Lines from the SNM President

As my year as president comes to a close, it is only natural to look back and consider the experience. When I agreed to run for the office, I did so for both altruistic and selfish reasons. I wanted to try to give something back to the field that has nurtured me for so long. I also knew that the challenges that faced the president would provide an opportunity for personal growth…and, boy, did they ever!

These challenges included those facing the field of nuclear medicine: over-regulation, under-reimbursement, inadequate isotope availability, and inadequate support for research and its rapid translation to clinical practice; and those facing the Society: cumbersome governance structure, lack of good working relationships with other societies, and a U.S.-centered focus. I discovered that virtually everyone had strong opinions about these subjects—opinions that did not always facilitate consensus. Even so, the Society has made significant progress on a number of fronts. I'd like to consider some of them here.

Last June, I identified innovative educational initiatives and international outreach as the two areas I hoped to influence personally. With respect to our educational programs, we know we're doing something right, because the Accreditation Council of Continuing Medical Education (ACCME) awarded the SNM a full and unprecedented 7-year accreditation.

The Society is making significant educational strides beyond the two mainstays of *The Journal of Nuclear Medicine* (*JNM*) and the annual meeting. The first is the hiring of Brenda Johnson, our new director of education. The Society has never had a separate education department within the professional staff structure; our main educational offerings were always supported by Publications and Meetings. The creation of a separate department and the hiring of a card-carrying educator (with a master's degree in education) have enormous symbolic and practical significance. Brenda has now successfully led two strategic planning sessions, one for the SNM as a whole and another specifically focused for the Technologist Section. You will see the results of these sessions play out over the next months. She has also led a successful effort to have DigiScript, an online medical education provider, agree to run a pilot program (at no cost to the Society) with offerings from the annual meeting in Toronto that will be available online by subscription to physicians and other interested parties. In this way, we're extending the fruits of the annual meeting to the Web. In a similar fashion, our journals (both *JNM* and *Journal of Nuclear Medicine Technology*) have gone online. Subscribers now have the opportunity in many cases to see articles before the hard-copy journal arrives in the mail.

This last point is particularly important for our international members. International members make up about 20% of the SNM, and we consider them full and valuable components of our membership. We actively want to do our best as a true international society. To this end, we've created SNMGlobal.org, a Web site "chaired" by Henry Wagner that offers news and communications links specifically for international members.

Jonathan Links, PhD
SNM President

We have also dedicated staff and member resources to international activities, accepted a support role with the World Federation of Nuclear Medicine and Biology (WFNMB) for the 2002 meeting in Santiago, Chile, and formed a new international advisory group within SNM to look at ways to better serve nuclear medicine around the world. I am also pleased to report that a number of continuing education sessions at the annual meeting are being organized by our international colleagues.

It is folly to think that, as president, I can or did accomplish any of these advances primarily through my own actions. Rather, these wonderful results depend on the hard work of a number of volunteers and professional staff members. I thank each and every one of them!

One area in which I do believe I made a difference as an individual is in our relationships with other societies. Perhaps because my own career has depended so heavily on valued colleagues with whom I collaborate, my "modus operandi" is to reach out actively to others to work together—to synergize, if you'll pardon the cliché. I've found that many of our relationships, good or bad, with other societies seem to depend on the personal relationships among the leaders. We've been able to develop strong and meaningful ties with a number of organizations—among them the European Association of Nuclear Medicine, the American Society of Nuclear Cardiology, WFNMB, ALASBMN—in ways that have not been possible in the past. I certainly do not take sole credit for these results. The times themselves are quite different. We all understand the need to marshal our resources and many people of good will worked hard to build relationships, but my personality meshes well with the active outreach and inclusivity called for by the Society's Strategic Plan.

In forecasting the future, I always talk about the unstoppable power of nuclear medicine. I believe this power is also a part of the Society's future, as long as you, its members, continue to support it and its efforts on behalf of the field. I give heartfelt thanks to all those who helped me and the Society this year—volunteers and professional staff—and vow to continue to work on behalf of the field we love.

Jonathan Links, PhD
President, SNM

Lines from the SNM–TS President

"The first responsibility of a leader is to define reality. The last is to say thank you. In between, the leader is a servant."
—Max De Pree, "Leadership is an Art"

My year as Society of Nuclear Medicine–Technologist Section (SNM–TS) president is coming to a close. Thank you so much for giving me the opportunity to serve. As Anton Chekhov said, "Any idiot can face a crisis—it's this day-to-day living that wears you out." I think that can be said about my year as president. Each day required the constant juggling of my personal, professional, church, and charity responsibilities, along with the addition of another full-time job. Although this day-to-day living has been wearing, it also has been a most wonderful experience, both personally and professionally.

Many things took place this year, a good number of them behind the scenes. We worked on developing the TS's relationships with the SNM, the Educational and Research Fund, and the Summit. There were continued efforts with respect to our liaison activities with a variety of organizations, including HPN and TAB. Many of the liaison activities resulted in additional meetings that added to the schedule but allowed for work to begin on special projects, such as the upcoming conference on Clinical Health Education Reform. We began an educational strategic plan (or master plan) that will serve to provide the framework for SNM–TS educational initiatives. We are revising our Roles and Responsibilities document and refining its elements into a scope of practice. The bill calling for national licensure was finally introduced in Congress. Drafts are being proposed that will address an SNM–TS stance on and definition of advanced practice and minimal entry-level education.

Kristen Waterstram-Rich, CNMT, FSNMTS
President, SNM–TS

By no means is this a complete list of the works in progress or the work completed this year, but it is representative of the array of activities in which the SNM–TS is involved and to which I tended as president. I want to thank you all for your kindness, encouragement, and support throughout this year. I also would like to thank you for all of the hard work you have done to keep the SNM–TS alive, vibrant, and progressing. Finally, in the words of A.A. Milne's Winnie the Pooh, "Thank you for making me feel like a very important somebody."

