■ Technologists Plan for Nuclear Medicine's Future

by Dawn Murphy

The Society's Technologist Section (SNM-TS) has embarked on an aggressive plan to advance nuclear medicine technology within the health care field. Steps in the plan include positioning nuclear medicine technologists (NMTs) to assume more diverse responsibilities as health care providers and to be well-informed nuclear medicine spokespersons. At the mid-winter meeting in February, the Technologist Section approved the new strategic plan that will take technologists into the year 2000.

"Among the reasons for the new strategic plan are that we completed many assignments of the previous plan and the health care environment is different than it was three years ago," said Martha Pickett, CNMT, president of the SNM-TS. The section built its new plan upon three years of work from the previous strategic plan, approved in May 1994. Pickett said the technologists now have a better vision of the future of health care and their objectives can be "more proactive to move the profession forward."

The Technologist Section's new strategic plan outlines six objectives. Pickett says that the most critical objective is for the SNM-TS to collaborate with the Society to attain fiscal viability. This step is the first priority because it is the foundation upon which all other strategic initiatives ultimately depend.

The other five objectives work together to improve the position of nuclear medicine and nuclear medicine technology within the health care field. After fiscal viability, the next priority is for technologists to educate providers and purchasers about nuclear medicine's unique role, value and cost effectiveness to make nuclear medicine technology an integral part of health care delivery. Pickett points out that this is a "very big initiative that is beneficial for the entire nuclear medicine industry" and relates well to the Society's new initiatives. This goal sets the groundwork for the remaining four interlinked SNM-TS strategic initiatives to: become a catalyst and a recognized leader in integrating nuclear medicine technology into health care; ensure the competence of NMTs; appeal to a broad spectrum of health care technologies to increase the SNM-TS market share; and identify career pathways to expand professional opportunities in nuclear medicine and related fields.

The new strategic plan evolved naturally from the technologists' accomplishments that met the goals of their previous strategic plan and from grassroots feedback on what the membership wanted. Many SNM-TS committee activities are projects that carry over from one strategic plan into the next, with each new plan providing guidance for a higher level of achievement.

As health care was heading into a period of great change in 1994, the strategic plan called for the Technologist Section to explore restructuring its governance. To evaluate their current structure and member needs, in 1996 the SNM-TS distributed a survey to members at all levels within the organization and identified several strong trends in what members wanted the Technologist Section to do. It became evident to the leadership that implementing solutions would require restructuring. Some of this restructuring would require changes in the bylaws to remove policy and streamline the process of change. Based on member feedback, the SNM-TS crafted a restructuring plan to respond faster to the changing health care environment, communicate better, work in a more cost-effective manner, mentor new leadership and provide greater leadership accountability.

The Technologist Section completed much of their restructuring over the past year. This reorganization already has freed the SNM-TS to conceptualize problems in new ways and to generate more creative solutions.

In addition to restructuring, several other important projects from the 1994 SNM-TS strategic plan were completed that set the stage for the 1997 strategic plan. The section launched the newsletter, *Uptake*, to provide timely communication to the membership in between the quarterly issues of the *Journal of Nuclear Medicine Technology*. Increased communication and collaboration with other health care organizations were achieved, as most exemplified by the Technologist Section's formation of the Health Professions Network. HPN has been praised by federal officials for providing a liaison between health care organizations and various government entities and commissions, such as the Pew Commission. These efforts not only provide more information for technologists but are raising awareness of nuclear medicine and building the SNM-TS leadership role within the health care field. This increased cooperation with other organizations provides a stronger voice for the SNM-TS on common goals, such as legislative issues.

