#### ■ VOICE Box

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# TECHNOLOGIST

**Continuing Education Committee Chair** We still are getting many questions from members about such concerns as their tran-

members about such concerns as their transcripts, backup documentation and audits, so Marcia Ferg is back to answer a few

more questions and clear up a few things. Marcia also has a reminder for everyone.

by Joni Herbst, CNMT

#### Ask Marcia

First, I want to clarify some information provided in the last *JNMT* "VOICE Box." The Nuclear Medicine Technology Certification Board (NMTCB) encourages continuing education (CE) as one means of maintaining professional competency but does not require CE and has no plans at this time to do so. In the case of noncertified technologists seeking an additional competency in nuclear medicine, the NMTCB does accept VOICE credit toward meeting the eligibility requirements to take the NMTCB certification examination. However, the ARRT and most of the licensure states *do* require continuing education to maintain certification/licensure.

Here are the contact numbers again: NMTCB 404-315-1739 and ARRT 612-687-0048. Call state licensing agencies directly or contact our office at 703-708-9000, ext. 230 for phone numbers.

## ARRT Audits Have Begun-Are You One of the Lucky Ones?

As a reminder, as soon as you get your transcript, make sure you have a matching piece of backup documentation for each item on the transcript. For example, if you attend a VOICE-approved meeting, the VOICE credit reporting form has a section at the bottom that you are to keep for your records. Some program directors create their own certificates to hand out at the meeting or to mail out after the course. In any case, the documentation should contain the following:

- Title of the activity;
- Date(s) of attendance or participation;
- Number of contact hours;
- Name of the sponsor;
- Authorized signature. (my signature *or* the program director's signature); and
- Reference number assigned by a Recognized Continuing Education Evaluating Mechanism (RCEEM). (The RCEEMs are: SNM-TS, ASRT, SDMS, ACR, AHRA and CAMRT.)

Recently we have heard from several technologists who were audited by the ARRT. Several of their credits were rejected because their names were missing from the backup documentation. I have spoken to the ARRT. They are being very diligent in their audit research and some of the auditors were not familiar with the format of our VOICE credit reporting forms. In the past, the bottom portion of these forms has not included a place for you to write your name. That has been changed. The ARRT assures me they will make sure all the auditors are familiar with our forms. As a safeguard, if you are audited, include a copy of your transcript with the backup documentation copies you submit. That will help the auditors tie everything together and make sure it ties to *you*. See your December 1997 *JNMT* "VOICE Box" for more information on backup documentation.

#### Speakers and Authors, Did You Notice?

In the VOICE Guidelines, published in the September 1997 *JNMT*, it is stated that you can get CE credit for being a speaker at a VOICE-approved meeting or for authoring an article in a peer-reviewed journal, such as *JNMT*. Here is what the guidelines say:

Authors and co-authors of an article relating to nuclear medicine in a peer-reviewed journal may each submit an application, including a copy of the published journal, to receive 5 CEHs each.

#### The guidelines also say:

A speaker at a meeting which has been approved for VOICE credit, may submit an application to receive 3 CEHs preparation time for every continuing education hour presented and 1 approved lecture credit not to exceed 6 CEHs per program annually. Application to include a copy of the final program in which the speaker appears.

So, if you write an article or speak at a VOICE-approved meeting, submit a completed VOICE credit approval application with the requested proof (journal or final program) and \$5 fee. The application will be reviewed and, when approved, you will receive a letter confirming your participation in this activity and the amount of credit. It is that simple.

Contact me with your name and address or fax number and I will send you as many VOICE credit approval applications, with instructions, as you need: Marcia F. Ferg; phone: 703-708-9000, ext. 210; e-mail: mferg@snm.org.

#### ■ Government Relations Office 1997 Annual Report

#### by David Nichols, Director ACNP/SNM Government Relations Office

The American College of Nuclear Physicians (ACNP) and SNM have had one of their most successful years in recent memory. Due to the dedication of volunteers on the Government Relations Committee and the time and direction given by the leadership, ACNP and SNM have had a positive influence on both the legislative and regulatory fronts. This report captures the highlights of the past year in government relations. For details on any of these issues, please consult the government relations web page at www.snm.org or contact the Government Relations Office at 703-708-9773.

