Revision Status of USP Chapter <797> Pharmaceutical Compounding—Sterile Preparations

The U.S. Pharmacopeia (USP) 28 is the official source of Chapter <797> Pharmaceutical Compounding—Sterile Preparations. It is currently enforceable by the U.S. Food and Drug Administration (FDA). State boards of pharmacy have either adopted it into statute and regulations or are considering whether it should be adopted. The Joint Commission on Accreditation of Health Care Organizations (JCAHO) has also incorporated this chapter into their standards. <797> has generated many concerns in pharmacies and health care facilities because of its new enforceable status. Radio-pharmaceuticals are considered a preparation or a compounded sterile product according to this chapter. The SNM Committee on Pharmacopeia together with the SNM Radiopharmaceutical Sciences Council communicated their concerns to the Sterile Compounding Committee (SCC) of the USP in the fall of 2004 (1).

As a result of comments received from SNM and many other organizations and individuals, the SCC of the USP met and approved proposed revisions to <797>. A summary of that proposal may be reviewed at the USP Web site: www.usp.org/standards/proposed797Revisions.html.

The revision of a chapter in the USP includes the involvement of the public. The 4-step process that the SCC used in the development and revision of <797> follows the general guidance given in the USP’s journal, the Pharmacopeial Forum (PF). The following is a summary of the USP revision process used by the SCC:

1. The SCC considers internal (from USP volunteers and staff) and external (from public sources, “PF provides interested parties an opportunity to review and comment . . .”) comments.
2. A draft containing both current official content and proposed revisions is published in PF.
3. A period of several weeks elapses for an opportunity to receive public comments.
4. The SCC reviews received comments, then determines whether additional revision is necessary before the next version is published in the PF as an Interim Revision Announcement (IRA) which bears a date for official USP adoption.

The cycle of steps 1–4 may be repeated; thus, 1 or more years could elapse between currently official <797> in USP 28 and the next official <797>. The next official <797> will appear either in an annual USP revision (e.g., USP 29 in 2006) or in 1 of the 2 semiannual...

Sam C. Augustine, PharmD, is a member of the 2000–2005 Sterile Compounding Committee (SCC), of the Council of Experts of the United States Pharmacopeial Convention, Inc. SCC is the committee that is responsible for the establishment and revision of the general chapter titled “Pharmaceutical Compounding—Sterile Preparations” (<797>) of the United States Pharmacopeia (USP). Dr. Augustine is the only board-certified nuclear pharmacist to serve as a member of this committee. He was recently invited to participate in the mid-winter meeting of the Committee on Pharmacopeia, Radiopharmaceutical Sciences Council, SNM, to update members on the proposed revision of <797>. Dr. Augustine was also invited to present a talk on the aforementioned topic during the 2005 SNM Mid-Winter Meeting. He has provided a brief summary of the current revision status of <797>. As mentioned in his article, the full text of the proposed revision of <797> is scheduled for publication in the Pharmacopeial Forum this spring. The Committee on Pharmacopeia will continue to closely monitor further developments in proposed revisions to <797> and will communicate our concerns and comments to the USP, as necessary, especially where any proposed revision of <797> might encroach on our professional practice.

Joseph C. Hung, PhD
Chair, SNM Committee on Pharmacopeia
supplements to each annual USP revision. The earliest possibility (but an unlikely probability) would be Supplement 2 to USP 28 in late 2005.

The following proposed revisions that may affect radiopharmaceutical preparations were reproduced from the summary prepared by Dr. David Newton, who serves as the chair of the SCC. His complete summary of the proposed revisions can be accessed at the USP Web site. The following summaries include only a selection of these revisions, with changes and added language appearing in italics.

1. Definitions to differentiate preparations from products are provided at the end of the introduction to the chapter, as well as revised standards and clarifications of what constitutes sterile compounding.

**PREPARATION.** A preparation, or compounded sterile preparation, CSP, is a sterile drug or nutrient prepared in a licensed pharmacy or other health care related facility pursuant to the order of a licensed prescriber, which may or may not contain sterile products.