Kristen Waterstram-Rich, CNMT, FSNMTS
President, SNM–TS

New NIH Imaging Institute Established; Grassroots Support Solicited

On April 20, the new National Institute of Biomedical Imaging and Bioengineering (NIBIB) became a part of the National Institutes of Health (NIH), when Department of Health and Human Services Secretary Tommy Thompson signed off on official paperwork. Donna Dean, PhD, Senior Advisor to Ruth Kirschstein, MD, Acting Director of NIH, has been appointed Interim Director of NIBIB. The offices of the new institute are currently in Building 31 on the NIH campus in Bethesda, MD.

In a news release announcing Dean's appointment, Kirschstein noted, "…the new Institute will coordinate the ongoing research of the NIH institutes and centers and will foster the exchange of information with other Federal agencies," adding that, "while dedicating an Institute to medical technologies rather than to diseases, organ systems, or populations may seem novel for the NIH, it is truly a reflection of what science is today—and where science will be taking us tomorrow."

In citing President George W. Bush's fiscal year 2002 budget of $40.2 million for NIBIB, Kirschstein went on to reassure existing NIH institutes and centers: "I expect that the majority of the activity in other institutes will continue," Dr. Kirschstein explained, "while NIBIB will support important basic and crosscutting research in the bioengineering and imaging sciences."

Awareness of possible disparities in funding has been the subject of an intensive effort on the part of the Academy of Radiology Research (ARR) to raise grassroots support for the

(Continued on page 38N)

Happy Birthday, Hal!

On May 24, Hal O. Anger celebrated his 81st birthday. Like many octogenarians these days, he is both active and sound of mind. It is appropriate at this time to remember what Hal has meant to all of us in nuclear medicine.

In 1951, a half century ago, Hal invented the well counter. He always said that this was not a very remarkable thing to do, because "someone else would have done it soon." Hal felt it was an "obvious" concept. Obvious or not, it remains the backbone of in vitro radionuclide work. The next time you count a sample or interpret a lab test, remember who made it possible.

In the early 1960s, after working with 4- and 8-in. pinhole versions, Hal finished his 11-in. gamma camera—the first model and size that most of us would recognize as an Anger camera. That Hal's camera is still in widespread use today, 40 years later, is remarkable.

In those pre-technetium days, the short-lived tracer that seemed most appropriate to use with this camera was positron-emitting ^{68}Ga-ethylenediaminetetraacetic acid (EDTA), which was readily obtained from a ^{68}Ge-^{68}Ga generator. Because ^{68}Ga comes off this as ^{68}Ga-EDTA, an extracellular space tag, it was suitable for direct intravenous injection for brain scanning at a time (pre-CT) when radionuclide brain scanning was our dominant examination. Hal had also built a coincidence detector to go with this camera. The system depended upon backprojection with a tomographic readout. In short, this was positron emission with tomography. This work, which also described the efficacy of this approach compared with the then current rectilinear scanning technique with ^{203}Hg or ^{197}Hg, has been detailed in the literature (*1,2*). A few years later, I spent time with Michael Ter-Pogossian at a nuclear medicine postgraduate course at Washington University in St. Louis, telling him about Hal's positron camera. Dr. Ter-Pogossian had maintained a cyclotron at Washington University for years and had always hoped to exploit it more fully. I continue to believe that this conversation detailing how well Hal's positron camera functioned was added incentive for him to steer his own laboratory into the development of what we now know as a dedicated PET device.

In the spring of 1964, ^{99m}Tc arrived at the Donner Laboratory, after its introduction into clinical work by Paul V. Harper and his colleagues at the University of Chicago. As we now know, the marriage of the Anger camera and ^{99m}Tc has been a multiyear success story.

Hal O. Anger. The year 2001 marks the 50th anniversary of his invention of the well counter. He is pictured here with his gamma camera.

In the late 1960s, Hal developed his longitudinal tomographic whole-body scanner. This device used a small camera head with a converging collimator to scan across the patient in a rectilinear fashion. This device was not a commercial success, but each of us who had one thought it made the best whole-body ^{67}Ga-citrate studies around. Effective tomography was achieved by relating the depth of the tomographic plane selected to the focal region of the converging collimator. This machine had its best resolution deep inside the patient. It is possible that we may see this concept undergo a future renaissance.

With today's large crystals, it is no longer necessary to scan across the patient to cover the body. Using a fanbeam collimator with moving table, today's computers are powerful enough to be programmed to provide the tomographic readout to replace the analog electronics Hal used in the original machine. Hal has even outlined the way this could be accomplished (*3*). This could be an excellent way to exploit new receptor tracers labeled with ^{99m}Tc or ^{123}I. A whole-body single-pass screen with tomography possibly could be obtained without the need to perform SPECT.

Hal has provided the instrumentation base for our specialty and allowed us to perform in vitro

(Continued on page 38N)

The well counter remains the backbone of in vitro radionuclide work. The next time you count a sample or interpret a lab test, remember who made it possible: Hal Anger.

How to Renew an NRC License: Practical Pointers for Medical Licensees Part 2

The second of a two-part article on new NRC initiatives and their effects on licensees

The cost consequences of not obtaining a full 10-year renewal license must be added to the costs of a compliance program in determining what compliance strategy to adopt.

This article details cost-effective strategies for meeting the Nuclear Regulatory Commission's (NRC's) new license renewal criteria. Attention is focused particularly on enhancing the likelihood of obtaining a renewed license for the maximum possible 10-year period. General and specific advice is provided. General advice is presented in terms of a spectrum of alternative compliance strategies that vary in their abilities to avoid noncompliances that would result in obtaining a license term of less than 10 years. Specific advice is presented in terms of strategies that address the NRC's philosophy of regulation by exception, i.e., identification and reaction to new technologies and noncompliances. Detailed advice on how to avoid noncompliances is based on the specific regulatory concerns enumerated in the NRC's focus elements.

General Cost-Effective Strategies

Several alternative compliance strategies are available for maximizing the cost effectiveness of a compliance program. Four broad compliance strategies can be identified. Different strategies reflect differences in costs and benefits as perceived by different licensees. For example, a licensee who is philosophically risk averse would assign a higher benefit to the avoidance of noncompliance than would a licensee that accepts the likelihood of some noncompliances as the cost of doing business. However, if the cost effectiveness of a compliance program is measured solely in economic terms, independent of individual philosophies toward risk, then the NRC's consideration of noncompliance as a factor in determining the grant of a full 10-year license changes the cost-benefit balance in an objectively measurable manner. The cost consequences of not obtaining a full 10-year renewal license must be added to the costs of a compliance program in determining what compliance strategy to adopt.