#### Legislation

#### P.L. 105-115-FDA Modernization Act of 1997

One of the major accomplishments of the year was our efforts with the FDA reform legislation. Working independently as well as in conjunction with ICP, CORAR and APhA, nuclear medicine had several sections pertaining to its field included within the bill. This type of legislative activity is rare and ACNP and SNM were well positioned to work with other organizations and congressional staff to influence the outcome.

There are three provisions in the FDA bill that pertain to nuclear medicine. The first is the provision on PET, then the approval process for radiopharmaceuticals and, finally, the application of federal law to the practice of compounding. President Clinton signed the bill on November 21, 1997.

#### Positron Emission Tomography (Section 121)

The PET language sets up the following provisions:

- USP standards are to be used to assure that PET drugs are compounded appropriately.
- The FDA will be required to develop appropriate procedures for the approval of PET drugs, and appropriate current good manufacturing practice requirements for such drugs.
- The agency will take into consideration when developing procedures for NDAs and ANDAs the relevant differences between not-for-profit institutions that compound the drugs for their patients and commercial manufacturers of the drugs. The agency also must consult with patient advocacy groups, professional associations, manufacturers and physicians and scientists licensed to make or use PET drugs.
- NDAs and ANDAs shall not be required for those drugs compounded under USP standards for a period of 4 years after the bill is signed or for 2 years after the date on which the secretary establishes procedures, whichever is longer.
- The legislation also terminates the application of the guidance document on the regulation of PET published in February 1995, the draft CGMP guideline also published in February 1995, and the final rule on CGMPs published in April 1997.

This language was the result of work done by the Institute for Clinical PET and Senator Ted Stevens (R-AK). It also was supported by ACNP and SNM.

#### **Requirements for Radiopharmaceuticals (Section 122)**

The requirements for radiopharmaceuticals as set out in the legislation are as follows:

- Not later than 6 months after the date of enactment, the secretary of DHHS (after consulting with patient advocacy groups, associations, physicians licensed to use radiopharmaceuticals and the regulated industry) shall issue proposed regulations governing the approval of radiopharmaceuticals.
- The regulations shall provide that the determination of the safety and effectiveness of such radiopharmaceuticals shall include:
- 1. Consideration of the proposed use of the radiopharmaceutical in the practice of medicine;
- 2. The pharmacological and toxicological activity of the radiopharmaceutical (including any carrier or ligand component of the radiopharmaceutical); and
- 3. The estimated absorbed radiation dose of the radiopharmaceutical.
- The final rule must be published no later than 18 months after the date of enactment of the legislation.
- There also was a stipulation that in the case of a radiopharmaceutical, the indications for which the radiopharmaceutical is approved for marketing may, in appropriate cases, refer to manifestations of disease (such as biochemical, physiological, anatomic or pathological processes) common to, or present in, one or more disease states.

#### Application of Federal Law to the Practice of Pharmacy Compounding (Section 127)

The pharmacy compounding language has been a topic of discussion in Congress for several years now. Originally it was supported by the nuclear medicine community as a means to seek relief from FDA regulation of PET. Following the introduction of language by Senator Stevens, particularly focusing on PET, the compounding provisions were no longer necessary to seek relief. ACNP and SNM continued to work with the pharmacy community, however, seeking a bill that would provide greater freedom for physicians and pharmacists to compound under state law. Senator Tim Hutchinson (R-AR) and Representative Richard Burr (R-NC) were instrumental in moving these provisions forward in the FDA reform bill.

The Senate addressed FDA reform first, and much of the negotiation took place there. In order to gain the support of the FDA and Senator Ted Kennedy (D-MA), a compromise on the bill was necessary, and the pharmacy community joined together to work on those changes. However, in the end the provisions negotiated were determined to be to restrictive for radiopharmaceuticals and an exemption to the provisions mentioned in the next section of this analysis would not apply to PET drugs or radiopharmaceuticals, legislative history was added that clearly stated that this regulation should be based on current law. (The current guidance is based on a 1984 guideline released by the FDA on nuclear pharmacy compounding).

The following provisions will apply to the rest of pharmacy compounding:

• A drug product must be compounded for an individual patient based on an unsolicited receipt of a valid prescription, or a notation, approved by the prescribing practitioner, that a compounded product is necessary for the identified patient; and the product compounded is by: (a) a licensed pharmacist in a state-licensed pharmacy or federal facility; or (b) a licensed physician, on the prescription order for such an individual patient made by a licensed physician; or (c) a licensed pharmacist or physician in limited quantities before the receipt of a valid prescription order for such an individual patient *and* is based on a history of receiving valid prescription orders.