Continuing education remains a key activity that contributes simultaneously to several of the Technologist Section's goals. Joni Herbst, CNMT, chair of the SNM-TS Continuing Education Committee, says that one of the committee's biggest goals has been to make continuing education more accessible to members. One project, soon to be available, is continuing education articles published on SNM's Internet site. The New Projects Task Force was created as a key subgroup to develop innovative ways to provide continuing education to meet the strategic goal of increasing technologist competence. This group produced the *Emission Tomography Road Show* and is developing a directory of continuing education resources. Both these programs allow technologists to choose from a variety of available resources, with preapproved VOICE credit, to put together their own customized programs. Herbst says, "These programs would provide the same quality of material as in national meetings, but on the local level." Teleconferencing is a long-term project of large scope that the committee is evaluating. It may be able to provide cutting edge technology programs, more cost effectively, to a larger audience.

The goal of ensuring the competence of NMTs is furthered through a project developed by the Socioeconomic Affairs Committee, chaired by Denise Merlino, MBA, FSNM-TS. This committee soon will release the *Developing Employee Assessments and Competencies* booklet that shows how three facilities developed and used their own documentation to measure their employees' competence. This book will help departments prepare to meet Joint Commission on Accreditation of Healthcare Organizations requirements on technologist competency evaluations and documentation.

Increasing membership market share is a step toward the goal of fiscal viability that involves the SNM-TS Membership Committee. This committee is removing barriers to membership by simplifying the membership categories, creating a

category for commercial members and making the membership year coincide with the fiscal year. Kathy Thomas, CNMT, Membership Committee chair and president-elect, says that the SNM-TS "needs to represent people with more diverse needs" and capture the market of multiskilled technologists who aren't currently served by any one professional society. There is a potential membership pool of more than 17,000 Nuclear Medicine Technology Certification Board-registered technologists that the SNM-TS can tap into. The SNM-TS currently has about 7,000 members.

Although the technologists have accomplished many of the goals from their previous strategic plan, it is difficult to credit any of those accomplishments with any particular committee. Each accomplishment has been the result of the efforts of many individuals on more than one committee toward the common goals. Denise Merlino says, "We can't change the world tomorrow, but we're laying the groundwork."

Pickett, Herbst, Merlino and Thomas agreed that cooperation between the technologists and the physicians and scientists is necessary for each to learn from the other to achieve the goals necessary to make nuclear medicine an integral part of health care delivery. The technologists' new strategic objectives have much in common with the Society's new strategic goals. Teamwork can create a synergism strong enough to bring about the changes necessary to ensure the future of nuclear medicine.

■ SNM Distributes 26 Approved Procedure Guidelines

by Wendy J.M. Smith, MPH
Associate Director of Health Care Policy
Society of Nuclear Medicine

The Society of Nuclear Medicine has developed 26 procedure guidelines to assist nuclear medicine practitioners in recommending, performing, interpreting and reporting the results of nuclear medicine imaging procedures. Each guideline describes a procedure that will maximize the diagnostic information obtained in a study while minimizing the resources that are expended. Procedure guidelines are not intended to describe cutting-edge or state-of-the-art procedures that may be under development at academic medical centers nor are they intended to be advocacy statements. Procedure guidelines also are not intended to describe the minimally acceptable procedure.

Methodology

The guideline development process is under the auspices of the Commission on Health Care Policy and Practice's Guidelines and Communications Committee, headed by Henry D. Royal, MD. The procedure guidelines are based on a combination of expert opinion and available scientific data. Relevant guidelines from other organizations are reviewed and incorporated when indicated. Procedure guidelines do not have the same instrument-specific details as a procedure manual. Site-specific procedure manuals can only be developed by local physicians. The long-term goal is to develop evidence-based guidelines when possible.

After the initial draft is written by the task force chairman, it undergoes approximately four detailed reviews and revisions by four to five subject experts (task force members) and by four to five methodologists (members of Guideline Development Subcommittee). The guidelines are reviewed line by line. All reviewer comments are entered into a database and a report is generated for the task force chair to consider for inclusion in the next guideline revision. The percent agreement for each reviewer and a total percent agreement for each revision are calculated. The experts are explicitly identified in an appendix to the guideline and the steps in the guideline development process are documented.

In addition, draft procedure guidelines are sent to many interested reviewers for review and comment through a brief evaluation form. Draft versions of procedure guidelines are widely distributed for comment from SNM members prior to their approval.