Each strategy and its associated risks can be described as part of a spectrum. At the lowest direct-cost end of the spectrum is minimal compliance based on creative interpretations of regulatory requirements. This is a high-risk strategy. Minimal compliance seeks to limit costs by interpreting requirements to limit compliance activities. However, this alternative limits only direct compliance costs and usually is not cost effective, because it leads to interpretation disagreements with the regulator—disagreements that usually are resolved by the regulator in its own favor. As a result, this strategy leads to a high likelihood of noncompliances that must be corrected at substantial cost. Added to that cost now would be the high likelihood of not obtaining a full 10-year renewal license.

The next higher direct-cost alternative in the regulatory spectrum is strict compliance. In this case, the letter of the law is followed exactly. This is a relatively low-risk strategy. Compliance is viewed as a cost with no benefits. This alternative is not free from indirect compliance costs, because the requirements are never completely known with certainty. By limiting the compliance program to strict compliance, the licensee leaves no margin for error in interpretation and, thus, has some residual likelihood of noncompliance and of indirect compliance costs necessary for coming into compliance. However, the likelihood of obtaining a full 10-year license is higher for this alternative than for the minimal compliance alternative.

A still higher direct-cost compliance alternative is pursued by licensees who are risk averse. These licensees avoid regulatory risk by adopting expansive interpretations of regulatory requirements. Such programs may be unnecessarily costly, especially because they do not result in benefits commensurate with their costs. In particular, such "gold-plated" compliance programs may include elements that do not increase the likelihood of obtaining a full 10-year renewal license.

Finally, the highest direct-cost compliance alternative may be the most cost-effective alternative if the compliance activities are integrated into the overall program for delivering services. Integration of compliance into the elements of the program for delivering services enables

compliance activities to also enhance revenues that contribute to the bottom line. For example, equipment maintenance and surveillance are necessary to meet regulatory requirements. Although these requirements may be met by a schedule of activities that limits costs, an increase in such activities may result in substantially increased equipment availability, which contributes more to the bottom line than the additional costs of those actions.

Four types of exceptional circumstances have been identified by the NRC as reasons for renewing license applications for periods shorter than the full 10 years.

Specific Strategies for Exceptional Circumstances

Four types of exceptional circumstances have been identified by the NRC as reasons for renewing license applications for periods shorter than the full 10 years. A five-year renewal term is usually considered in these cases. They are: an application that involves high-risk technology new to the industry, the NRC or the licensee; a licensee who has experienced escalated enforcement in a prior inspection or in the previous three years; an application for a possession-only license because the facility has been shut down; and circumstances that cause the renewal application to warrant a comprehensive review (*1*). Suggestions are included here for addressing the first two, the most common of the exceptional circumstances. Also discussed are ways to avoid the exceptional circumstance of escalated enforcement.

New, High-Risk Technology

Applications that involve program elements that the NRC considers to involve high-risk technology can be formulated to support a full 10-year license renewal term by addressing the NRC's underlying concerns. These NRC concerns arise from the possibility of inadvertent exposure or misadministration as a result of licensee unfamiliarity with the new technology. Concerns may also arise from a perception that the licensee's program or regulatory performance has not demonstrated the strength that would give the NRC confidence to let the licensee adopt new technology subject only to the limited oversight provided by the NRC's inspection program. To address these concerns effectively, it is necessary to accept them on their own terms as important to the NRC rather than fighting their legitimacy.

Regarding the use of a new technology, it is helpful to differentiate among technologies that are new to the industry, to the NRC, or to the licensee. Technologies that are new to the industry will be the technologies that are most likely to be licensed initially for use for less than 10 years. Nevertheless, to the extent that the new technology can be shown to be similar or analogous to other technologies with which the industry is familiar, a case can be made for granting full 10-year licenses. An individual licensee can reinforce this position by showing a successful adoption of other new technologies without raising compliance concerns. Even where a licensee has not had experience as one of the early users of a new technology, if the licensee has had a good compliance record and been viewed as having a strong compliance program, a good case can be made for a full 10-year license on these bases.

When a technology is new to the NRC but not new to the industry, this implies that state regulators have had experience with that technology. In such cases, licensees should show that they have adopted programs that have been developed by other users for the successful control of the uses of that new technology. Finally, where a technology is new to a licensee but is not new to either the industry or to the NRC, the licensee should show that it has implemented programs that have been successfully used by others to control the uses of that new technology. In addition, in both cases, licensees should also support their applications with a recitation of a good compliance history, if available.

History of Escalated Enforcement

A history of escalated enforcement cannot be avoided. It must be addressed. What is important to the NRC about a history of enforcement is the way in which the licensee has responded to enforcement actions. Any attempt to minimize the importance of the event that led to escalated enforcement will be seen by the NRC as evidence of management's failure to understand its responsibilities as a licensee. Therefore, to effectively mitigate a history of escalated enforcement, a licensee should focus on the comprehensiveness and effectiveness of the corrective actions taken in response to the event that led to escalated enforcement. Emphasis also should be placed on increased management oversight taken since the event that resulted in escalated enforcement.

How to Avoid Escalated Enforcement

The advice in this section could be summarized by stating the obvious: escalated enforcement is avoided by avoiding noncompliances that the NRC

considers substantial enough to warrant escalated enforcement. To avoid such noncompliances cost-effectively, licensees should be sure to devote adequate resources to all regulatory requirements. In addition, licensees should devote additional management attention to the program elements that the NRC considers to be most important, because noncompliances involving these program elements have a higher than average likelihood of resulting in escalated enforcement.

The NRC has identified in a temporary inspection instruction the program elements, called Focus Elements (FEs), that it considers important (*2*). They are:

- Adequate program surveillance;
- Adequate corrective actions;
- Knowledgeable staff and management;
- Occupational/public doses that meet regulatory limits;
- Adequate security and control of licensed material;
- Use of licensed material only as authorized; and
- Administrations that follow written directives.

