# From Washington: A Government Relations Update

*The directors of the joint government relations office of The Society of Nuclear Medicine and American College of Nuclear Physicians present the following digest of regulatory and legislative events affecting the practice of nuclear medicine:*

Washington, DC Convention and Visitors Association

## Food and Drug Administration

### Radiopharmaceutical Review Process

ACNP and SNM have worked throughout the year with FDA to bring changes in the radiopharmaceutical approval process. In August 1991, industry representatives met to debate the issue and agreed on the need for a consensus paper before talks with regulators could continue. Industry has since invited the director of government relations for SNM and ACNP to participate in the discussions with the FDA.

The radiopharmaceutical makers developed a position paper outlining a streamlined FDA approval process, but have been held up in presenting their comments due to potential conflicts of interest within the FDA Ombudsman's office. FDA Ombudsman, Amanda Pedersen, and her assistant, Edwin Dutra, both have stock investments in the radiopharmaceutical industry, and thus are unable to meet with the nuclear medicine industry until the potential conflict has been resolved.

### Chemistry Documentation in Radiopharmaceutical Drug Applications

The FDA issued for public comment a set of draft guidelines for submitting chemistry documentation in radiopharmaceutical drug applications. In a *Federal Register* announcement of the availability of the guidelines, the FDA says the document is intended to answer requests by the radiopharmaceutical industry and the nuclear medicine community for detailed guidance on preparing the chemistry section of new drug applications (NDAs) for radiopharmaceuticals. The guideline describes acceptable approaches to NDA documentation and complements other FDA guidelines on chemistry documentation. The ACNP and SNM intend to submit comments to the FDA before the expiration of a March 18 deadline.

### Review and Regulation of Combination Products

The FDA published a final rule on "Assignment of Agency Component for Review of Premarket Applications" in November 1991. The rule describes how the FDA will determine which center of the FDA will have primary jurisdiction for the premarket review and regulation of a combination drug, device, or biologic product, or any drug, device, or biologic product where the center with primary jurisdiction is unclear or in dispute. The rule seeks to eliminate the need for an NDA sponsor to obtain approval from more than one FDA center, as required by the Safe Medical Devices Act of 1990.

In developing the final rule, the FDA ombudsman chaired a public hearing in September 1991, to give interested parties the opportunity to comment on the content and the scope of the regulation. Naomi P. Alazraki, MD, immediate past-president of SNM, testified at the public hearing (see *Newsline,* December 1991, p. 21N). Dr. Alazraki recommended criteria to define a combination product, called for coordinating consulting reviews, and warned against dual reviews of combination products. She also urged the FDA to develop guidelines specific for the evaluation and regulation of radiopharmaceuticals.

According to the final rule, the definition of a combination product is intended to exclude most concomitant uses of drugs, devices, and biological products. The definition also excludes products comprised exclusively of two or more drugs, two or more devices, or two or more biologic agents. The review of radiopharmaceuticals is not changed by

promulgation of the FDA's final rule on combination products.

### Medical Device User Reporting Requirements

ACNP and SNM responded to a proposed rule issued by the Food and Drug Administration (FDA) that requires medical facilities and device distributors, including importers, to report to the FDA and to manufacturers any deaths, serious illnesses and serious injuries related to medical devices. The Safe Medical Devices Act of 1990 authorized the FDA to issue these regulations.

