■ Blue Cross/Blue Shield Recommends PET Coverage for Neurological Indications

In a move likely to boost the clinical utilization of PET, the national Blue Cross and Blue Shield Association recommended in July that affiliated insurers provide limited coverage of positron emission tomography (PET) for patients with recurrent brain tumors or epilepsy.

Blue Cross and Blue Shield is the largest private insurer in the U.S. and its advisory panel recommendations are intended to help standardize coverage among affiliated insurers across the country. Blue Cross and Blue Shield affiliates in 16 states now provide some coverage for PET scans, according to the Institute for Clinical PET (ICP), a nonprofit organization based in Washington, D.C. "PET is definitely going forward," says J. Michael McGehee, executive director of ICP.

Coverage Not Guaranteed

Individual Blue Cross and Blue Shield organizations are not bound by the Medical Advisory Panel's decisions. Affiliates such as Blue Shield of California have adopted coverage similar to the national recommendations, while others, such as Iowa Blue Shield and Kansas Blue Shield, review PET claims case by case. Some companies flatly deny coverage for PET studies.

"We're not paying for PET," says Marvin B. Blitz, MD, medical director of Empire Blue Cross in New York. Nor does Pennsylvania Blue Shield pay for any applications of PET, according to medical director Joseph A. Ricci, MD. Neither company has immediate plans to reconsider PET coverage as a result of the national recommendation, the two medical directors say.

Approved Indications

The Blue Cross and Blue Shield national panel qualified its recommendations for PET and stopped short of recommending coverage of PET in clinical cardiology. PET scans are useful, the panel said, in the differentiation of recurrent brain tumors from treatment-related tissue necrosis, but should be eligible for coverage only when all conventional diagnostic techniques have been tried without success. The panel also endorsed PET for localization of epileptogenic foci in patients with complex partial epileptic seizures, when such patients have failed to respond to medical therapy and are candidates for surgical resection. The advisory panel considers "investigational" all other applications of PET in the diagnosis and treatment of diseases of the central nervous system.

At least two affiliates, Blue Cross of California and Florida Blue Shield, have gone beyond the national recommendation and adopted payment policies for PET studies of heart disease. The American Heart Association (AHA) has tentatively endorsed the usefulness of PET in assessing myocardial viability, as long as the information could be expected to influence clinical management of the patient. The AHA found PET effective for myocardial perfusion imaging but not clearly superior to less expensive alternatives, such as single-photon emission computed tomography, for the detection or assessment of coronary artery disease.

Assessment Criteria

The Blue Cross and Blue Shield national panel uses five basic criteria to assess new medical technology, including the stipulation that new devices require regulatory approval. The panel reviews the scientific literature to see that sufficient studies document the effectiveness of the technology. The panel also considers whether the device or procedure influences health outcome, and furthermore, whether the outcome is comparable to or better than existing alternatives. Finally, positive outcomes should be widely obtainable, not available just in specialized research hospitals.

ICP officials say the national policy decision will pave the way for broad coverage of clinical PET. "This is a very significant development since this makes official on a national level those decisions that individual state Blue Cross and Blue Shield organizations have already made to pay for cardiac, neurological, and oncological PET studies," says John Mazziotta, MD, professor at UCLA School of Medicine and a past president of the ICP. "The stage has now been set for Medicare reimbursement," he said.

Medicare Coverage to Follow?

Over two years ago, The Society of Nuclear Medicine and the American College of Nuclear Physicians petitioned the Health Care Financing Administration (HCFA) to extend Medicare reimbursement to selected PET studies. HCFA initially delayed its decision contingent on a review by the Office of Health Technology Assessment (OHTA), which was asked to evaluate the clinical efficacy of PET in the localization of seizure focus, the differentiation of radiation necrosis from recurrent brain tumor, the assessment of myocardial viability, and the diagnosis and evaluation of coronary artery disease.