These FEs are all basic elements of any good byproduct material program. Many of these FEs are simply restatements of professional behavior. A strong showing on the FEs can support a full license renewal term despite previous performance issues. In a case in which a licensee's prior performance has been a concern to the NRC and the licensee has recently improved performance, that licensee should support its request for a 10-year renewal license by including in the renewal application summaries of improved performance for each of the FEs. Specifically, a licensee should describe major programmatic changes to improve performance, explain why those programmatic changes were appropriate under the circumstances, and show how those changes have prevented recurrence of any prior noncompliances. Training, especially for new activities, also should be described.

Self-Assessment Program

An effective self-assessment program serves at least two important functions. First, critical self-assessment can help to avoid noncompliance with NRC requirements and, thus, help to avoid NRC enforcement action and preserve the ability to obtain a renewed license for the full 10-year period. Second, a self-assessment program that is integrated into all activities can help to identify cost-saving efficiencies and other program improvements. The required audit program can be a significant contributor to cost-effective self-assessment. Although compliance can be achieved by adopting the model procedures in Appendix K (*3*), the adoption of additional program elements can convert the audit program from only a cost to a source of benefits that more than repays the cost. Information obtained from an audit program can be used to improve work processes and reduce expenses. Reliance on self-audits by support staff as a matter of course during all activities will improve support staff performance to more than repay program costs.

The development and implementation of an effective self-assessment program includes five critical aspects: basic principles; processes for identifying and acting on problems and on opportunities for improvement; criteria for effective self-assessment; using self-assessment results; and evaluation of a self-assessment program.

Self-Assessment Basics

Experience with self-assessment programs consistently shows that the single most important factor for success is management support and involvement. Management's provision of adequate resources and willingness to hold personnel accountable are essential for successful self-assessment. Management must establish clear expectations regarding self-assessment and periodically communicate that commitment to self-assessment to all personnel. Finally, as with any other important program, management must assign program responsibility to a qualified individual who has access to executives.

To be successful, self-assessment must be integrated into the conduct of program activities. Although trite, the saying that quality cannot be "inspected in" after the fact is nonetheless true. Self-assessment cannot be fully effective if it is viewed as a burdensome additional activity. One way of supporting the establishment of an appropriate attitude towards self-assessment is to include it in personnel policy procedures. Another support activity is to make the conduct of self-assessment a job evaluation criterion.

Each individual must be encouraged and trained to make self-assessment an integral part of all activities. Training helps each program

Each individual must be encouraged and trained to make self-assessment an integral part of all activities.

participant to achieve an enhanced self-awareness of their actions as they are being taken. Such training must be repeated regularly and supported by internal and external oversight. Training should include tailored discussions of specific activities to illustrate the importance of self-assessment and include industry examples of failures and cost-saving alternatives to show that self-assessment works.

Because the self-assessment program is a program like any other, its effectiveness should be evaluated periodically. Internal self-assessment can be conducted by quality assurance personnel. In addition, to avoid isolation from changing regulatory expectations and advances in the industry, external experts should be included in some self-assessments.

An effective self-assessment process involves all individuals.

Self-Assessment Process

An effective self-assessment process involves all individuals. A simple form should be made readily available to enable all individuals to report every unusual or unexpected event and all opportunities for improvement and cost savings. Management should regularly review all reports in a timely manner and prioritize them quickly by applying a simple triage ranking. Clear problems and opportunities for substantial cost savings or program improvements should be readily identifiable and acted on promptly. Minor annoyances and outlandish suggestions for program changes can be identified and dismissed. Intermediate problems and suggestions may require more information for response.

In all cases, appropriate responses should be developed and managed for timely closure. Generic implications of problems should be identified and addressed. Root causes should be determined for all significant events. Addressing symptoms instead of causes leads only to the repetition and sometimes worsening of problems.

Accountability for acting on action items should be clear and consistent. Responses should be provided to all contributors, even for contributions for which it has been determined that no further action is required. Even where action is taken on a contribution, do not assume that such action constitutes an adequate response.

Self-Assessment Criteria

Self-assessment criteria should be tailored to specific program requirements. In particular, to support the likelihood of obtaining a full 10-year renewal license, focus on the areas of regulatory concern indicated by NRC escalated enforcement actions. These are: (1) adequacy of program elements designed to preclude significant mis-administrations; (2) effectiveness of implementation of the quality management program; and (3) establishment of a safety-conscious work environment that does not tolerate harassment of or discrimination toward individuals who raise safety concerns.

Using Self-Assessment Results

Self-assessment will identify two broad classes of program improvements. One class of improvements is corrective actions to remove program and/or implementation deficiencies. Corrective actions should be prioritized in a way that is consistent with risk, taking into account costs and benefits. Corrective actions should be completed in a timely manner in accordance with schedule. The other class of program improvements is enhancements. Enhancements should be prioritized in a way that is consistent with costs, benefits, and overall program needs. Significant results should be disseminated promptly as lessons learned.

Self-Assessment Evaluation

An evaluation of the self-assessment program should be designed to determine whether the self-assessment program elements are adequate and being implemented well.

Management's communication of expectations and participation in all program phases should be determined. Management's consideration of peer reviews and independent assessment findings should be reviewed. Management's commitment to timely corrective actions should be assessed by reviewing the tracking to completion of corrective, preventive, and improvement actions.

Program planning should be reviewed to determine the comprehensiveness of coverage of program activities, the regularity of updates to the self-assessment program to reflect substantive program changes, the adequacy of management involvement, the extent to which activities are prioritized by risk, and whether management's expectations are being met.