Procedure guidelines must be approved by the Guideline Development Subcommittee prior to being forwarded to the steering committee of the Commission on Health Care Policy and Practice. If approved by the commission, the guidelines are forwarded to the Board of Directors and then to the House of Delegates for their approval. Approval of a guideline requires a simple majority of the members of each group. Procedure guidelines should be regarded as living documents that will be reviewed and revised as appropriate, approximately every two years.

Developmental Issues

After embarking on the development of procedure guidelines, two problems became apparent: consensus and what constitutes "good practice." Consensus among nuclear medicine subject experts was not an easy task. Toward this end, members of the Guideline Development Subcommittee (methodologists) and members of each guideline task force (subject experts) convened twice a year to review and critique guidelines on a line-by-line basis. These face-to-face meetings have been quite successful in resolving issues of contention, in part because each member has the opportunity to express concerns and provide the rationale and relevant literature to support their argument. This environment of mutual respect is conducive to consensus.

The other obstacle in guideline development was deciding what constitutes good practice. The practice of nuclear medicine is diverse and the goal of guideline development was to describe much of what is acceptable in order to decrease undesirable behavior. The guidelines depict broad indications for procedures and interpretive criteria, as well as acceptable ranges of practice. By reviewing guidelines on a line-by-line basis it always became clear when a section of the document was troublesome and might not be considered acceptable practice. The comment reports are laid out by line number. Therefore, if multiple reviewers believe that the statement in lines 51-59 is incorrect, for example, these comments would appear together alerting the guideline author to the problem.

Another safety net to ensure that the guidelines depict good practice is review by a large number of members (more than 500), but in particular review by the member-select group. After the guideline has been through several review stages it is sent to 175 members who represent a cross-section of the SNM membership based on: urban versus rural geographic location; full-time versus part-time nuclear medicine practice; academic versus nonacademic practice; private versus hospital-based practice; and primary specialty by board certification. This group is crucial to guideline testing to assure that the guidelines developed are applicable to as broad an area as possible.

Distribution and Implementation

Since May 1997, 26 procedure guidelines have been completed and approved

by the SNM. Two additional guidelines are in the final stages of development. The Commission on Health Care Policy and Practice has recently published the *Society of Nuclear Medicine Procedure Guideline Manual 1997* that contains all 26 guidelines. In addition, procedure guidelines are being published periodically in the *Journal of Nuclear Medicine*. The guidelines also are available free of charge by downloading them from the SNM web site under the health care policy heading at http://www.snm.org.

The commission has distributed the approved guidelines to major third-party payers and managed care organizations in order to educate them on the benefits and cost effectiveness of nuclear medicine. In May, a letter was sent to more than 5,000 nuclear medicine departments in the U.S. inviting them to purchase the manual. After wide distribution, the commission plans to conduct a survey to determine the outcome of the approval and publication of procedure guidelines.

Format of Procedure Guidelines

I. Purpose
II. Background information and definitions
III. Common indications
IV. Procedure
  A. Patient preparation
  B. Information pertinent to performing the procedure
  C. Precautions
  D. Radiopharmaceutical
  E. Image acquisition
  F. Interventions
  G. Processing
  H. Interpretation/reporting
  I. Quality control
  J. Sources of error
V. Disclaimer
VI. Issues requiring further clarification
VII. Concise bibliography
VIII. Last House of Delegates approval date
IX. Next anticipated approval date
X. Appendix: description of guideline development process

Completed (Approved) SNM Procedure Guidelines

Guidelines for Guideline Development

Procedure Guideline for Bone Pain Treatment

Procedure Guideline for Thyroid Uptake Measurement

Procedure Guideline for Thyroid Scintigraphy

Procedure Guideline for Extended Scintigraphy for Differentiated Thyroid Cancer

Procedure Guideline for Bone Scintigraphy

Procedure Guideline for Gated Equilibrium Radionuclide Ventriculography

Procedure Guideline for Hepatobiliary Scintigraphy

Procedure Guideline for Gallium Scintigraphy in Inflammation

Procedure Guideline for ^{111}In Leukocyte Scintigraphy for Suspected Infection/Inflammation