Since OHTA completed the review, however, HCFA has refused to release the results until the Food and Drug Administration (FDA) approves the radiopharmaceuticals. The FDA has approved rubidium-82 chloride, which is used for assessing myocardial viability. But approval of fluorine-18 fluorodeoxyglucose (FDG), an important tracer used in brain, heart, and cancer PET studies, is mired in regulatory problems affecting cyclotron-produced tracers (see *JNM*, Newsline, September 1992, p. 24N).

An advisory panel to the FDA,

which is considering drug master file data from the ICP, recommended approval for FDG earlier this year, indicating some progress. Working with the ICP, Methodist Hospital of Peoria, Illinois has submitted a new drug application (NDA) for FDG and, according to Mr. McGehee, the NDA is "complete and in the final stages of evaluation."

J. Rojas-Burke
Newsline Editor, *JNM*

■ SNM Manpower Survey Report

The Society of Nuclear Medicine's Manpower Survey Committee has collected information on physicians, scientists and technologists performing nuclear medicine in the U.S., having surveyed more than 80% of facilities. The purposes of the survey were to document the extent to which nuclear medicine services are provided by nuclear medicine specialists, to build a database of practitioners and technologists in nuclear medicine for the Society's use, and to gather data applicable to reimbursement issues in nuclear medicine and radiology.

For the current survey, the committee collected data on technologists involved in the practice of nuclear medicine in any setting, including offices, and the amount of time spent by each in nuclear medicine. Since the survey was conducted by telephone, it involved only three basic questions.

Survey Design

A list of 4,598 facilities involved in nuclear medicine was purchased from Technology Marketing Group. The list included 3,880 hospitals and 718 outpatient facilities. A system of group leaders appointed by SNM chapter presidents recruited volunteer callers in each state. The callers contacted facilities statewide to obtain information about individuals working in nuclear medicine departments, as well as individuals performing nuclear medicine procedures in other departments. Further calling from the SNM central office was repeated until an overall response rate of 80% of facilities in each state was achieved.

TABLE 1. Geographic Distribution of Responders

Regions*	U.S. Population	No. of Physicians	%	No. of Scientists	%	No. of Techs	%
1	13206943	570	5.5	49	6.8	546	5.4
2	25720643	858	8.2	78	10.9	869	8.6
3	25917214	1119	10.7	76	10.6	1283	12.8
4	44706766	2263	21.7	144	20.1	1930	19.2
5	46384041	1801	17.2	137	19.1	1968	19.6
6	11949787	655	6.3	46	6.4	610	6.1
7	28217862	1247	11.9	74	10.3	1056	10.5
8	7804701	364	3.5	41	5.7	355	3.5
9	9265805	348	3.3	17	2.4	317	3.2
10	35735311	1221	11.7	56	7.8	1105	11.0
Total	248709073	10446	100.0	718	100.0	10039	100.0

*Region 1: Maine, Vermont, New Hampshire, Massachusetts, Connecticut, Rhode Island. Region 2: New York, New Jersey. Region 3: Pennsylvania, Delaware, Maryland/DC, West Virginia, Virginia. Region 4: Kentucky, Tennessee, North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi. Region 5: Wisconsin, Michigan, Illinois, Ohio, Minnesota, Indiana. Region 6: Nebraska, Iowa, Kansas, Missouri. Region 7: New Mexico, Texas, Oklahoma, Arkansas, Louisiana. Region 8: Colorado, Utah, Wyoming, South Dakota, North Dakota, Montana. Region 9: Washington, Oregon, Idaho, Alaska. Region 10: California, Nevada, Arizona, Hawaii.