- The relief provided by the compounding act only applies if:
- 1. The product is compounded using bulk drug substances, as defined in regulation by the FDA, that: (a) comply with the USP monograph and the USP chapter on pharmacy compounding; (b) if such a monograph does not exist, then by using drug substances that are components of drugs approved by the FDA; or (c) if such a monograph does not exist and the drug substance is not a component of an FDA-approved drug, then they are on a list developed by the FDA through regulation; (d) the bulk drug substances must be manufactured by an FDA-registered facility; and (e) the bulk drug substances must be accompanied by valid certificates of analysis
- 2. The compounding of a drug product using ingredients (other than bulk drug substances) complies with the standards of an applicable USP monograph and the USP chapter on pharmacy compounding.
- 3.It does not compound a drug product that is on an FDA-published list of products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective.
- 4. It does not compound regularly or in inordinate amounts (as defined by the FDA) any drug products that are essentially copies of a commercially available drug product.
- 5. Is not a drug product that the FDA has determined presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product.
- 6. Is a drug product compounded in a state that has a

memorandum of understanding (MOU) with the FDA addressing the distribution of inordinate amounts of compounded drug products interstate, or is in a state that does not have an MOU, but is from a facility where the product does not exceed 5% of the total prescription orders dispensed or distributed by such a pharmacy or physician.

- 7. A drug may be compounded only if the pharmacy, licensed pharmacist or physician does not advertise or promote the compounding of any particular drug, class of drug or type of drug. The pharmacy, licensed pharmacist or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.
- All of these restrictions on compounding, in addition to the additional power given to the FDA to determine some of the applicable situations in which compounding would be allowed, was of significant concern to the nuclear medicine community which led to the exemption of radiopharmaceuticals and PET drugs. This class and subset of drug products was the only subset to be excluded in the provisions and governed under current law.
- As of today, the current law governing PET is mentioned in Section 121 of the FDA Reform Bill, and the law governing radiopharmaceuticals is the 1984 guideline on nuclear pharmacy compounding. Nothing in the provision forbids the FDA from revising the 1984 guideline.

Copies of the actual text of all three provisions as well as the conference report language that becomes part of the legislative history can be found under the government relations section on the SNM web site (www.snm.org). The text above is only a summary, and all interpretation of the provisions should be based solely upon the official statutory language.

#### P.L. 105-78-Labor, HHS and Education Appropriations Bill for FY 1998

The SNM-Technologist Section, in conjunction with other members of the Allied Health Roundtable, was successful in increasing the appropriation for allied health funding under Title VII. Overall health professions training received an increase from FY 1997 of \$13,695,000 to a total in FY 1998 of \$306,513,000. Within that budget amount, the Allied Health Special Project was increased from FY 1997 by \$13,000 to a total of \$3,845,000 for FY 1998. This money is used, in part, to support training programs for nuclear medicine technologists. Approximately six to eight programs receiving money from Title VII involve such training.

#### P.L. 105-62–Energy and Water Development Appropriations Bill for FY 1998

The Energy and Water Development Appropriations bill covers all isotope production appropriations through the DOE. The isotope production program received \$7 million for operations at four facilities, Los Alamos National Laboratory, Brookhaven National Laboratory, Pacific Northwest Laboratory and Oak Ridge National Laboratory. This was almost \$4 million less than the DOE recommended and is expected to severely affect the ability to continue many of the research and development initiatives at these labs. In addition, the DOE received \$9 million for its <sup>99</sup>Mo project at Sandia, as well as reprogramming another \$3.7 million, bringing the total up to \$12.7 million.

#### Regulations

#### 10 CFR 35-NRC's Medical Use Program

The NRC has been reviewing their medical program regulations contained in 10 CFR 35 for approximately 6 months now. Following the end of one phase of their strategic assessment, the commission directed the staff to engage in a process that would bring about a revision to 10 CFR 35. The agency has conducted two public workshops, in Philadelphia and Chicago, as well as a meeting with the Agreement States in California. ACNP and SNM has had members representing physicians, pharmacists and technologists attend these workshops.