Program conduct should be reviewed to determine whether all scheduled assessments are

(Continued on page 36N)

New SNM Officers Announced

On May 14, Dr. Robert Carretta and the members of the Society of Nuclear Medicine (SNM) Committee on Nominations announced the results of this year's elections. New officers and delegates include:

Vice President-Elect
(becomes SNM President in 2003)
Henry D. Royal, MD
Associate Professor of
Nuclear Medicine
Mallinckrodt Institute of Radiology
St. Louis, MO

Secretary/Treasurer
(serves a 3-year term, beginning June 2001)
Leonie Gordon, MD
Professor of Nuclear Medicine
and Radiology
Medical University of South Carolina
Charleston, SC

Delegates-At-Large to SNM House of Delegates
(serves a 4-year term, beginning June 2001)

David R. Brill, MD
Director of Nuclear Medicine
Chambersburg Hospital
Chambersburg, PA

Mathew L. Thakur, PhD
Professor of Diagnostic Radiology and Director,
Radiopharmacy Research
Thomas Jefferson University Hospital
Philadelphia, PA

William H. McCartney, MD
Professor of Radiology and Chief,
Nuclear Medicine Section
University of North Carolina
School of Medicine
Chapel Hill, NC

Warren Moore, MD
President, Southwest Imaging Associates
Associate Professor of Radiology (Nuclear
Medicine) and Chief, Nuclear Medicine Section
Baylor College of Medicine
Houston, TX

The three Delegates-At-Large appointed by the three underrepresented chapters for the year 2000–2001 (each serves a 4-year term, beginning June 2001) are:

New England Chapter

Kevin J. Donohoe, MD
Department of Nuclear Medicine
Beth Israel Hospital
Boston, MA

Pacific Northwest Chapter

Daniel Worsley, MD
Department of Nuclear Medicine
Vancouver General Hospital
Vancouver, British Columbia, Canada

Missouri Valley Chapter

Michael M. Graham, MD
Director of Nuclear Medicine
University of Iowa
Iowa City, IA

HISTORY CORNER

The Evolution of the Radiation Symbol

Dennis Patton, MD
SNM Historian

One of the most universally recognized symbols is the three-bladed magenta-on-yellow propeller indicating a radiation source. Where did the symbol come from, and how were these unusual colors selected?

After E.O. Lawrence invented the cyclotron in the early 1930s, it became possible for the first time to produce a wide variety of useful (although expensive) radioactive tracers in quantity for research. Everyone knew about the cyclotron, but the development of the nuclear reactor in 1942 was cloaked in wartime secrecy. After the war, the then Manhattan District (which the Atomic Energy Commission [AEC] took over in 1947) maintained absolute control over all reactor-produced radionuclides. Things changed in 1946. The June 14, 1946, issue of *Science* announced that the AEC had decided to allow the shipment of radioactive isotopes produced by the Oak Ridge reactor for open scientific research and medical applications (*1*). The response far exceeded the expectations of the Oak Ridge scientists. In that year they mailed out more than 1,000 Ci of activity, most of it in microcurie amounts but some in curie amounts, for teletherapy. The radionuclide most commonly shipped was ^{60}Co. Among the most popular was ^{32}P, which had cost $15,000/Ci from the cyclotron but was only $32.50/Ci from the reactor.

These first packages were not required to carry any particular label or, for that matter, any label at all. For years, scientists at the Berkeley cyclotron had been shipping millicurie quantities of cyclotron-produced radionuclides in unmarked envelopes through the regular mail (*2*). In 1948, the Oak Ridge National Laboratory shipped roughly 3,000 Ci of radioisotopes in more than 2,000 containers to 236 addresses in 32 states (*3*). At some point in this process, U.S. Post Office representatives voiced their opinion that perhaps such shipments ought to carry some kind of label.

The first label suggested was a skull and crossbones. The Oak Ridge scientists, proud of their outstanding safety record, maintained that radiation, after all, was not a poison and successfully vetoed this symbol. One Hawkins at Oak Ridge proposed a circle divided into six equal segments of alternating black and white (Fig. 1). Although no evidence suggests that Hawkins had a propeller in mind, the design came to be called the "three-bladed propeller." The three black blades stood for the α, ß, and γ radiation produced by the Oak Ridge plant. Each black blade contained a wiggly arrow pointing outwards, to indicate electromagnetic radiation going in all directions. Paul Aebersold, chairman of the AEC, reportedly maintained that all three black blades showed the symbol for electromagnetic radiation because all three types of radiation ultimately produce X rays (*3*). The wiggly arrows were soon dropped, because

(Continued on page 33N)

Figure 1. Hawkins's original black-and-white propeller design with wiggly arrows indicating electromagnetic radiation. (Reproduced, with permission, from Brucer M. *A Chronology of Nuclear Medicine.* St. Louis, MO: Heritage; 1990:319.)

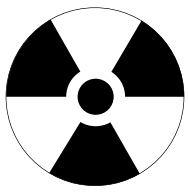

Figure 2. Redesign of Hawkins's layout, minus wiggly arrows and rotated 60°.

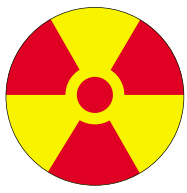

Figure 3. The red and yellow version of the three-propeller logo, designed for greater visibility.

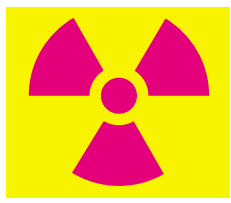

Figure 4. The current three-bladed magenta (not red!) propellers on yellow background.

PUBLIC AFFAIRS UPDATE

NRC Part 35. On Friday, April 13, the Nuclear Regulatory Commission (NRC) rejected the American College of Nuclear Physicians (ACNP)/SNM petition to reduce the regulation of diagnostic nuclear medicine to levels consistent with the risk presented. The rejection letter and a responding press release can be viewed at www.acnponline.org. The amended Part 35 is currently at the Office of Management and the Budget (OMB) for review under the Paperwork Reduction Act. ACNP submitted a cost analysis demonstrating that compliance with the new rules will cost nuclear medicine $474 million in the first year and an additional $127 million each year thereafter. OMB still has Part 35 under review. ACNP has also approached Congress seeking relief.