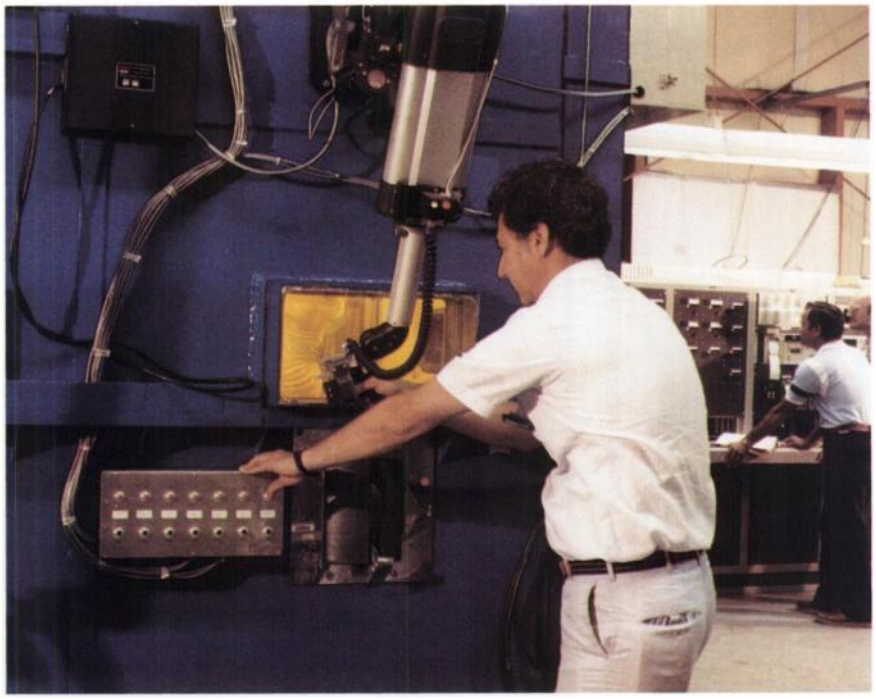
According to the 1990 law, designated medical facilities include outpatient diagnostic clinics. The act requires a medical facility to determine whether there is a probability that a device caused or contributed to a death, serious illness, or injury and to report such incidents to both the FDA and the manufacturer. The 10-day time period is the maximum time allowed by the statute.

Of concern to the ACNP and SNM was a provision requiring medical device reports on failures that resulted in the misdiagnosis of a patient if that misdiagnosis resulted in death or injury. ACNP and SNM believe that current professional quality control programs minimize this type of malfunction. Due to the near impossibility of identifying the effect of a misdiagnosis within 10 days, SNM and ACNP recommended that the MDR for diagnostic studies be eliminated.

## Department of Energy

### National Biomedical Tracer Facility (NBTF)

ACNP and SNM representatives have met with Senator Bennett Johnston, chairman of the Senate Energy and Water Appropriations Committee and Representative John Myers, ranking minority member of the House Energy and Water Appropriations Committee to drum up support for the National Biomedical Tracer Facility (NBTF). Mr. Johnston predicted that gaining funding through the Energy Department would be difficult and suggested that ACNP and SNM advocate shifting nuclear medicine research funding from DOE to NIH. Mr. Myers was more enthusiastic and indicated that he would consider going to bat for the NBTF project in 1992.



Brookhaven National Laboratory

***Energy Department accelerators at Brookhaven National Lab and Los Alamos National Lab provide isotopes used in medicine. Because declining research budgets have restricted the operating time of these accelerators and limited the supply of radioisotopes, SNM is working for the establishment of a dedicated medical accelerator. Shown above are researchers working at the Brookhaven Linac Isotope Producer (BLIP).***

The White House Office of Science and Technology Policy (OSTP) has agreed to research the need for the NBTF. Carl Erb, PhD, of the President's science advisory staff, is conducting interviews with selected nuclear medicine physicians and scientists to assess problems in availability of radioisotopes. OSTP plans to hold a hearing on the issue this year and has requested a study on radioisotope supply from the Institute of Medicine, an arm of the National Academy of Sciences.

ACNP and SNM submitted a statement to the DOE Health and Environmental Research Advisory Committee (HERAC) about the potential for crisis in radioisotope supply and need for increased funding for nuclear medicine research. Leon S. Malmud, MD, SNM President, wrote to DOE Secretary Watkins reinforcing the community's position on these issues, but received a noncommittal response. In a recent conversation, DOE Deputy Secretary Henson Moore expressed doubt about DOE's ability to initiate the development of the NBTF. Mr. Moore was recently tapped to serve as a White House deputy chief-of-staff, and if he accepts he will be in a better position to urge the Administration to support the accelerator project.

An immediate goal of SNM and ACNP is to win support for a "request for proposal" (RFP) to start the siting process for the NBTF. The DOE's isotope production program requested two million dollars for fiscal 1993, but budgeteers deleted the funding before the DOE sent its request to the Office of Management and Budget (OMB) for approval. ACNP and SNM will testify before both the House and Senate Appropriations Committees to encourage Congress to include funding.

Meanwhile, Congressman Mike

Synar, chairman of the House Science and Technology Committee requested a study from the General Accounting Office (GAO) regarding the availability of isotopes in the United States and a review of the DOE Isotope Production Program (see *Newsline*, February 1992, p. 16N). According to committee staffers, the congressman questions whether the DOE should even be in the business of producing isotopes.