Based on commission direction, the agency is taking a multiple-modality approach with different regulations for nuclear medicine as compared to radiation oncology. Within nuclear medicine, the NRC staff have offered a two-tiered approach. The first tier would be diagnostic nuclear medicine considered by many to be low risk. The second tier involves therapeutic nuclear medicine which NRC believes to have a higher risk associated with it.

ACNP and SNM over the past year have sought a fair and open process that involves comments and dialog with all the stakeholders. To respond to the request of ACNP and SNM, the commission structured the two workshops, extended its comment period, and used the Internet to receive and display comments and dialog. This open process can be attributed directly to the work of ACNP and SNM. In addition to the public process, the NRC has expressed an interest in working with the specialty societies to gather comments. There already have been several meetings among the leadership of ACNP, SNM and key NRC staff and commissioners. These meetings and discussions will be the key to developing comments to the NRC in the coming year as text of the proposed rule becomes available. Key issues revolve around: (a) training and experience for physicians and technologists; (b) the quality management program; (c) the role of the radiation safety committee; and (d) the criteria for reporting events to the NRC. A draft proposed rule is expected to be disseminated at the end of January with an official proposed rule and more public workshops during the summer of 1998.

#### Patient Release Rulemaking (10 CFR Part 35)

The NRC issued a final rule in 1997 regarding the release of patients administered radioactive material. There has been a shift of focus to the potential dose to individuals who may come in contact with the patient. This rule is consistent with recommendations of the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP). The following are the provisions of that rulemaking:

- 1. The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).
- 2. The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the dose to a breast-feeding infant or child could

exceed 1 millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions also shall include: (a) guidance on the interruption or discontinuation of breast-feeding; and (b) information on the consequences of failure to follow the guidance.

- 3. The licensee shall maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the total effective dose equivalent is calculated by: (a) using the retained activity rather than the activity administered; (b) using an occupancy factor less than 0.25 at 1 meter; (c) using the biological or effective half-life; or (d) considering the shielding by tissue.
- 4. The licensee shall maintain a record, for 3 years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent to exceeding 5 millisieverts (0.5 rem).

#### Unauthorized Usage Rule-NRC (10 CFR Part 20)

On February 20, 1997 the NRC staff forwarded to the commission a draft final rule for their consideration. The rulemaking, which would have created additional regulations and notification requirements upon the discovery of an unauthorized usage of byproduct material, was presented along with three additional options for the commission to consider. These options included: (a) finalize the rule as drafted; (b) re-notice rule and solicit public comment; and (c) terminate rulemaking. The commission decided to terminate the rulemaking. This is consistent with the comments provided to the Commission from ACNP and SNM.

#### Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea–NRC (10 CFR Parts 30 and 32)

In December 1997, the NRC amended its regulations to permit NRC licensees to distribute a radiopharmaceutical containing one microcurie of <sup>14</sup>C urea to any person for in vivo diagnostic use. The NRC has determined that the radioactive component of such a drug in capsule form presents an insignificant radiation risk and, therefore, regulatory control of the drug for radiation safety is not necessary. This amendment makes the drug more widely available and reduces costs to patients, insurers and the health care industry.

#### Legal Issues

### ACNP and SNM Successfully Appeal FDA PET Regulations

SNM, Syncor International, the ACNP and the American Pharmaceutical Association (APhA) were successful in their appeal of the original decision by the U.S. District Court. The case brought by SNM and others questioned the FDA's 1995 regulation with required NDAs and ANDAs for PET drugs. The U.S. District Court ruled in favor of the FDA, claiming that the policy change was consistent with the Administrative Procedures Act. The professional and industry groups, represented by Alvin J. Lorman of Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo, appealed, and the U.S. District Court decision was overturned 3-0 by the U.S. Court of Appeals.

In reversing the District Court decision in Syncor v. Shalala, the appeals court held that the FDA should have engaged in notice and comment rulemaking to adopt the challenged regulation. The FDA had argued that it simply was issuing a policy statement or an interpretive rule, rather than imposing substantive new requirements-an argument the court rejected.

The court decision now would require the FDA to enter an official notice and comment period should they desire a change to any of the regulations governing PET. This case also sets a precedent that potentially could require an official notice and comment period pertaining to any changes involving radiopharmaceuticals.