At the NRC oversight hearing in the U.S. Senate on May 8, Environment and Public Works Subcommittee Chair Senator George Voinovich (R-OH) read into the record a letter from Edward Silberstein, MD, SNM member and chair of the Society's Commission on Radiopharmaceuticals. After reading the letter, Senator Voinovich asked that NRC chair Richard Meserve respond to him about the apparent over-regulation of diagnostic nuclear medicine under Part 35 as described by Dr. Silberstein in his letter. Senators Inhofe (R-OK) and Reid (D-NV) were present for the exchange. After the hearing, staff for other members of the committee indicated that their bosses would be submitting additional questions to Meserve on this subject.

The ACNP and SNM are currently engaged in an extended effort to educate new Congressional staffers (and their bosses) about the safety and benefits of nuclear medicine. These issues will continue to be pressed in the Senate Appropriations Energy and Water Development Subcommittee, of which Senator Reid is the ranking member.

HCFA PET Coverage. Although May 4 was the self-imposed Health Care Financing Administration (HCFA) deadline for announcing whether they will extend coverages announced on December 15, 2000, to coincidence PET, that deadline was subsequently extended to May 18. ACNP and SNM members were involved in several conference calls with HCFA staff urging the broader coverage. As we go to press, it is expected that HCFA will grant the expanded reimbursement to coincidence imaging for at least two years but require that new mandatory quality assurance programs be developed for continued payment. The most up-to-date information is on www.acnponline.org.

HIPAA Privacy Rules Implemented. On April 14, 2001, the Health Insurance Portability and Accountability Act (HIPAA) privacy regulations became effective, despite doubts among many observers that the current administration would implement the rules without substantial changes. Two days before the act was to go into effect, Department of Health and Human Services Secretary Tommy Thompson announced that the Bush administration had decided to go forward with the HIPAA rules as developed by the Clinton administration. Entities covered by the new privacy rules do not have to be in compliance until 2003, and the exact requirements and legal implications of the act are still being debated among industry observers. The administration is expected to release guidance documents and may take other steps to clarify the Privacy Rule this summer.

More PET News. The Diagnostic Imaging Panel of the Medicare Coverage Advisory Committee will hold hearings in Baltimore on June 19 to review whether coverage should be extended to the use of FDG PET in diagnosing and staging breast cancer. SNM is working with the Academy of Molecular Imaging and PET imaging systems manufacturers to develop strong presentations on the utility of FDG PET in breast cancer. The hearing notice can be viewed at www.snm.org.

Physician Supervision Revised. On April 19, HCFA released a new Medicare Program Memorandum to carriers, specifying the level of physician supervision required for diagnostic tests in physician's offices and independent diagnostic testing facilities (IDTFs). The agency originally proposed supervision levels more than three years ago, but the policy was delayed because of opposition from the medical community. The earlier proposal required stringent supervision levels for ultrasonography, echocardiography, and nuclear studies that would have posed significant difficulties for many freestanding or mobile imaging centers. The new policy appears to have relaxed the requirements substantially from the earlier proposal. For most general ultrasonography and echocardiography codes (including the imaging portion of the echo test), only general supervision

is required (the doctor need not be in the suite). Direct supervision is required for the cardiology service in stress testing (93015 line of codes; doctor must be in the suite but not necessarily in the room), and personal supervision is required for transesophageal echo (the doctor must be in the room). The dignostic nuclear medicine codes (78000 line of codes) and most PET codes (G codes) now require only general supervision. The program memorandum also provides clear definitions of the levels of physician supervision (general, direct, and personal) and a listing of the required level of supervision by Current Procedural Terminology Code. A copy of the program memo is available on the SNM Web site at www.snm.org.

Licensure Update. Every opportunity is being used to spread the word about the Consumer Assurance of Radiologic Excellence (CARE) Act. Society of Nuclear Medicine–Technologist Section (SNM–TS) member D. Scott Holbrook (Coeburn, VA) took advantage of visits to his Virginia senators and congressmen to urge their support of the CARE Act. He was in Washington, DC, for training under the auspices of the Coalition of Allied Health Leadership. The primary purpose of visits under this year's leadership program was to restore funding to allied health education programs that was cut under the proposed FY 2002 budget.

Montana Hearings Scheduled. The Board of Radiologic Technologists of the State of Montana has scheduled hearings on May 9, 2001, to consider an expansion to the state's licensure rule. If adopted, the rule will provide licensure for all of the imaging professions covered by the CARE Act. As written, the state's rule is an expansion of the radiologic technologist license and implies that only RTs can secure the additional licenses. The SNM and SNM–TS submitted comments before the deadline, and these can be viewed at www.snm.org.

William Uffelman
Director, SNM Public Affairs
SNM Counsel

History Corner

(Continued from page 26N)

they were too hard to draw and their significance was too subtle. This left a design with six segments alternating black and white (Fig. 2). At the same time, the design was rotated 60°, but the reason for this change remains unclear.

To make the symbol more visible, the background white was changed to yellow, a color calling attention to itself. The black blades were initially changed to red (Fig. 3), but this was discarded because Aebersold wanted the symbol to say "hesitate-for-a-moment-and-follow-the-rules," not "STOP." He ordered the first signs to be printed in yellow and plum—specifically not red. The printer, however, substituted magenta. The symbol thus became a design with six segments in alternating yellow and magenta. The current symbol (Fig. 4) was adopted officially by the AEC in 1950 and by the National Bureau of Standards in 1954.

The history of the radiation symbol, then, is briefly this: it was first designed at the behest of the Post Office. The three propellers stand for α, ß, and γ radiation, the yellow is for visibility, and the magenta (deliberately not red) is Paul Aebersold's "pause and think" rather than "stop." It has become an almost universally recognized symbol of radiation.

Dennis D. Patton MD
SNM Historian
Professor of Radiology and Optical Sciences
University Medical Center
Tucson, Arizona

REFERENCES

1. *Science.* June 14, 1946. This interesting development will be the subject of a future History Corner.
2. Segrè E. The adventurous discovery of technetium. Lecture presented at: Annual Meeting of the American College of Nuclear Physicians; Tucson, AZ; Oct. 26, 1976. A cassette of this talk is available in the Society of Nuclear Medicine Archives.
3. Brucer M. Personal communication and notes in the Brucer Collection; his first-hand recollections provided the material for much of this article. Some of this material appears in Brucer M. *A Chronology of Nuclear Medicine*. St. Louis, MO: Heritage; 1990.