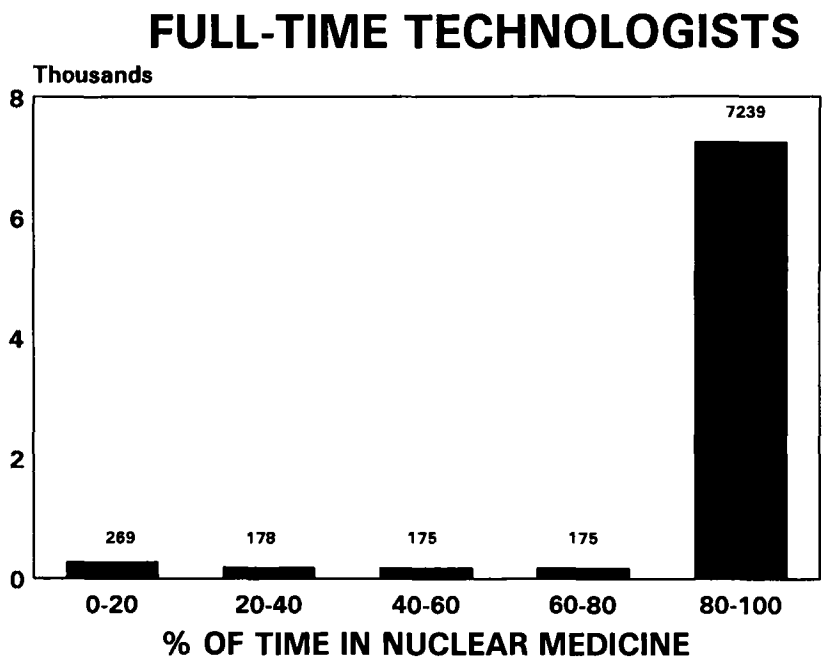

FIG. 1. Time spent by full-time technologists in nuclear medicine.

Survey Results

The regional distribution of nuclear medicine technologists is roughly proportional to the population (Table 1). The table of geographical responders shows that most technologists live regions 3–5, 7, and 10.

An interesting finding is contained in Figure 1, showing the percentage of time that technologists employed in full-time positions spend in nuclear medicine. It is surprising to note that

the majority of full-time technologists (7,239) spend over 80% of their time providing nuclear medicine services, and within this subgroup, almost all (7,146) spend 100% of their time in nuclear medicine. The remaining full-time technologists (874) spend between 10% and 80% of their time in nuclear medicine; they also work in radiography, ultrasound, and radiation therapy. Among nuclear medicine technologists employed in part-time positions (Fig. 2), the time spent in nuclear medicine varied widely with peaks at 20%, 40%, and 80%.

Data obtained on certification of technologists (Tables 2 and 3) show the mix of certifications held by technologists. Although the majority of technologists responding are certified by the Nuclear Medicine Technology Certification Board (NMTCB), it is interesting to note that over 1400 are listed as being certified only as radiographers. It will be interesting to see in the next few years what effect mandatory state licensure will have on those technologists not certified in nuclear medicine technology.

FTEs And Hospital Bed Size

The technologist data have been tabulated to correlate the number of nuclear medicine technologist full-time equivalents (FTEs) by hospital type and bed size.

The hospitals participating in this study have been classified into three major types: university, government, and community-based hospitals. These range in bed size from 200 to 3,000 beds. A total of 3,202 hospitals participated in this census comprising a total of 3,677 facilities that perform nuclear medicine procedures. The data provided by this study concerning nuclear medicine technologists are probably more accurate in describing those technologists who are actively involved in the performance of nuclear medicine procedures, since the technologist data, unlike the physician data, do not require differentiation as to where the nuclear medicine procedures are actually performed and are