While the victory was substantial in reversing the tide of overregulation by the FDA, it is overshadowed by the requirements advocated by ACNP, SNM and ICP in the FDA Reform Bill passed by Congress. The FDA reform legislation section on PET mandates a process over the next 2 to 4 years that would require rulemaking to clarify what facilities using PET would be required to file with the FDA. This legislation sets up a construct to place certain requirements on PET users, while recognizing some of the distinctions between academic and commercial facilities.

In response to this decision, the Justice Department filed a motion to vacate the ruling on the grounds that the passage of the PET provision in the FDA Modernization Act renders the case moot. ACNP and SNM, along with APhA and Syncor, filed in opposition to the government's motion and the court agreed, denying the government's motion. This led to a completion of all matters on this action. Had this motion been granted, the nuclear medicine community could have lost the following:

- The decision by the appeals court validates the actions of PET facilities not complying with the FDA's policy statements and final rules from 1995 to 1997. Removal of the appeals court decision would have made those actions illegal and subject to potential liability lawsuits/or action by the FDA, however unlikely.
- The decision also indirectly protects the nuclear medicine community from facing internal change to the 1984 nuclear pharmacy guideline by the FDA without appropriate notice and comment. This is the guiding document for FDA jurisdiction over radiopharmaceutical compounding.

#### **Other Issues**

#### **Health Professions Network**

The Government Relations Office continues to work with the Health Professions Network (HPN), sponsored in part by the SNM-Technologist Section. This federation of allied health organizations provides an opportunity for different allied health disciplines to meet on a regular basis to discuss the promotion and dissemination of information highlighting the importance of the allied health field. As part of this effort, the network is working with the Bureau of Health Professions under the Department of Health and Human Services to present an emerging leaders workshop on how the government works. This five-day forum in April 1998 is being coordinated by the SNM-TS and the allied health roundtable as part of HPN's commitment to this project.

#### **Outreach to Chapter Meetings**

The Government Relations Office conducted several chapter visits by Dr. Robert Carretta, chairman of the Government Relations Committee, in an effort to expand the visibility of the ACNP and SNM's government relations efforts. Chapter visits included the Pacific Northwest, Greater New York, Missouri Valley, Northern and Southern California meetings. Chapters interested in arranging for a government relations speaker at an upcoming meeting should contact David Nichols, Director of Government Relations, at 703-708-9773.

#### **Political Action Committee**

The SNM, through the Government Relations Office, is establishing a political action committee that should be up and running by April 1998. This PAC will allow the nuclear medicine profession to be more visible in Congress and assist those members who are friends of nuclear medicine in their re-election campaigns.

#### Legislative Network

The SNM-TS continues to operate a legislative network that was very successful in 1997. With over 50 members in the legislative network, spread out amongst all the chapters of the SNM, the network enables members to keep informed on legislative issues and contact their members of Congress before key votes on Capitol Hill. If you are interested in participating in this legislative network or being included as a key contact in the nuclear medicine database, please contact Amanda Sullivan in the Government Relations office at 703-708-9773.

#### Conclusion

The Government Relations Office has been involved in and influenced a significant number of issues over the past year. This year has been one of our most successful, having a significant impact on the practice of nuclear medicine. While it is difficult to quantify monetarily the value of these efforts, it is important to note that through the volunteers working with the Government Relations Office, regulations have been scaled back or prevented from getting worse, which leads to a financial impact on each and every nuclear medicine practice. We are optimistic that the ACNP and SNM will carry this momentum into 1998 and continue to provide substantial benefits to its members.

For more information on any of these topics, members are encouraged to routinely check the government relations page on the web at www.snm.org or to contact the Government Relations Office at 703-708-9773.

#### ACNP News

#### by Sandra Griffith, CNMT Proficiency Testing Program Director

#### **Quality and Confidence in Nuclear Medicine**

The ACNP Nuclear Medicine Imaging Committee (NMIC) received the ACNP President's Award at the ACNP Annual Meeting in Las Vegas in January 1998. The award was presented in recognition of the NMIC's outstanding contribution to quality assurance in nuclear medicine. The Proficiency Testing Program was initiated by the College of American Pathologists in 1974 as an interlaboratory comparison imaging survey. Since 1983 a joint phantom program has been available to the nuclear medicine community, which includes representatives of the CAP, ACNP, SNM and SNM-TS.