### Nuclear Medicine Research Funding

The DOE is expected to propose a decrease in nuclear medicine research funding for FY 1993. DOE appropriated approximately $34 million for fiscal 1992. ACNP and SNM submitted comments to the DOE HERAC committee to protest reductions in support for medical research using isotopes (see *Newsline*, February 1991, p. 15N). ACNP and SNM intend to testify before Congress to seek commitments to nuclear medicine research funding.

## Nuclear Regulatory Commission

### User Fees

Government relations staff met January 13 with the solicitor and general counsel of the Nuclear Regulatory Commission (NRC) to explore the possibility of negotiating for changes in the fee schedule for medical licensees. Subsequent to that meeting, the NRC published a revision to the fee schedule in the *Federal Register*, which was open for comments until February 10, 1992. The proposed changes create another level of small users by capping user fees at $400 for licensees whose net receipts are under $250,000. The SNM and ACNP government relations office considers the change extremely unlikely to benefit any nuclear medicine facilities, in fact, the office anticipates increases in fees for medical licensees.

The NRC solicitor suggested that ACNP and SNM should formally petition for a modification in the fee schedule as part of their comments to the recently published revision. The ACNP and SNM petition will request NRC to establish fees on a sliding scale, exempt not-for-profit and teaching medical centers, and seek approval for increases from the Department of Health and Human Services, which could adjust nuclear medicine relative value units to accommodate user fee increases (see also under "Regulatory Oversight," p. 23N).

***The appointment of E. Gail de Planque, PhD to the U.S. Nuclear Regulatory Commission was approved by the Senate in November.***

### New Commissioner

ACNP and SNM endorsed the appointment of E. Gail de Planque, PhD to fill the fifth seat on the Commission. Dr. de Planque, a radiation physicist and environmental health scientist, was director of the Environmental Measurements Laboratory and serves as an adjunct professor at New York University Medical Center. The Senate approved Dr. de Planque's appointment on November 23, 1991.

### Medical Quality Management Rule

ACNP and SNM pursued their case against the NRC's "quality management" (QM) rule by filing a brief to a federal appeals court in early February. SNM and ACNP say that costly and redundant measures imposed by the QM rule, including increased record-keeping burdens, will consume work hours, drive up medical expenses, and adversely affect the delivery of health care. SNM and ACNP have asked the NRC to defer consideration of the suit in an effort to negotiate out of court for a modified rule. The QM rule took effect on January 27, 1992. The NRC submitted the final rule to the Office of Management and Budget (OMB) for review as required by the Paperwork Reduction Act. The OMB's responsibility is to measure the benefits against the costs of a regulation and to identify redundant and unnecessary measures. The ACNP and SNM submitted comments to OMB maintaining that the burdens of the QM rule far outweigh the benefits and that the rule duplicates the authority of the Department of Health and Human Services and professional quality assurance programs. OMB agreed with the principles of ACNP's and SNM's argument in a letter to the NRC. The OMB letter urges the nuclear regulators to meet with medical and other licensees to explore other options. Government relations staff are working with Congress to facilitate this process.

Should the NRC choose to hold a public hearing to review the QM rule, the medical community will have another opportunity to address the Commissioners directly. If the rule is reconsidered, Chairman Ivan Selin and Commissioner Gail de Planque—who are both new to their positions—may vote differently than their predecessors who approved the rule.

### Below Regulatory Concern

The NRC maintains a moratorium on its "below regulatory concern," or BRC, policy. Shortly after Stanley J. Goldsmith, MD, was chosen to represent medical licensees on a consensus-building panel convened by the NRC to salvage BRC, the regulators canceled the process because environmental interest groups steadfastly declined to participate (see *Newsline*, January 1991, p. 25N).

The consensus building concept held promise as a productive approach to regulation that the NRC could have applied to other areas, and may yet. As to BRC, the NRC retains the option to apply its principles rule by rule.