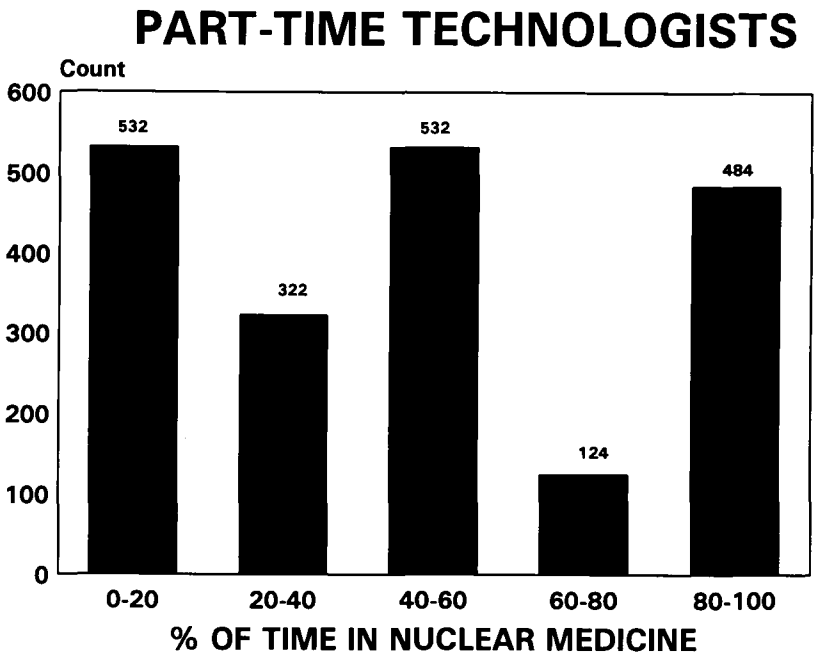

FIG. 2. Time spent by part-time technologists in nuclear medicine

TABLE 2. Technologist Certifications

Certification (degree)	Total	Only Cert.	Multiple Cert.
Nuclear Medicine Technology Certification Board (CNMT)	6045	3691	2354
American Society of Clinical Pathology (Med. Technology) (MTASCP)	42	19	23
American Society of Clinical Pathology (Nuclear Medicine) (NMASCP)	119	23	96
American Registry of Radiologic Technologists (Nuc. Med.) RT(N)	3619	1223	2396
American Registry of Radiologic Technologists (Radiography) RT(R)	2589	1409	1180
American Registry of Radiologic Technologists (Radiation Therapy) RT(T)	28	8	20
State Licensure Only (S)	314	164	130
Ultrasound Only (US)	29	11	18

TABLE 3. Number of Technologists with Multiple Certifications

Other Certifications*	CNMT	RT(N) (No CNMT)	RT(R) (No CNMT)
RT(N)	1463		
RT(N,R)	561		
RT(R)	231	334	
RT(T)		6	6
S	73	23	42
NMASCP	85	9	
MTASCP	23	1	
US	12	7	10

*See Table 2 for definition of acronyms.

TABLE 4. Technologist FTEs by Hospital Bed Size: University Hospitals

Total FTEs Reported	Hospital Bed Size			
	<100	100–199	200–599	600–3000
0.00–0.24				1
0.25–0.49				
0.50–0.99				1
1.00–1.49	2	2	4	
1.50–1.99		1		
2.00–2.99	1	3	3	2
3.00–3.99	1	1	4	
4.00–5.99			13	1
6.00–7.99			13	2
8.00–9.99		1	9	2
10.00 or more			2	8
Total Hospitals	4	8	48	17

TABLE 5. Technologist FTEs by Hospital Bed Size: Community Hospitals

Total FTEs Reported	Hospital Bed Size			
	<100	100–199	200–599	600–3000
0.00–0.24	105	27	14	1
0.25–0.49	77	18	5	1
0.50–0.99	165	71	8	3
1.00–1.49	326	318	113	4
1.50–1.99	37	70	42	
2.00–2.99	88	271	276	4
3.00–3.99	10	94	271	6
4.00–5.99	4	36	289	20
6.00–7.99	2	13	97	22
8.00–9.99	1	1	28	15
10.00 or more	3	1	17	22
Total Hospitals	818	920	1160	98

TABLE 6. Technologist FTEs by Hospital Bed Size: Government Hospitals

Total FTEs Reported	Hospital Bed Size			
	<100	100–199	200–599	600–3000
0.00–0.24				
0.25–0.49	2			
0.50–0.99			1	
1.00–1.49	1	13	5	4
1.50–1.99		1		
2.00–2.99	2	9	18	3
3.00–3.99	1	5	15	1
4.00–5.99		2	16	6
6.00–7.99		1	8	7
8.00–9.99			5	1
10.00 or more			1	1
Total Hospitals	6	31	69	23

not dependent upon the type of physician interpreting the study.