The ACNP assumed operational responsibility for the Nuclear Medicine Proficiency Testing Program with the 1994 program. The ACNP Nuclear Medicine Proficiency Testing Program is now managed by the NMIC, which is comprised of members from the ACNP, CAP, SNM and SNM-TS. Members of this committee have many years of long-standing dedicated service. The combined laboratory and nuclear medicine imaging experience of the four organizations affords the program the foremost expertise in the medical specialty of nuclear medicine.

The ACNP Proficiency Testing Program enters its 25th year with two exciting exercises to celebrate its silver anniversary. The program is AMAP approved, ACNP accredited for CME and offers VOICE credits to participating technologists. The spring 1998 phantom (IM-A) is a Myocardial Perfusion Imaging Simulator and the fall 1998 phantom (IM-B) is a Mammoscintigraphy and Oncologic Lesion Detection Exercise.

The spring 1998 IM-A Myocardial Perfusion Study is designed to test the subscriber's ability to: acquire, process and interpret images; determine the presence of defect(s); detect changes in sequential studies; and quantitate the defects. SPECT images are to be acquired and processed according to the participant's own clinical protocols. Alternative processing options may be suggested for comparison. A clinical history will be provided to assist in interpreting the findings. The spring phantom will be shipped on April 14, 1998.

The fall 1998 (IM-B) Mammoscintigraphy and Oncologic Lesion Detection Exercise will be a transmission phantom with a simulated mammoscintigraphy study and an oncologic lesion detection exercise with a receiver operating characteristic (ROC) analysis of warm lesions. This mammoscintigraphy exercise will allow users to evaluate lesion size and contrast, and provides a location simulation of a two-view planar study of the breast. In addition, a matrix of lesions of varying contrast is included that will test the observer's ability to detect lesions as seen in nuclear oncology studies. An ROC curve will be produced for each observer. Pixel size evaluation will be included as a quality control exercise. The effect of camera distance on imagine quality also will be examined. The shipping date is September 15, 1998.

Each subscriber will receive a phantom with instructions for imaging and a questionnaire. After the results have been submitted and evaluated by the NMIC, each subscriber will receive a copy of their results compared with all other participants. A final critique is provided that includes a discussion of the exercise, a summary of the results of all subscribers and recommendations for improved imaging based on the results of the exercise. The subscriber may keep the phantom for continued quality assurance testing.

For more information, please contact Sandra Griffith, CNMT, at 800-447-2267 or 202-244-7904; fax 202-244-7355; ACNP, 4400 Jenifer St., NW, Suite 230, Washington, DC 20015-2113.

#### ■ P.E.T.Net<sup>™</sup> Announces Medicare Coverage for Fluorine-18-FDG PET for Lung Cancer

P.E.T.Net Pharmaceutical Services received notification that Medicare has expanded coverage to include PET studies with <sup>IN</sup>F-FDG for diagnosing and initial staging of lung cancer. The expanded coverage was effective January 1, 1998.

Reimbursement of FDG-based scans will have a major impact on the management of patients with lung cancer and will improve access to the best health care for Medicare beneficiaries. Research shows PET with FDG is clinically effective and reduces health care costs in diagnosing and staging lung cancer. In a recent review of peer-reviewed studies, the national Blue Cross/Blue Shield Association Technical Evaluation Center report concluded that positron imaging with FDG can improve health outcomes in certain patients with lung cancer. The increased accuracy of PET with FDG over conventional medical imaging modalities may eliminate the need for multiple medical tests, biopsies or surgeries thereby reducing health care costs and improving diagnostic efficiency.

Martin P. Sandler, MD, FACNP, professor of radiology and medicine and chief of nuclear medicine/PET at Vanderbilt University Medical Center, Nashville, said, "This is a very important announcement for the health care industry and Medicare recipients. This is a major step in the evolution of positron imaging and in the management of patients with lung cancer. Hopefully, Medicare reimbursement will soon follow for additional oncology indications, evaluation of brain disorders, such as dementia, and for cardiac viability studies." According to a November 6, 1997 press release from Senator Ted Stevens (R-AK), Health and Human Services Secretary, Donna Shalala, has committed to expedite the review of other uses of positron imaging for Medicare coverage within the next 18 mo.