## Department of Health and Human Services

### Medicare Reimbursement

The Health Care Financing Administration (HCFA) published the final version of the revamped Medicare fee schedule in November 1991. The following is a summary of HCFA's responses to comments submitted by ACNP and SNM:

- Medicare will pay for radiopharmaceuticals in addition to payments for the nuclear medicine procedures. HCFA plans to relate payments for radiopharmaceuticals to an estimated "acquisition cost." ACNP and SNM government relations staff are compiling a listing of radiopharmaceutical prices that HCFA plans to share with the carriers to assist them in estimating costs.
- The specialty differential for nuclear medicine was resolved by using the "adjusted historical payment base" established by Congress in 1989 for specialists whose practice involved more than 80% nuclear medicine. The result is higher reimbursement rates for all nuclear medicine services (see also under "Separate Consideration" below).
- Payment reductions as the fee schedule is phased-in will be capped at 9% in 1992 for radiology, which by HCFA's definition includes nuclear medicine. The phase-in reduction for other specialties is 15%.
- HCFA will not impose a site of service differential for nuclear medicine services performed at hospitals versus services at free-standing practices or clinics.

### Separate Consideration

SNM and ACNP continue to press for HCFA to treat nuclear medicine services separately from services surveyed under the radiology fee schedule. SNM and ACNP maintain that the RVUs for nuclear medicine are significantly undervalued. After the radiology fee schedule was announced in the *Federal Register* in March 1989, the nuclear medicine organizations commissioned Abt Associates to survey nuclear medicine charges using the same methods as the American College of Radiology (ACR).

The data collected by Abt indicated that the radiology fee schedule (RFS) undervalued nuclear medicine procedures by about 17%. Congress acknowledged the deficit in the RFS and passed special rules in 1989 and 1990 that separated payment for full-time nuclear medicine physicians from the RFS for an interim period.

HCFA perceives the matter to be beyond its authority. In response to ACNP/SNM comments, the final rule states that Congressional provisions "did not include an ongoing increase in the values assigned to these [nuclear medicine] services relative to other radiology services."

ACNP and SNM argue that Congress intended for HCFA to treat nuclear medicine separately and will ask Congress to clarify its intent in specific legislative language to ensure appropriate interpretation of the law.

### Relative Value Unit Update Committee (RUC)

The American Medical Association (AMA) expanded its CPT contract with HCFA to include a process for updating and revising the relative value units (RVUs) used in determining payment rates under the new Medicare fee schedule. The RUC program consists of an "advisory panel" open to all specialty societies, and an "editorial panel" with 23 permanent seats and two rotating seats. Although ACNP and SNM didn't manage to gain a permanent seat, they will serve jointly on a rotating seat for 1992. ACNP and SNM originally appealed AMA's decision not to grant nuclear medicine a seat on the editorial panel, however, leaders of the Society and College say they are pleased to have a rotating seat and will work to obtain permanent status on the committee.

### Nuclear Medicine Comments on RVUs and Interim Values

The Joint Government Relations Office is conducting an informal survey with ACNP and SNM volunteers to study the effects of the new fee schedule on practices nationwide. Survey findings will help form the basis for comments to HCFA on the fee schedule. Meanwhile, more extensive data collection programs are in the works. HCFA will accept comments on RVUs until March 25, 1992, but arguments for modifications must be based on sound data. Of particular interest are the interim values assigned by HCFA for new and revised nuclear cardiology codes, or CPT-4 codes, about 20 of which were revised to accommodate new cardiac agents and other technical advances.

### SPECT Reimbursement

The ACNP embarked in December on a project to collect data on single-photon emission computed tomography (SPECT). The effort is part of an anticipated larger "SPECT Project," for which government relations staff are seeking support from industry. ACNP leaders and members of the ACNP Corporate Committee intend for the SPECT Project to be a joint effort between industry and medical professionals to address reimbursement issues. ACNP leaders have mailed letters to interested companies to encourage their participation in the SPECT Project. At press time, an inaugural meeting of participants was scheduled for February 6, 1992 in Dallas, Texas, before the SNM Mid-Winter meeting where SNM leaders were to consider endorsing the project.

### New Physicians

The new fee schedule provides for reduced Medicare payments to physicians in their first through fourth years of practice. The ACNP and SNM object to the inconsistency of cutting payment rates for qualified "new" physicians while

paying all other practitioners regardless of training or experience. The ACNP and SNM believe that HCFA should take into account the experience and training necessary for a physician to be board eligible. ACNP and SNM will join with other medical specialties to oppose the new physician rule and will urge Congress to revise the law.