The majority of university hospitals (Table 4) in this study fell in the 200-599 bed range. In this hospital type, total FTEs for nuclear medicine technologists ranged from 1 to 10, with the majority of institutions reporting between 4 and 8 FTEs. Of interest in this table is the fact that of the seventeen hospitals responding with 600 or more beds, four had less than three FTE nuclear medicine technologist positions. If one compares total nuclear medicine FTEs in community-based hospitals (Table 5) with university hospitals, it is apparent that there is a significantly lower number of nuclear medicine technologists in the community-based hospitals that have a capacity of over 200 beds. Nuclear medicine technologists in these facilities are clustered in the 2–6 FTE range. There are also significantly more community-based hospitals with greater than 600 beds and fewer with 200 or less beds, compared to the university hospitals. In the community hospitals with bed capacity of less than 200, the FTE range was from 1 to 3.

Most of the government hospitals (Table 6) surveyed were in the 200-599 bed range. When compared to the university and community-based hospitals, the number of full-time FTEs ranged from 2 to 6. The probable reasons for the increased number of FTEs in government and university hospitals are the patient mix, teaching programs, research involvement, and support of continuing education.

Table 7 shows the number of FTE technologists in an outpatient setting; most facilities reported 1 to 1.5 full-time positions per facility. This suggests that most of these outpatient facilities have only one gamma camera.

The data collected during the Manpower Survey should provide extremely useful information to the Technologist Section as it can now base strategic planning and recruitment efforts in specific areas. Data on the distribution of technologists will be very important for future planning purposes, such as

membership, certification efforts, continuing education requirements, and government relations activities.

The SNM Manpower Survey was conducted by the SNM Manpower Survey Committee: Schuyler V. Hilts, MD (Manpower Committee chair); Myron Pollycove, MD; Robert F. Carretta, MD; and James C. Clouse, DO. The committee was assisted by Jerald Katzoff (U.S. Public Health Service statistician) and Virginia Pappas, CAE (SNM associate executive director). This report was compiled by Virginia Pappas, CAE in collaboration with Paul Hanson, CNMT (SNM—TS president); Schuyler Hilts, MD; and Gretchen Rehberg, CNMT.

TABLE 7. Technologist and Physician FTEs Per Facility: Outpatient (No Beds)

FTEs	Physician No. of Facilities	Technologist No. of Facilities
0.00–0.24	154	40
0.25–0.49	95	17
0.50–0.99	99	58
1.00–1.49	98	201
1.50–1.99	12	23
2.00–2.99	10	85
3.00–3.99	3	23
4.00–5.99	3	17
6.00–7.99	1	7
8.00–9.99		2
10.00 or more		

■ News Briefs

Europeans Celebrate First International Nuclear Medicine Week

This year marked the first celebration of Nuclear Medicine Week as a worldwide event. One of the prime movers behind the internationalization of Nuclear Medicine Week was Professor Serge Askienazy, MD, PhD, president of the European Association of Nuclear Medicine (EANM) and chief of nuclear medicine at C.H. Sainte-Anne in Paris, France. Professor Askienazy talked to *Technologist News* about the EANM's plans for celebrating Nuclear Medicine Week, which in Europe will be referred to as World Week of Nuclear Medicine (WWNM).

Professor Askienazy outlined EANM's three target objectives for WWNM. First, nuclear medicine practitioners will stress the importance of differentiating nuclear medicine from atomic weapons and nuclear power plants through public speaking, educating members of the media, and talking to legislators. Second, they will educate the public that undergoing nuclear medicine procedures does not cause cancer. Third, they will tell the public that a patient receives less radiation from a typical diagnostic nuclear medicine procedure than from a standard X-ray procedure. Professor Askienazy emphasized that it is of the utmost importance to dispel the myths about nuclear medicine that are currently held by the public. As anecdotal evidence of the pervasiveness of these myths, he cited a poster about nuclear medicine that he had seen recently in a hospital hall. The graffiti scrawled on it said "Radiation Kills."