Currently, there are more than 500 private insurance carriers and managed care organizations that already reimburse for certain PET scans with FDG. Some private insurance carriers and health maintenance organizations (HMOs) reimburse for all medically necessary indications. George M. Segall, MD, acting chief nuclear medicine service at VA Palo Alto Health Care System, Palo Alto, CA, stated, "The VA Palo Alto has recently entered into an agreement with a large HMO to be a preferred provider of positron imaging services for members of the health plan." Dr. Segall continued, "Approval of all medically necessary positron imaging studies by major payors significantly enhances access to this valuable diagnostic imaging tool."

Fluorine-18-fluorodeoxyglucose (FDG) is a simple sugar labeled with radioactive fluoride. The <sup>18</sup>F-FDG tracer is administered intravenously and is used to determine how certain organs and tissues in the body are functioning. FDG imaging measures the utilization of this sugar in these organs and tissues and is widely used to determine normal and abnormal tissue in the brain and heart and to detect and evaluate certain types of cancer.

P.E.T.Net Pharmaceutical Services, headquartered in Norcross, GA, manufactures and distributes PET drugs and related services. The company's primary radiopharmaceutical is <sup>18</sup>F-FDG. P.E.T.Net currently operates 12 positron manufacturing and distribution centers throughout the U.S.

#### News Briefs

#### **AECB** Announces Recent Decisions

Canada's Atomic Energy Control Board (AECB) announced several licensing decisions last November. The board approved the renewal of the operating licenses, for two-year terms, for the Cameco Corporation's uranium refinery facility in Blind River, Ontario, and for the fuel fabrication plant owned by Zircatec Precision Industries Inc., in Port Hope, Ontario. The AECB also authorized the issuance of an operating license, for a four-year term, for a particle accelerator facility at the Centre Universitaire de Santé de l'Estrie in Fleurimont, Quebec.

#### BARCO Builds New North American Facility

Last November BARCO Display Systems began constructing a new 80,000-sq ft facility in Gwinnett County, about 25 mi northeast of Atlanta. The new building will house manufacturing operations, engineering departments and corporate offices for the North American division of Belgium-based BARCO nv, Display Systems. Construction is scheduled to be completed at the end of the summer in 1998. BARCO Display Systems designs and manufactures high-resolution monitors and display subsystems for command control computer communication intelligence (C4I), avionics, vessel and air traffic control, industrial process control, medical imaging and prepress applications.

This new facility marks the first time that this Belgium manufacturer has acquired property in the U.S. The new building is necessary to accommodate the company's continued growth in its Display Systems Subdivision. The BARCO Display Systems' North American operations have grown at a rate of more than 50% in the last 2 yr. This Atlanta division primarily designs and manufactures high-performance graphics and video controller boards. It also provides and services high-resolution avionics, industrial and commercial monitors, as well as flatpanel displays for the defense, medical, avionics, air traffic and industrial control markets.

# SNM Commission Offers Reimbursement Roadshow

The Society of Nuclear Medicine's Commission on Health Care Policy and Practice will offer its roadshow, titled *Reimbursement for Nuclear Medicine Procedures*, several times in 1998. This course was first presented as a categorical seminar in Denver at the 1996 Society of Nuclear Medicine Annual Meeting and as a roadshow in 1997. Due to its success, it will be offered this spring at several locations across the U.S. and at the 1998 SNM Annual Meeting in Toronto.

This one-day workshop covers major procedural aspects of nuclear medicine services including proper code selection, claim submission and documentation. Nuclear medicine physicians and technologists, medical office managers, and key billing and medical records personnel will learn to properly use the current CPT and ICD-9-CM manuals; use HCPCS II for effective coding and billing; understand third-party payments; learn about the new G codes for PET imaging; be updated on the new editions of CPT and relevant Medicare changes; be fully cognizant and knowledgeable on the current Correct Coding Initiative and its implications for fraud and abuse; review common procedures; and fine tune coding skills and reimbursement algorithms. The registration fee is \$225.00, which includes workbook, case studies, continental breakfast, lunch and afternoon breaks. Speakers include Becky Cacciatore, CNMT, Kenneth McKusick, MD, and Michael Wilson, MD.

SNM is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians and will offer 6.0 hr of Category 1 credit towards the AMA Physician Recognition Award. A maximum of 6.0 continuing education hours (CEHs) will be available to VOICE participants.