FDG PET Reported to Affect Patient Management

In a study of FDG PET in a community hospital over a one-year period, a team of researchers has concluded that the technique contributes significantly to the management and treatment of cancer patients and that its high accuracy makes it a "cost-effective radiologic procedure in the work-up of all suspected and/or recurrent cancer patients" (*J Clin Oncol.* 2001;19:2504–2508). Dr. Robert V. Tucker and colleagues at the Queen's Medical Center (Honolulu, HI) conducted two surveys. One survey was given to 463 physicians referring patients to PET to discover whether PET changed patient management or had decision-making value in the patient's clinical experience. The second survey was given to one surgeon and one pulmonologist to determine how PET affected surgical and therapeutic treatment for the 53 cancer patients they referred.

In survey one, PET was found to change patient management or therapy in 45% of all patients referred and had inferential/decision-making value in another 44%. In the second survey, PET affected management/therapy in 70% of cases and had decision-making value in another 26%. The authors concluded that "…when combined with complementary anatomic imaging techniques, FDG PET can contribute significantly to the clinical treatment of cancer patients."

New Neurology Guidelines Assess Functional Imaging in Dementia

In comprehensive new guidelines on the diagnosis of dementia, released during the first week of May, the American Academy of Neurology (AAN) recommended as appropriate the use of noncontrast CT or MR but stopped short of recommending PET or SPECT because of "insufficient data on validity" (*Neurology.* 2001;56:1143–1153). In generating the guidelines and accompanying report, the Quality Standards Subcommittee of the AAN evaluated clinical definitions of dementia and its subtypes, and the utility of neuroimaging, biomarkers, and genetic testing in increasing diagnostic accuracy. A literature search resulted in a large information database on previous studies, and the published report includes an extensive list of references.

The report includes a section on the utility of SPECT and PET in diagnosing Alzheimer's disease (AD) and other forms of dementia. The authors of the report concluded that the sensitivity of SPECT was lower than that of clinical diagnosis. SPECT faired somewhat better in differentiation of AD from non-AD dementia. FDG PET was determined to have a higher diagnostic accuracy than hexamethylpropyleneamine oxime SPECT in differentiating AD from vascular dementia and to be superior to MRI measures of hippocampal atrophy. Although the authors noted PET's "promise for use as an adjunct to clinical diagnosis," they concluded that "further prospective studies with PET are needed to establish the value it brings to diagnosis over and above a competent clinical diagnosis."

The final guidelines in the report state that: "For patients with suspected dementia, SPECT cannot be recommended for routine use in either initial or differential diagnosis as it has not demonstrated superiority to clinical criteria," and "PET imaging is not recommended for routine use in the diagnostic evaluation of dementia at this time."

SPECT Provides Useful Diagnostic Data in Alzheimer's Disease

Despite assertions to the contrary (see previous Newsbrief), new studies continue to support the beneficial and complementary role of SPECT in the diagnosis of Alzheimer's disease (AD). In an article published in the April 10 issue of *Neurology* (2001;56:950–956), William Jagust, MD, from the University of California Davis Medical Center, and a group of American, British, and Canadian researchers reported on efforts to determine "whether SPECT imaging provides diagnostically useful information in addition to that obtained from a clinical examination." The study population consisted of 70 patients with dementia, who were followed to autopsy; 14 control patients followed to autopsy; and 71 control subjects, among whom no autopsies were performed. Clinical history, pathologic findings, and SPECT images were each evaluated by raters blind to other features, and clinical and SPECT diagnoses were compared with pathologic diagnoses. When all participants were included in the results, the clinical diagnosis of "probable" AD was associated with an 84% likelihood of pathologic AD. This percentage was raised to 92% with a positive SPECT scan. SPECT was most useful in cases in which the clinical diagnosis was "possible." The authors concluded that SPECT imaging can provide useful information *in addition to* that provided by clinical evaluation.

FDA Takes Action in Pediatric Clinical Trials and in New Human Research Office

On April 20, 2001, the U.S. Food and Drug Administration (FDA) issued an interim rule to provide additional safeguards for children enrolled in clinical trials of medical pharmaceuticals and devices regulated by the agency. This action was mandated by the Children's Health Act of 2000, which calls for specific measures to better promote the unique needs of children participating in clinical trials. According to a press release from the FDA, the new rule is designed to help the agency and clinical researchers address many of the ethical issues that will accompany the expected increase in the enrollment of

children in clinical trials.

Under the new regulation, Institutional Review Boards responsible for maintaining safeguards for clinical trial subjects will now have specific standards for determining whether proposed pediatric clinical trials can be conducted ethically. A key aspect of the new rule sets standards and procedures for assuring (when possible) that children have assented to participation in clinical trials and that their parents or guardians are able to give fully informed consent to the child's participation in a study. The new rule will be open for public comment until September.

In another action in response to growing concerns about protection of individuals in clinical investigations, the FDA named David Lepay, MD, PhD, as director of a newly created Office for Human Research Trials (OHRT). Dr. Lepay had previously served as director of the Division of Scientific Investigations in the Office of Medical Policy of the Center for Drug Evaluation and Research. The new office will have a central role in the FDA's human subject protection and Good Clinical Practice (GCP) policy and coordinate FDA's bioresearch monitoring program for human clinical trials. It will participate in international GCP and human subject protection activities and in GCP education and outreach. OHRT will also work closely with the Office for Human Research Protections in the Department of Health and Human Services as well as with other government agencies and the medical community. The new office will be located within the Office for Science Coordination and Communication in the Office of the FDA Commissioner.

Shipment Embargo May Shut Down MURR

Disagreements between the state of Missouri and the U.S. Department of Energy (DOE) are threatening to shut down the University of Missouri Research Reactor (MURR) at Columbia. Unless disputes about shipping radioactive waste materials on Missouri highways are resolved, MURR will reach its legal storage limit and be forced to suspend operations on June 30, according to Mary Joe Banken, news director at the University of Missouri-Columbia.