To publicize WWNM, the EANM created and distributed 2-cm (~1 in.) stickers that said Nuclear Medicine Week, in white letters on an dark blue background. The stickers were distributed to hospitals throughout western Europe and were used on the letterheads of nuclear medicine departments during WWNM. The EANM also distributed five different language versions of SNM's NMW poster.

In France, all general practitioners get a daily medical newspaper and the paper ran a free insert, consisting of a poster-form fact sheet on nuclear medicine. The insert encouraged people to "write and ask" about nuclear medicine. Readers were provided with a P.O. box number and were told that they would receive a response to their inquiry within 36 hours.

Professor Askienazy also noted that dissemination of nuclear medicine information material may be easier in Europe than in the U.S. because 80% of the European Community market is in public hospitals (state or regional), providing a government network for distribution of nuclear medicine literature.

To further highlight the existence of the first WWNM, Professor Askienazy wrote an editorial in the October issue of EANM's journal, which stressed the importance of all practitioners of nuclear medicine becoming involved in a massive campaign to educate the public as to the diagnostic and therapeutic importance of nuclear medicine—due to its ability to investigate organ function and to educate the public as to the cost effectiveness of nuclear medicine (*1*).

Reference

1. Askienazy S. The world week of nuclear medicine—a must! *Eur J Nucl Med* 1992;19: 835.

Congress Supports National Biomedical Tracer Facility

The U.S. Congress has taken a decisive step toward establishing a large-scale particle accelerator dedicated to biomedical radioisotope production. In September the House and Senate

agreed on legislation that directs the Department of Energy (DOE) to begin preliminary funding for the proposed National Biomedical Tracer Facility (NBTF). The legislation was signed into law by President Bush on October 2, 1992.

The Society of Nuclear Medicine and the American College of Nuclear Physicians have backed the NBTF as a means to solve the mounting radioisotope supply problems that are hampering biomedical and other researchers. (An SNM task force carried out a feasibility study for the project with funding from the DOE in 1991.)

Citing the "lack of available domestically produced radioisotopes," Congress is directing the DOE to "address the situation by providing adequate funds to begin the one-year National Biomedical Tracer Facility Project Definition Phase." Rather than specify a sum, Congress refers to the 1991 feasibility study, which calls for a $2 million appropriation to support the development of competing proposals for building the NBTF.

"I think it's a smashing success," says Richard C. Reba, MD, of the University of Chicago, the president-elect of SNM who has been involved in the effort to establish the NBTF. "It will be very difficult for the DOE not to go forward with this," he adds, alluding to earlier decisions by the DOE to exclude the project.

While the measure's passage is a great boon to the NBTF project, Dr. Reba says significant hurdles remain. Although Congress asked the DOE for a status report on the NBTF by February, the legislation gives DOE the leeway to put off doing anything substantial until next October when fiscal year 1994 begins. And so far, no money has been set aside for the actual construction of the NBTF. When the DOE completes the project definition phase, and a winning proposal is selected, "then the real work begins," says Dr. Reba.

A string of events over the summer helped bring the severity of isotope supply problems to the attention of lawmakers. The threatened strike by the near-monopoly supplier of molybdenum-99, Nordion International, caused a stir soon followed by the release of dire warnings from Congress's General Accounting Office about the near bankruptcy of the DOE's isotope production and distribution office.

A congressional hearing convened in August by Rep. Mike Synar of Oklahoma made much ado about the threatened strike and focused considerable attention on the need for an NBTF (even though the NBTF would not be used to produce molybdenum-99 and is not conceived as an answer to the problem of dependence on a single supplier of molybdenum-99). Rep. Synar and members of his subcommittee criticized DOE officials for failing to include funds for the NBTF in the 1993 budget.