**PRODUCT.** A product is a commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the U.S. Food and Drug Administration, FDA. Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer’s labeling or product package insert.

Sterile compounding pertains to all pre-administration manipulations of CSPs, including compounding, storage, and transport, but not to administration of CSPs to patients.

Sterile compounding differs from nonsterile compounding primarily by requiring the maintenance of sterility when compounding exclusively with sterile ingredients and components, and the achievement of sterility when compounding with unsterile ingredients and components.

Use of sterile products is not subject to <797> unless their preparation, packaging, and storage deviates from their product package inserts, or their preparation requires sterilization (i.e., involves a high-risk level component).

2. The exemption for “immediate use” (this exemption was honored by the JCAHO in 2004):

Three or fewer sterile products may be prepared in worse than ISO Class 5 air when there is no direct contact contamination, and administration begins within 1 hour and is completed within 12 hours of preparation.

3. Hazardous drugs:

This new section addresses safety precautions and practices when hazardous drugs (e.g., those that can cause abortion, allergy, birth defects, blisters, burns, cancer, cytotoxicity, genetic damage, infertility, irritation, sensitivity, vital organ toxicity, or other adverse effects) are ingredients in CSPs. It refers to applicable state and federal guidelines and standards, and NIOSH Publication No. 2004-165 at www.cdc.gov/niosh/docs/2004-165/ for safe practices. This section refers PET compounding to USP <823>, and it contains a statement about safe practices for all other radioactive sterile compounding. Currently official <797> requires positive pressure for all sterile compounding, but that is wrong for compounding radioactive and other hazardous drugs.

4. Physical inspection:

Direct visual inspection of highly radioactive CSPs is not required based on maintaining radiation exposures As Low As Reasonably Achievable (ALARA).

5. Storage and Beyond Use Dating:

Technetium-99m/Molybdenum 99 generator systems shall be stored and eluted (operated) under conditions recommended by their manufacturers and applicable state and federal regulations.

The full revision of <797> should be published this spring in the PF. Comments on the revision should be directed to Dr. Claudia Okeke at cco@usp.org. Access the USP Web site for the date of publication of the full text in PF.

Sam C. Augustine, RP, PharmD, BCNP, FAPhA
Member, 2000–2005 Sterile Compounding Committee
Council of Experts of the United States Pharmacopeial Convention, Inc.

**REFERENCES**


SNMTS Names Scholarship Recipients; Announces New Awards

The Society of Nuclear Medicine Technologist Section (SNMTS) announced the names of the first recipients of 2 newly created scholarships and also announced 2 additional scholarships that will be awarded at the SNM 2005 Annual Meeting in Toronto.

On February 25, SNMTS officers reported that Said Diabes Figueroa, MS, CNMT, RT(N), of Columbia, MO, a 2nd-year doctoral student in the Nuclear Science and Engineering Institute at the University of Missouri–Columbia, had been named as the recipient of the first Professional Development Scholarship. Figueroa, who has a bachelor’s degree from the University of Puerto Rico, earned his nuclear medicine technology certificate and master’s degree in nuclear engineering/medical physics from the University of Missouri–Columbia. His doctoral research will involve imaging and dosimetry related to new radiation-based therapeutic agents for treating cancer. The Professional Development Scholarship provides $5,000 to assist nuclear medicine technologists in pursuit of a master’s or doctoral degree. Members of an SNMTS scholarship committee selected Figueroa for the scholarship based on his statement of career goals, recommendations, academic performance, and other factors.

On the same day, the SNMTS announced that Shree Taylor, an undergraduate student at the University of Arkansas for Medical Sciences at Little Rock, is the first recipient of the Mickey Williams Minority Student Scholarship. The scholarship provides $5,000 to a minority student entering or enrolled in a molecular/nuclear medicine technologist program. The scholarship is named in honor of Mickey Williams, who was 1990–1991 SNMTS president. Taylor, of Dumas, AK, was also awarded one of 30 SNMTS Paul Cole Scholarships for 2005, a $1,000 award that provides support for nuclear medicine technology students. Cole, a champion of student education, died in 1986 while serving as SNMTS president. “SNMTS’s need-based scholarship program will benefit deserving students across the nation in pursuing their dreams of becoming nuclear medicine technologists through cash awards that recognize the circumstances and hardships of students as well as their accomplishments,” said SNMTS President Nanci A. Burchell, CNMT, FSNMTS.