## Regulatory Oversight

The Nuclear Regulatory Commission (NRC) imposes nuclear license user fees and extensive reporting requirements on nuclear medicine that other medical specialties do not have to contend with. SNM and ACNP maintain that added costs arising from new and revised regulations should be reflected in the conversion factor for nuclear medicine services or in the technical component RVU.

ACNP and SNM will request a new requirement for HCFA review and approval for any proposed regulations that would financially affect the practice of nuclear medicine. Under such a scheme, if HCFA accepts a new regulation it would factor the additional cost into the reimbursement technical component for nuclear medicine procedures. The U.S. Small Business Administration (SBA) supported the idea in a February 1992 brief to the NRC in response to the revised user fee schedule. The Joint Government Relations Office intends to encourage both the NRC and HCFA to consider the issue (see also under "User Fees" on p. 18N).

## Practice Guidelines

The SNM recently introduced an Office of Health Care Policy (see *Newsline*, December 1991, p. 24N). This office was established to encourage the development of quality standards and guidelines for enhancing the efficacy and efficiency of nuclear medicine studies. The Office will participate in inter-specialty development of practice policies.

The ACNP is in the process of conducting an economic impact study to demonstrate the clinical value and economic efficiency of selected nuclear medicine procedures. The data derived from this study will play a significant role in the development of practice guidelines. The study will also provide data for patient outcomes analysis and research. The ACNP anticipates data on the first procedure to be available in late 1992.

## Data Collection

HCFA is certain to rely upon specialty societies for the development of RVUs. The process of developing and conducting statistically valid surveys on a regular basis will be a costly undertaking. ACNP and SNM urged PPRC, Congress, and the Department of Health and Human Services (HHS) to create a standard survey form and models for data collection. AMA's RUC committee has appointed a subcommittee to develop a template for consideration. A draft will be reviewed at the next RUC meeting.

## Rebundling of CPT-4 Codes

HCFA began a "rebundling" of CPT-4 codes in February 1991. According to instructions issued to the carriers at the time, the 68 CPT-4 codes were meant to assist carriers in detecting improperly reported procedures, that is, procedures reported under separate codes that were components of one procedure and billed by the same physician on the same day. HCFA published comprehensive list of codes, which included several nuclear medicine procedures (cardiac stress testing and EKG interpretation). The list proposed that 78460/93018 and 78461/93018 be bundled. This would have had an unintended effect on reimbursement for these studies. Comments submitted to HCFA requested that the nuclear medicine codes be corrected. The final list, which became effective January 1, 1992, restored the appropriate coding (see *Newsline*, January 1992, p. 19N).

## Self-Referral

Representative Fortney (Pete) Stark (D-California) is expected to introduce legislation this Spring that will prohibit physician referral to a facility in which the doctor has any ownership interest. Mr. Stark, chairman of the House Ways and Means Health Subcommittee, held a joint hearing on October 17, 1991 with the Oversight Subcommittee chairman, Representative J. J. Pickle (D-Texas) on physician ownership and referral arrangements.

Among the witnesses at the hearing were the authors of a Florida State University Study which showed a higher rate of utilization when a physician has an ownership interest. The study was prepared for Florida's Health Care Cost Containment Board. Other witnesses included the American College of Radiology, the American Physical Therapy Association and the Consumer Federation of America.

A report prepared by a Washington, D.C. health care consulting firm for the American Academy of Neurology contests the findings of the Florida study. According to the consultants' report, the study's conclusions in the areas of utilization, profitability and access raise questions about the validity of the comparisons made and the subsequent conclusions. The Government Accounting Office is conducting a study to examine the issue of over-utilization of facilities owned by referring physicians.

## Outpatient Hospital Reimbursement

In a report to be delivered to Congress on March 1, 1992, the Prospective Payment Assessment Commission (ProPAC) is expected to recommend that payments for outpatient radiology services be prospective and computed to ensure budget neutrality. The report is in response to a congressional mandate to the Secretary of Health and Human Services to develop recommendations on prospective payment for outpatient services. The Secretary has yet to release the report to ProPAC for their review. The report was due by September 1, 1991. In the interim, ProPAC initiated a study of payments to hospitals for ambulatory surgery and outpatient radiology services.