Concerted efforts by the SNM and ACNP Office of Government Relations helped kindle congressional interest. Accompanied by physicians and scientists, government relations staff met with congressional staffers and administration officials to explain the need for the NBTF. The government relations office also coordinated a letter-writing campaign from SNM and ACNP members to Congress. "We played every front," says Kristen D.W. Morris, director of government relations for SNM and ACNP.

Given the growing momentum behind the NBTF, there is an outside chance that the DOE could find money in the current budget to go ahead with the competitive siting phase. Ms. Morris says one reason she urged lawmakers not to specify any particular appropriation was to give the DOE flexibility to act sooner. Says Ms. Morris, "The ball is in their court now."

Election Result Addendum:

Mickey T. Clarke, CNMT of St. Louis, Missouri, newly elected treasurer of The Society of Nuclear Medicine Technologist Section, was inadvertently omitted from the list of Technologist Section election results printed in the September issue. The election box has been reprinted below to include Mickey Clarke's name.

TECHNOLOGIST SECTION ELECTION RESULTS

President-Elect
Theresa M. Boyce, CNMT
Albuquerque, New Mexico

Treasurer
Mickey T. Clarke, CNMT
St. Louis, Missouri

Secretary/Historian
Lois M. Padellford, CNMT
Des Moines, Iowa

Trustee
Author Hall, CNMT
Houston, Texas

Finance Committee
Andrew L. Friden, CNMT
Miami, Florida

Membership Committee
Kathleen Jones, CNMT
Allentown, Pennsylvania

Nominating Committee
Donna M. Brinlee, CNMT
Roselle, Illinois

Miriam K. Miller, CNMT
Washington, DC

Moira K. Mahoney, CNMT
Pittsburgh, Pennsylvania

Kathleen Davis, CNMT
West Haven, Connecticut

Office of Health Care Policy

The Society's new Office of Health Care Policy (OHCP) proposed a mission statement, which the SNM Board of Trustees unanimously approved. The mission of OHCP is "to establish a forum through which nuclear medicine physicians, scientists, and technologists may contribute to the national effort to improve health care." OHCP will coordinate the establishment of quality standards for nuclear medicine and represent nuclear medicine in the inter-specialty development of practice policies. The office also intends to make recommendations for increasing the cost-effectiveness of medical care.

NRC Withdraws Training Criteria Proposal

The Nuclear Regulatory Commission (NRC) is withdrawing an Advance Notice of Proposed Rulemaking on training and experience criteria for all individuals who use NRC-regulated radioactive materials in the practice of medicine.

Currently the NRC reviews the training and experience of physicians, teletherapy physicists, and radiation safety officers involved in or supervising the use of radioactive materials for medical purposes. The NRC was considering whether it should also have criteria for technologists and other nonphysician workers who assist in handling the radioactive materials.

The existing requirements set out the training and experience requirements generally believed necessary for a physician to use radioactive materials safely and to protect workers, patients, and the public from unnecessary radiation exposure.

On January 27, 1992, the NRC's medical Quality Management (QM) Program and Misadministration Rule became effective. The NRC stated that implementation of this rule would result in increased direction and oversight by the authorized physician user, thus mitigating the need for the NRC to specify training and experience criteria for technologists and other nonphysician workers who handle byproduct material.

The NRC staff will continue to review and evaluate the adequacy of existing training and experience criteria for medical uses and will continue to monitor the role of inadequate training or experience as a contributing factor to misadministration events reported to the NRC.

Title VII Appropriations and Allied Health Project Grants

Congress authorized slightly more than $1 billion through fiscal year 1994 for the Health Professions Education Extension Amendments of 1992, which revises and reauthorizes Title VII of the Public Health Service Act. The authorization for allied health traineeships includes $5,000,000 for each of the fiscal years 1993 through 1995. The reauthorizing legislation for Title VII and VIII of the Public Health Service Act emphasizes encouraging more students to train to become providers of "primary" health-care services, particularly in geographic areas with shortages of medical personnel.