Members of an SNMTS scholarship committee selected Taylor for the scholarship from a group of individuals in entry-level associate’s or bachelor’s degree nuclear medicine sciences programs who represented wide-ranging cultural and economic backgrounds. The award was also based on a personal essay that detailed applicants’ career goals and reasons for entering the molecular/nuclear medicine technology field.

Both the Professional Development Scholarship and the Mickey Williams Minority Student Scholarship are funded by the Corporate Friends of the Professional Development and Education Fund: Alliance Imaging, Biogen Idec, Bristol-Myers Squibb, Capintec, GE Healthcare, and MDS Nordion. The Education and Research Foundation (ERF) for the SNM funds the Paul Cole Scholarships.

New Scholarships Added

On February 23, the SNMTS announced the creation of 2 new annual awards funded by the ERF: the Outstanding Educator Award and the Outstanding Technologist Award. Winners of the 2005 awards will be presented with $750 and plaques at the 2005 SNM Annual Meeting.

The Outstanding Educator Award recognizes an SNMTS member who has significantly contributed to providing knowledge that advances and promotes the field of nuclear medicine technology through outstanding work in education. The award is not limited to educators as traditionally defined. Eligible candidates may include industry and clinical professionals. Candidates will be considered on the basis of educational contributions to the field of nuclear medicine, such as:

- Positive educational influence on the careers of other nuclear medicine technologists;
- Development of effective methods/materials for teaching, training, and/or dissemination of information;
- Outstanding service as a mentor;
- Sharing of educational techniques and technology with colleagues;

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SNM LEADERSHIP UPDATE

ICANL Accreditation: A Sign of the Times . . . and the Future

Eight years ago, SNM and SNMTS recognized the importance of having an independent accrediting body for nuclear medicine, PET, and nuclear cardiology laboratories. Joining with the Academy of Molecular Imaging, the American College of Cardiology, the American College of Nuclear Physicians, and the American Society of Nuclear Cardiology, the Society strongly supported the development of an independent, multidisciplinary accrediting organization: the Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories (ICANL).

The importance of this action continues to grow, especially considering the many changes occurring with medical insurance reimbursement. Third-party payers realize that not all facilities provide the same level of service and quality of patient care. Medical insurance companies are beginning to look toward voluntary accreditation programs utilizing peer review to demonstrate quality and validate payment for certain services—"pay for performance." This could transform the way physicians and hospitals are paid. Some commercial plans have already implemented pay-for-performance policies. Medicare, the nation’s largest payer, appears to be headed down that path, with its first public pay-for-performance demonstration set to launch this month and run for the next 3 years. “It is time that we pay for the quality of the health care provided to our beneficiaries, not simply the amount,” said an administrator for the Centers for Medicare & Medicaid Services recently.

Some providers have now enacted reimbursement policies that require laboratory accreditation. For example, compensation is tied to accreditation for nuclear cardiology and/or PET laboratories, affecting molecular/nuclear medicine imaging procedures in 6 states: Alabama, Connecticut, New Jersey, New York, Pennsylvania, and Wisconsin. Similar payment policies are pending throughout the country.

What does this mean for you? When health care organizations are being held to increasingly high levels of accountability by the general public, by their peers, and by Medicare and other payers, an ICANL accreditation provides the way for laboratories to evaluate and demonstrate the level of patient care they provide.

An ICANL accreditation is a symbol that represents a commitment to quality. It lets third-party payers—and the general public—know that they can expect a higher level of service efficiency, quality, and safety and a higher level of patient care. Laboratories that attain accreditation before it’s required for reimbursement demonstrate a willingness to surpass current expectations.