For outpatient radiology services, Medicare pays hospitals the lower of their costs or a 42:58 blend of hospital

specific costs and 62% of the global fee schedule amount. ProPAC's recommendations indicate that payment rates for outpatient radiology services should be national and based on average hospital costs and a proportion of the technical component of the Medicare Fee Schedule.

HCFA is expected to publish regulations this Spring to encourage cost effectiveness in hospital outpatient departments. According to an article published in the January 19, 1992 *New York Times* the new rules reflect the policy of the Administration, supported by Congress, to bundle Medicare services. Diagnostic and treatment services provided to Medicare outpatients would have to be tracked formally by hospitals and billed to Medicare, even if provided outside the hospital. In billing Medicare, hospitals couldn't unbundle these services. In addition, hospitals would be required to establish formal contracts with outside service providers. Violators would risk $2,000 fines or expulsion from Medicare.

### CLIA-88

A coalition of the American Hospital Association, the American Medical Association, the Health Industry Distributors Association and the Health Industry Manufacturers Association have undertaken an impact study of the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88). CLIA-88 extends the applicability of federal laboratory regulation to all laboratory testing sites.

According to a Part I report on the study completed in November 1991, the personnel and proficiency testing requirements of the proposed CLIA-88 will be particularly burdensome for physician office labs. The second part of the study is scheduled for completion in early 1992 and will include the results of a cost-benefit analysis. Several regulatory alternatives will also be considered in Part II, including recommended revisions to the proposed CLIA-88 regulations. Final CLIA-88 regulations are expected early this year.

## Physician Payment Review Commission

### Medicare Volume Performance Standard

The Omnibus Budget Reconciliation Act of 1989 (OBRA 89) established Medicare Volume Performance Standards (MVPS) for physicians services. The MVPS sets a target rate of growth on outlays for Medicare physician services. Fee updates will depend in part on the difference between the MVPS rate of increase and the actual change in expenditures.

According to OBRA 89, the Secretary of Health and Human Services must recommend by April 15 of each year a fee update for the next calendar and fiscal year. The Physician Payment Review Commission (PPRC) must comment on the Secretary's recommendations and make its own recommendation by May 15 of each year.

OBRA 89 directs PPRC overseers to take into account evidence on the appropriateness and accessibility of new technology when setting the MVPS. PPRC requested that the ACNP and SNM submit comments on significant new technologies in nuclear medicine. The comments were due on February 14, 1992.

### Access to Care

The PPRC initiated a study on access to care and plans to develop measures of access to evaluation and management services and procedural services. The Commission asked physician consultants, recommended by medical specialty societies, to complete questionnaires to identify problems that could arise from diminished access to evaluation, management, and procedural services. The SNM and the ACNP jointly appointed the following individuals to serve as physician consultants: Terence Beven, MD; Darrell W. McIndoe, MD, August Miale, Jr., MD; Kenneth McKusick, MD; and Edward A. Eikman, MD.

### Statement on Medicare

On December 11, 1991, PPRC held three days of hearings on the Medicare fee schedule. ACNP and SNM submitted a statement for consideration highlighting nuclear medicine's achievements and goals. The statement also addressed concerns about data collection and introduced ACNP and SNM efforts in practice policy development.

## Environmental Protection Agency

### National Emission Standards for Hazardous Air Pollutants (NESHAPs)

ACNP, SNM, and industry groups convinced Congress in 1990 to pass an amendment to the Clean Air Act that directed the Environmental Protection Agency (EPA) to exempt medical, research and education facilities from the national emission standards for hazardous air pollutants (NESHAPs) that apply to radionuclide air emissions. The EPA has since initiated a thorough study of whether these Nuclear Regulatory Commission (NRC) licensees operate within an ample margin of safety.

At a December meeting to discuss the status of the (EPA) data collection on radionuclide air emissions, Roy W. Brown of Mallinckrodt Medical, Inc., Leneord Smith of DuPont Co., Jim Massie, a lobbyist for industry, and a representative from the Joint Government Relations Office met with Al Colli, environmental standards branch chief for the EPA. A survey has been sent to approximately 570 facilities in an effort to obtain information from a statistically valid sample of medical, research, and education NRC licensees. The EPA has until November 15, 1992 to complete its analysis and publish a final rule.

The EPA expected to complete by February the survey to decide whether to apply the NESHAPs to radionuclide emissions. EPA officials say they are willing to share the survey data with SNM and ACNP after the NRC has had a chance to review it. The EPA is scheduled to publish a proposed rule in April or May and the proposal will be open for comment for 30 days.