The dispute stems from a 1998 decision by Missouri state officials to deny permission to the DOE to ship spent nuclear fuels from foreign reactors on the state's highways. For the last two years, such shipments have been routed around the state. The shipments have been heavy and frequent, as part of the DOE's efforts to shift nuclear waste storage sites from South Carolina to Idaho.

Missouri officials believe that DOE's recent refusal to authorize shipments out of the MURR facility is in retaliation for the state's ban on cross-state shipment of foreign nuclear waste. The state has routinely allowed such shipments from its own reactor. Roy Brown, chair of the Council on Radioisotopes and Radiopharmaceuticals, told the *Columbia Tribune*, "For something to be held hostage like that for political reasons, I think that is outrageous."

Among its other activities, MURR is the sole producer of isotopes of holmium and lutetium and also produces samarium used in the palliative radiopharmaceutical Quadramet. The effect of a shutdown would have an almost immediate effect on supply at the local level. According to Banken, radiopharmaceutical manufacturers and their customers would begin to experience shortages within 7–10 days of a shutdown. As Newsline goes to press, MURR officials are hopeful that the impasse will be resolved before the June 30 shutdown deadline.

How to Renew an NRC License

(Continued from page 20N)

performed and completed on time. Effective of the processes for analyzing, tracking and trending assessment results should be reviewed. Qualifications of participating personnel should be reviewed, along with timeliness of documentation and the distribution of results.

Effectiveness of corrective actions should be verified as effective by the absence of recurrence of the problems corrected. Improvements would be validated as having added value.

Conclusion

Renewal of an NRC license for the medical uses of byproduct material need not be a major effort. Cost-effective actions can be taken to simplify the renewal process and enhance the delivery of medical services. Dedicated management and critical self-evaluation are cost effective in the long run.

Sheldon Trubatch, JD, PhD
Foley & Lardner
Washington, DC

REFERENCES

1. U.S. Nuclear Regulatory Commission. *Consolidated Guidance About Material Licenses, Guidance about Administrative Procedures.* NUREG-1556. Volume 20, Checklist C3. Washington, DC: Nuclear Regulatory Commission; 1999.
2. U.S. Nuclear Regulatory Commission. *Temporary Instruction 2800/029*. Nuclear Medicine Program (April 24, 2000).
3. U.S. Nuclear Regulatory Commission. *Consolidated Guidance About Material Licenses, Guidance about Administrative Procedures.* NUREG-1556. Volume 20, Appendix K. Washington, DC: Nuclear Regulatory Commission; 1999.

Happy Birthday, Hal!

(Continued from page 13N)

imaging. He has created our current workhorse and made prototype advances, paving the way for current PET. We may even redo another Anger concept with cyber flourishes in the future. So, for all this, we thank you, Hal, and we wish you a very happy (if somewhat belated) 81st birthday.

Alexander Gottschalk, MD
Michigan State University
East Lansing, Michigan

REFERENCES

1. Gottschalk A, McCormack KR, Adams JE, et al. A comparison of results of brain scanning using gallium-68-EDTA and the positron scintillation camera, with mercury-203-neohydrin and the conventional focused collimator scanner. *Radiology.* 1965;84:502–506.
2. Schaer LR, Anger HO, Gottschalk A. Gallium edetate Ga-68 experiences in brain-lesion detection with the positron camera. *JAMA.* 1966;198:811–813.
3. Anger HO. Tomographic gamma-ray scanner with simultaneous readout of several planes. In: Gottschalk A, Beck RN, eds. *Fundamental Problems in Scanning.* Springfield, IL: Charles C. Thomas; 1968:195–211.

New NIH Imaging Institute Established

(Continued from page 12N)

new institute. In a message sent to a wide range of imaging specialists during the week of April 23, representatives of the ARR asked for letters of support to encourage lawmakers to adequately fund the new institute. ARR president C. Douglas Maynard, MD, and executive director Ed Nagy stressed the urgent need to persuade members of Congress to provide sufficient funding. "It is vital that Appropriations Subcommittee members hear from imaging professionals and engineers about the importance of properly funding this new institute in its first year," they said. "The next six weeks [with Congressional hearings on the NIH budget beginning in mid May] are likely to be critical in determining whether NIBIB gets off to a strong start. We cannot stress enough the importance of constituent contact in determining funding levels."

The message included a draft letter that could be signed and sent to appropriate Congressional representatives. The letter stated that: "radiology and bioengineering communities believe that NIBIB needs to be a medium-sized institute within 3–5 years to fulfill its broad mission. To reach that level, NIBIB probably requires an appropriation of new funds for Fiscal Year 2002 totaling $300 million." NIH is currently requesting an appropriation of only $40 million for this purpose. The letter goes on to say that this NIH request for NIBIB is "likely to have a profoundly negative impact on investigators in imaging science and bioengineering and to discourage the submission of innovative research proposals in basic imaging science."

The ARR takes a less-than-optimistic view of promised opportunities for funding to come from imaging grants currently funded at other NIH institutes. The letter states, "Regrettably, all indications are that the total amount to be transferred will be negligible despite NIH testimony to the House Commerce Subcommittee on Health and Environment last September claiming that it spent more than $800 million on imaging and bioengineering research in FY 1998 and presumably more in subsequent years. It appears that NIH support for basic research in imaging and bioengineering is more rhetorical than concrete."

On April 30 the ARR Executive Committee, Board of Directors, and Long-Term Planning Committee met at the American Roentgen Ray Society meeting in Seattle, WA. Dr. Naomi Alazraki, a member of all three ARR governing bodies and a representative of the SNM to the ARR reported that the ARR submitted names of individuals to be considered for the new institute's Advisory Council, including the names of SNM members Michael Phelps, PhD, and Henry Wagner, MD. Announcements in the *Federal Register* for Council nominations and for the position of director (which also will be advertised in imaging journals, including *The Journal of Nuclear Medicine*) will be appearing soon. The director will be chosen by a search committee and appointed by Secretary Thompson.

The ARR urges SNM members to send letters to Congress in support of NIBIB. Copies of ARR letters appropriate for each state that has a representative on the Appropriations Subcommittee are available at: www.acadrad.org/apprletter.htm. Letters can be authorized and sent to representatives directly from the site.