia from blood into intracellular glutamine in the cortex varied significantly, at 13.4 μmol/min/L tissue in patients with cirrhosis with HE, 7.4 in patients without HE, and 2.6 in healthy controls. The authors concluded that "increased cerebral trapping of ammonia in patients with cirrhosis with acute HE was primarily attributable to increased blood ammonia and to a minor extent to changed ammonia kinetics in the brain."

Hepatology

PET and Surgical Management in Melanoma

In an article e-published on December 1 ahead of print in the *British Journal of Surgery*, Bastiaannet et al. from the University Medical Centre Groningen (The Netherlands) reported on a retrospective, multicenter study of the effect of ^{18}F-FDG PET imaging on surgical management in patients with melanoma. The study included 257 patients with melanoma, and data collection included indications for imaging, imaging findings, unexpected findings of tumors other than melanoma, and treatment plans before and after imaging. The majority of scans (71.2%) were ordered for staging to detect distant metastases in patients with stage III disease. PET imaging resulted in upstaging in 56 patients (21.8%) and in treatment changes in 44 patients (17.1%). Unexpected tumors were detected in 11 patients (4.3%). The authors concluded that ^{18}F-FDG PET is "most valuable in patients with stage III melanoma for detection of distant metastases and identification of candidates for surgery and/or systemic treatment" and cautioned that unexpected findings on PET should not be disregarded.

British Journal of Surgery