Procedure Guideline for ^{99m}Tc-Exametazime (HMPAO)-Labeled Leukocyte Scintigraphy for Suspected Infection/Inflammation

Procedure Guideline for Gallium Scintigraphy in the Evaluation of Malignant Disease

Procedure Guideline for General Imaging

Procedure Guideline for Imaging with Radiopharmaceuticals

Procedure Guideline for Myocardial Perfusion Imaging

Procedure Guideline for Lung Scintigraphy

Procedure Guideline for Parathyroid Scintigraphy

Procedure Guideline for Diagnosis of Renovascular Hypertension

Procedure Guideline for Brain Perfusion Single-Photon Computed Tomography Using ^{99m}Tc Radiopharmaceuticals

Procedure Guideline for Hepatic and Splenic Imaging

Procedure Guideline for ^{14}C Urea Breath Test

Procedure Guideline for Tumor Imaging Using ^{18}F-FDG

Procedure Guideline for Pediatric Sedation in Nuclear Medicine

Procedure Guideline for Radionuclide Cystography in Children

Procedure Guideline for Diuretic Renography in Children

Procedure Guideline for Renal Cortical Scintigraphy in Children

SNM Procedure Guidelines in Development

Procedure Guideline for Gastric Emptying and Motility

Procedure Guideline for Acute Gastrointestinal Bleeding Studies

Procedure Guideline for First-Pass Radionuclide Angiography

If you have additional questions or would like to order the *Society of Nuclear Medicine Procedure Guideline Manual 1997* for $20.00 (includes shipping), please contact Olivia Wong, Health Care Policy Administrator, at 703-708-9000 X250 or by e-mail at owong@snm.org

■ Government Relations Updates

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

Compounding Language Drafted by Congress

Representatives Richard Burr (R-NC), Gary Condit (D-CA) and Tom Delay (R-TX) have introduced legislation (H.R. 1060) in the 105th Congress that would provide important protection for physicians and pharmacists against unwarranted regulation by the Food and Drug Administration (FDA). The legislation clarifies that states, not the FDA, have regulatory authority over pharmacy compounding. The bill also extends to licensed physicians involved in compounding.

In addition to compounding provisions, the legislation also would withdraw FDA-proposed regulations of PET drug products. The legislation would make the FDA proposal to expand regulation of PET drugs null and void, and return this issue to the state boards of pharmacy.

Representative Burr's office is currently gathering co-sponsors. ACNP and SNM members are urged to contact their own members of Congress to encourage them to co-sponsor the bill. For a copy of the legislation and a sample letter, contact Leonard Getzin, SNM/ACNP Government Relations Office associate coordinator at 703-708-9773.

Government Relations Committee Meets in Palm Springs

The SNM/ACNP Government Relations

Committee met on February 8 in Palm Springs, CA to discuss several issues pending with the Nuclear Regulatory Commission (NRC) and the FDA. The key issue with the NRC dealt with responding to the NRC's Strategic Assessment Project. The SNM and ACNP previously had suggested to the NRC that it consider general licensing for diagnostic nuclear medicine and a workshop to discuss the regulatory requirements necessary for therapeutic nuclear medicine. In Palm Springs, the Government Relations Committee reaffirmed that this approach should be included as one of its goals for 1997.

The SNM/ACNP Government Relations Committee, in one of its resolutions, passed the following goals for 1997:

1. NRC adoption of a general license for diagnostic and therapeutic nuclear medicine to eliminate unnecessary and inappropriate regulations;
2. Implementation by the FDA of a policy that allows fast-track approval of diagnostic cancer agents;
3. Legislative reform of the FDA's radiopharmaceutical approval process and other initiatives affecting nuclear medicine; and
4. Monitor all government activities affecting nuclear medicine, provide updates and respond when necessary.