The legislation includes the following initiatives. A commission on allied health is established to make recommendations to the Secretary and appropriate congressional committees on issues such as the supply and distribution of allied health personnel, and current and future shortages of allied health personnel. According to the conference agreement, "Although historically only the special projects authority has received appropriations, the conferees believe that provision of traineeships and other assistance designed to increase enrollment in allied health fields with critical shortages is an appropriate investment of limited health professional funding. The contribution of allied health professions to health reform becomes increasingly important with the growing sophistication of medical technology and the effect that an aging population has on demand for skilled health providers who are not physicians, nurses or dentists. . . The Conferees believe that individuals trained at the master's level can be effective educators. In view of the need to establish new or significantly expanded training programs in such critical professions as physical and occupational therapy, the limited funds made available during this reauthorization period should be channeled into programs that will expand the number of educational opportunities available to students desiring to enter these professions."

The initiative on project grants and contracts authorizes grants and contracts to be awarded for the purpose of expanding or establishing programs that will increase the number of individuals trained in allied health professions. The authorization for allied health project grants and contracts includes $5,000,000 for each of the fiscal years 1993 through 1995.

Congress also agreed to a compromise bill for Title VII appropriations for fiscal year 1993. The House and Senate approved a $245.7 billion bill for appropriations for the Departments of Labor, Health and Humans Services and Education. This measure includes funding for allied health programs under Title VII. During their work on the bill, negotiators agreed to reduce the measure's domestic discretionary spending level so that it did not exceed the President's $61.97 billion request.

The Senate had recommended $3,500,000 for allied health project grants; the House requested $2,045,000. The Senate/House conference agreement includes $3,500,000 less a 0.8% reduction applied to all programs included in the bill. Therefore, appropriations for fiscal year 1993 allied health project grants are $3,472,000. For fiscal year 1992, appropriations were $2,754,000.

JNMT Reader Survey

A copy of the 1992 JNMT Reader Survey is bound into this volume. Please take the time to fill out the survey and return it to the Editor. (No postage is required in the U.S. and the return address is attached to the survey form.) This is your chance to express your opinion and affect the future subject matter of the Journal. So make your voice heard!

NRC Drops Record-Keeping Requirements

The U.S. Nuclear Regulatory Commission has deleted the record-keeping requirements for deviations from a manufacturer's instructions for the use of radiopharmaceuticals. Effective October 2, 1992, amendments to Parts 30 and 35 of the NRC's regulations eliminate requirements for a written justification for each departure, a precise description of each departure, and the number of procedures performed that depart from registered indications.

The Society of Nuclear Medicine and the American College of Nuclear Physicians had strongly objected to the record-keeping requirements, and praised the coordinated effort of the NRC and the U.S. Food and Drug Administration in reaching the decision.

The NRC imposed the requirements in August 1990 as part of an interim final rule that allowed departures from manufacturer's instructions for preparing diagnostic radiopharmaceuticals using generators and reagent kits for which the FDA approved a new drug application. The rule also included the record-keeping requirements.

The NRC drafted the interim final rule in response to a petition filed by SNM and ACNP in 1989 that requested rule changes to allow departures from manufacturer's instructions and to allow the use of radiopharmaceuticals for therapeutic indications and methods of administration not included in FDA-approved package inserts. But SNM and ACNP objected to the criteria included in the interim final rule, maintaining that they limited the physician's ability to exercise medical judgement, particularly in situations of emergency care.

In June the NRC announced that after examining the records collected under the interim final rule and consulting with the FDA, regulators decided that the information collection requirements were no longer necessary. NRC officials said that they and FDA staff agreed that the major trends in departures that might be identified by the record-keeping requirements were already clear and that the collection of additional data was therefore unnecessary.

The amended rules say that for diagnostic studies, a licensee may depart from a manufacturer's instructions for FDA-approved eluting generators and reagent kits by following the directions of an "authorized user physician." For preparing therapeutic radiopharmaceuticals, the NRC still requires an authorized physician's written directive for any indication or method of administration not listed in package insert instructions.