The EPA may, however, have difficulty meeting the November deadline, but by law the EPA must publish a rule defining its position on radionuclide air emissions. The EPA does not have an official contingency plan should it miss the deadline; the agency will likely extend the stay on NESHAPs for medical facilities.

The nuclear medicine community has emphasized the need for an exemption for medical facilities from the NESHAPs. SNM and ACNP have offered assistance to the EPA and stressed the importance of meeting the November 15, 1992 deadline.

## Occupational Safety and Health Administration

### Blood Borne Pathogens

The Occupational Safety and Health Administration (OSHA) approved regulations in December 1991 to eliminate or minimize occupational exposure to hepatitis B virus, human immunodeficiency virus (HIV) and other blood-borne pathogens. The regulations include standards for engineering and work practice controls, for the use of personal protective clothing and equipment, for training, medical surveillance, hepatitis B vaccinations, and for distinctive signs and labels. The standards apply to all occupational exposure to blood and other potentially infectious material and become effective on March 6, 1992.

The Exposure Control Plan must be completed within 60 days of the effective date of the final standard. Employee education and training must take effect within 90 days of the effective date. The estimated total compliance costs for all affected industries is approximately $813 million.

## Allied Health

### Title VII Appropriations

Congress appropriated $2,830,000 for allied health project grants and contracts in fiscal 1992. This amount represents an increase of 70% from last year's appropriations of $1,659,000. The current appropriations will make it possible to support approximately another 10 projects. The significant increase for allied health professions resulted from the efforts of several allied health organizations, including the SNM Technologist Section (SNM-TS).

The House and Senate approved reauthorization legislation for Title VII, however, Congress adjourned before taking action. A conference committee is expected to meet soon. The Senate legislation, the Health Professions Training and Nurse Education Improvement and Reauthorization Act of 1991, would extend Title VII authorities through 1996. The House measure, the Health Professions Education Amendments of 1991, would authorize Title VII initiatives through 1994.

Both the House and Senate bills include authorizations for project grants and contracts and advanced training programs. The Senate would also authorize funds for student loan repayment, create a division of allied health within the Public Health Service, establish a subcommittee of the National Advisory Council on Health Professions Education to study allied health personnel shortages, and request the Office of Technology Assessment to study the effectiveness of Title VII.

Neither the House nor the Senate bills include the proficiency examination provision of The Rural Clinical Laboratory Personnel Shortage Act (H.R. 2405). Last Fall, members of the SNM-TS contacted their representatives in Congress to emphasize that the examination approach in H.R. 2405 would, if adopted, serve as a precedent to address rural manpower problems in other allied health fields including nuclear medicine.

The current House legislation includes compromise language that calls for a study of the shortage and all possible solutions. The bill directs the Secretary of Health and Human Services to study and report to Congress by October 1, 1992 on the extent and causes of the shortages of clinical laboratory technologists in rural and urban areas and to develop recommendations to alleviate the problem. The Secretary also would be required to consider the effectiveness of any mechanisms that are available for alleviating shortages, including competency-based examinations as an alternative route for certification of competence and to consider the role of entities that provide such certification. Similar language is included in the Senate bill, which would require the Subcommittee on Allied Health to conduct the study and to report their findings to Congress by October 1, 1993.

### NRC's Information Notice on Supervision by an Authorized User

The NRC issued in November 1991 an information notice on "Training and Supervision of Individuals Supervised By An Authorized User." The notice was published shortly after a November meeting of the NRC's Advisory Committee on the Medical Uses of Isotopes. At the meeting, the NRC indicated that they are attempting to establish in their regulations an "authorized nuclear pharmacist," an individual who would have the authority and responsibility for compounding radiopharmaceuticals.

According to the NRC, the notice does not impose new requirements, rather it was issued "to remind licensees of the importance of providing adequate instruction and supervision to individuals working under an authorized user." Supervised individuals who infrequently use radioactive materials, such as part-time or cross-trained technologists, and technologists whose services are used under contract of a temporary employment service are said to be "of particular concern." The notice cites six misadministrations which occurred, according to the NRC, due to a lack of "adequate" instruction or supervision. Copies are available upon request from the Joint Government Relations Office.

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