The committee also discussed the creation of a political action committee (PAC) to further its interests in Congress. The SNM would sponsor the PAC and allow individual members to make contributions that would then be parceled out to friends of nuclear medicine in Congress. This idea was approved by both the SNM/ACNP Government Relations Committee and the SNM Board of Directors. The issue of presidential appointments was a lively topic of discussion because both the FDA commissioner's spot and, in June 1997, the NRC commissioner's spot may be vacant. The committee discussed and approved support for Randy Juhl, PhD, dean of the School of Pharmacy at the University of Pittsburgh, for FDA commissioner. The committee also discussed the benefit of placing a nuclear medicine physician as commissioner of the NRC and agreed to explore that option further. The next meeting of the Government Relations Committee will be in San Antonio, TX during the SNM Annual Meeting.

ACNP/SNM Support Randy Juhl for FDA Commissioner

The ACNP and SNM recommended to Donna E. Shalala, secretary of Health and Human Services, that she advise President Clinton to appoint Randy P. Juhl, PhD, to the position of commissioner. Dr. Juhl's leadership qualities, management skills, academic reputation and experience serving the FDA and the public were cited in this recommendation. He served as the first chair of the FDA's Nonprescription Drugs Advisory Committee, where he tackled issues related to the transfer of drugs from prescription to over-the-counter status, an area where the FDA had yet to engage its authority. As dean of the School of Pharmacy at the University of Pittsburgh, Juhl transformed a failing program into one that is highly regarded nationally.

ACNP and SNM File Petition for FDA Stay of Action

The ACNP and SNM have submitted a petition to stay the effective date of the FDA's regulations governing PET. The ACNP and SNM explained that the stay is justified because the FDA is unprepared to implement the regulation. Also, by granting a stay, the interests of justice will be served by preventing irreparable injury to the PET community, and the public interest will be served by protecting patients whose treatment is otherwise endangered. Granting a stay would remove an unfair legal cloud from the operation of PET centers and allow for continued high-quality medical care to patients. The ACNP and SNM are currently appealing a decision by the U.S. District Court regarding the process and legality of these PET regulations.

NRC Publishes Final Patient Release Criteria Rulemaking

The NRC has issued a final rule 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 and the International Commission on Radiological Protection. It will go into effect May 29, 1997. The provisions of the rulemaking are:

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 mSv (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 mSV (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast feeding, the instructions shall also include: (a) guidance on the interruption of 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 three 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 m; (c) using the biological or effective half-life; or (d) considering the shielding by tissue.
4. The licensee shall maintain a record, for three 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 exceeding 5 mSv (0.5 rem).

■ ACNP News

by Sharon Surrel, CNMT
ACNP Program Manager

Proficiency Testing Program Goes On the Road

With the generous assistance of DuPont Merck Radiopharmaceuticals , the Proficiency Testing Program (PTP) has received broad exposure recently. Several spokespersons have gone on the road to a variety of locations to talk about camera quality control and the necessity of technical proficiency. Edward M. Smith, ScD, FACNP, an ACNP scientist member of the Nuclear Medicine Imaging Committee (NMIC), has delivered a

number of talks and a paper to alert the nuclear medicine community of the necessity of establishing good methodology to achieve acceptable patient study results. A seminar entitled *A Working Quality Control Program for Scintillation Cameras* has been presented at the New England and Greater New York Chapters combined meeting (Nov. 1–3, 1996), at the ACNP Annual Meeting in Palm Springs as a combined seminar for physicians and technologists (Feb. 5, 1997) and at the Eastern Great Lakes Chapter Meeting in Toronto, Canada (May 1–2, 1997). An interactive categorical course on *511-keV SPECT and Coincidence Imaging: The Contemporary Scintillation Camera and Quality Control* will be offered at the SNM Annual Meeting in San Antonio, Texas. Paul Christian, CNMT, an active Technologist Section member of the NMIC, will speak on *Quality Control for Planar Imaging* at the categorical course.