The following 1998 dates have been confirmed for the *Reimbursement for Nuclear Medicine Procedures Roadshow:* 

Saturday, April 18, 1998 at the Renaissance Madison Hotel in Seattle, WA; Saturday, April 25, 1998 at the Hotel Sofitel in Chicago, near O'Hare Airport;

Saturday, May 9, 1998 at the Westin DC City Center in Washington, DC; and

Sunday June 7, 1998, as a categorical seminar, at the SNM Annual Meeting in Toronto, Canada.

Registration for the June 7th categorical seminar at the SNM Annual Meeting is limited to 75 participants. Preregistration for this categorical seminar is available on the SNM web site at http://www.snm.org or call the fax-on-demand service at 888-398-7662. If you would like to register for a spring seminar or have additional questions, contact Marie Davis at 703-708-9000, X250.

The Society's Commission is considering reformatting the course for the three sessions scheduled for fall 1998 which are all in conjunction with the following SNM chapter meetings:

Thursday, October 15, 1998 at the Southeastern Chapter; Birmingham, AL;

Wednesday, October 21, 1998 at the Western Regional Chapter; Long Beach, CA; and

Thursday, November 5, 1998 at the Greater New York/New England Chapters; Newport, RI.

#### Education and Research Foundation Announces Award Winners

The SNM Education and Research Foundation (ERF) approved the following awards at the SNM midwinter meeting in Las Vegas. Updates on ERF activities are available on the foundation's new homepage at www.pet.upenn.edu/snmerf/.

#### **Pilot Research Grants**

Stephen L. Eck, MD, PhD, Hospital of the University of Pennsylvania, Philadelphia, PA

Richard Freifelder, PhD, Hospital of the University of Pennsylvania, Philadelphia, PA

Hong-Gang Liu, MS, University Hospital, University of Alabama, Birmingham AL

Alan B. Packard, PhD, Children's Hospital, Boston, MA Chyng-Yann Shiue, PhD, Hospital of the University of Pennsylvania, Philadelphia, PA

#### **Student Fellowship Awards**

Douglas A. Dougherty, Stonybrook University Hospital, Stony Brook, NY

Sean Shahram Erami-Avedon, Mt. Saini Hospital, Toronto, Canada

Matthew Arkin, Hospital of the University of Pennsylvania, Philadelphia, PA

Nida Totonchian, Hospital of the University of Pennsylvania, Philadelphia, PA

Christine O'Neill, Winthrop University Hospital, Mineola, NY

#### Women's Health Information Kit Released

The SNM-TS Public Education and Professional Enhancement (PE2) Committee recently released a *Nuclear Medicine Women's Health Information Kit*. The kit provides topical information on current women's health issues and appropriate nuclear medicine solutions. The information kit consists of a series of seven fact sheets. Each fact sheet contains the latest information about a specific health issue and the ways in which nuclear medicine provides a diagnostic and sometimes therapeutic tool. Background and historical information about nuclear medicine is included also.

The Nuclear Medicine Women's Health Information Kit is designed to provide a tool for promoting nuclear medicine to physicians, patients and the general public. The kit can be used by hospitals to increase referrals to their nuclear medicine departments and to educate women about how nuclear medicine can provide answers to some of their most urgent health questions. The kits are sold for \$7.00 each or \$5.00 for the set of fact sheets alone and must be paid for in advance by check, VISA or MasterCard. Call SNM's Women's Health Information Kit Hot Line at 703-708-9000, X248 for more information or to order kits.

#### **SNM Convention Booths Available**

The SNM traveling convention booths are available for use by members at official SNM functions and private events. A tabletop and a small 10 ft X 10 ft booth are available to fit various needs. Requests are filled on a first-come, first-served basis and booth availability is limited. There is a \$25 maintenance fee for the tabletop display and a \$50 maintenance fee for the 10 ft X 10 ft booth. SNM pays to ship out and the user pays to ship the booth back to SNM. A sample box of promotional materials is available free upon request. Last year the booths were shipped to more than 20 events around the country. If you would like to reserve a booth for your event, contact Jessie McLane Petit at 703-708-9000, X226.



The SNM tabletop booth attracted many visitors at the Pittsburgh Chapter meeting last year.