For a detailed description of the PTP, see the *Journal of Nuclear Medicine Technology* article by Edward M. Smith ScD, FACNP and Bennett S. Greenspan, MD, FACNP entitled "The Proficiency Testing Program of the American College of Nuclear Physicians" *(J Nucl Med Tech* 1996; 24:342-348). It provides an excellent understanding of the purpose and scope of the PTP program. A partial listing of past exercises gives an overview of the educational benefits that can be obtained in participating in the program. In this highly competitive health care market, the winners will be those who consistently provide quality health care service and products.

The 1997 Fall Exercise

As more facilities begin using monoclonal antibodies, medium-energy SPECT imaging procedures will be more commonplace. The use of ^{67}Ga, particularly in the assessment of AIDS patients and other infectious processes, has increased significantly in recent years. Many facilities have forgotten or never before performed procedures employing medium-energy radionuclides. The acquisition and processing of a medium-energy study, whether gallium or indium, is not the same as the 140-keV technetium pertechnetate study. Performing a medium-energy study correctly is vitally important in achieving correct diagnosis and treatment for the patient. Therefore, the NMIC offers a Medium-Energy SPECT Exercise for those facilities who want to ensure quality in their medium-energy studies.

The 1997 IM-B medium-energy SPECT phantom is designed to test the performance characteristics of subscribers' systems when obtaining SPECT images with medium-energy radionuclides, such as ^{67}Ga and ^{111}In. Because SPECT imaging with these radionuclides is becoming more frequent, it is important for subscribers to be able to evaluate the performance characteristics of their systems and acquisition protocols using a medium-energy source. However, many quality control procedures are currently performed using low-energy, single-photon sources such as ^{57}Co or ^{99m}Tc, which may not produce the same system response.

The medium-energy SPECT phantom will allow subscribers to determine the ability of their systems to localize and resolve unknown targets of varying sizes. The exercise will also allow subscribers to test uniformity of spatial resolution and evaluate reconstructed flood field uniformity using medium-energy radionuclides. Subscribers will perform this study using a low-energy, single-photon source for comparison.

After the results have been submitted and evaluated, subscribers will receive an individual report for each set of results submitted. Subscribers will also be provided with a summary critique, which summarizes the results obtained by all participating facilities. The critique also contains the ACNP Nuclear Medicine Imaging Committee's discussion of the exercise and recommendations for future practice.

The 1997 Fall Exercise imaging simulator, to be shipped on September 16, 1997, will be retained by subscribers for future quality assurance testing. For more information or to place your order, call the ACNP National Office at 202-857-1135 and ask for Sharon Surrel.

■ News Briefs

New Radioiodine Pamphlet Available

The Society will soon release a new version of its radioiodine pamphlet that it prepared jointly with the Nuclear Regulatory Commission. *Guidelines for Patients Receiving Radioiodine Treatment* gives patients instructions for when they go home following treatment. The brochure explains how a patient can expose others to radiation and how the patient can reduce such exposure. This pamphlet may be used to meet the NRC's new requirement, 10 CFR Section 35.75(b), for giving written instructions to released radioiodine patients regarding general precautions about reducing radioactive contamination of other people. In addition to the pamphlet, more specific patient instructions may be required concerning case-specific factors.

DOE to Provide Research Isotopes

The Department of Energy will provide limited quantities of accelerator-produced isotopes for research purposes every month for two years beginning in October, 1997. Owen Lowe, associate director of DOE's Office of Isotope Production and Distribution, stated that some funds will be available to subsidize the development and production costs. The isotopes will be produced in accelerators at the Brookhaven National Laboratory, Los Alamos National Laboratory and the Tri University Meson Facility. The DOE is developing criteria for establishing priorities for development and production. Priorities will be based on such factors as whether there are multiple users of the isotope, what the potential benefits are from the use of the isotopes, the level of cost sharing that the researcher can make available to leverage DOE's funds, the quantities required, and the cost and time required for development. Suggestions concerning the criteria or interest in the isotopes may be addressed to Dr. Norton Haberman at 301-903-4321 or by e-mail to Norton.Haberman@hq.doe.gov.