ICANL has standards in place that address issues such as lab operation, performance, and interpretation and reducing errors and variation in clinical practice—factors behind the motivation for pay for performance. ICANL’s standards define minimum requirements for nuclear medicine, PET, and nuclear cardiology labs to deliver high-quality care. Through ICANL’s accreditation process, laboratories assess every aspect of daily operation, often revising protocols and validating quality assurance programs. Because accreditation must be renewed every 3 years, accredited laboratories must commit to and maintain quality and self-assessment programs.

ICANL is one of the few available accrediting bodies for general nuclear medicine, PET, and nuclear cardiology facilities, and it is the only one that incorporates mandatory site visits . . . This last requirement was mandated by SNM when it merged its own accreditation program with ICANL. Members of each sponsoring organization sit on the ICANL board of directors, providing an arm’s-length arrangement that allows for independent peer review of facilities.

To date, there are nearly 650 ICANL-accredited sites—a fraction of the possibly thousands of private offices, clinics, and hospitals in this country. As we hear more talk about pay for performance, more facilities will apply for accreditation. Last year, the number of ICANL applicant laboratories nearly doubled from the previous year.

Keep an eye to the future—no one wants to be at the bottom of the list that says “quality” on top.

More information about the ICANL accreditation program can be found online at http://www.icanl.org.

Virginia Pappas, CAE
SNM Executive Director

SNM NEWSLINE

THE JOURNAL OF NUCLEAR MEDICINE  Vol. 46  No. 4  April 2005
FROM THE SNM PRESIDENT

Meeting Our Patients’ Current, Future Needs for Radionuclides

The future of radionuclide therapies and innovative research in molecular imaging/nuclear medicine depends on a reliable, affordable, and sustainable domestic supply of radionuclides. Realizing the continued criticality of this issue in the nation, SNM has developed an important, new position paper on a proposed National Radionuclide Production Enhancement (NRPE) program.

Members of the NRPE Task Force, who are experts in the field, have charted a multiyear course of activities that our lawmakers must take to initiate a long-term solution to the nation’s radionuclide production shortage. The task force has identified 5 specific goals that would make the NRPE program a reality. This suggested program addresses the current and projected shortfalls of radionuclides in this country; it is fiscally sound and responsible in both its cost assumptions and federal budget implications. Federal funding of approximately $69–$79 million over the next 10 years will be needed to implement identified goals, such as upgrading the University of Missouri Research Reactor (MURR), the only research facility in this country that provides reactor-produced radionuclides for therapeutic applications. SNM has received several letters of support for the plan from prominent national biomedical organizations, and more may be on the way. SNM wants to promote a unified voice for this plan, which, when implemented, will assure our nation of a stable and secure supply of radionuclides for future generations.

Reports over the past 20 years identify a number of trends, including an increased growth in radionuclide use. Statistics show that annually radiopharmaceuticals are used in more than 16 million diagnostic and therapeutic procedures and 100 million laboratory tests in the United States. Each year nearly 1 in 3 patients who are admitted to a hospital in this country undergo a test or treatment that depends on radiolabeled compounds, and that number is expected to grow exponentially in coming years.

Reports indicate that the majority of radionuclides used in applications every day are imported on a daily basis, and disruption of their availability threatens to interrupt tens of thousands of nuclear medicine procedures each day. Those radionuclides required for innovative research are either available only sporadically and in limited quantities or not available at all. New radionuclide production is not being developed for diagnostic and therapeutic uses, as the national radionuclide infrastructure is chronically underfunded at the Department of Energy.

Among its suggestions, the NRPE national program calls for developing the capability to produce large quantities of radionuclides to maintain existing technologies and stimulate future growth in the biomedical sciences. It suggests that medical and industrial users collaborate to assess radionuclide needs and transfer technologies to accelerate applications. It proposes that the transfer of commercially viable radionuclide programs be facilitated to the private sector and an investment be made in research and development to improve radionuclide production, processing, and utilization. To this end, SNM and the National Cancer Institute held a workshop in September 2003 that resulted in the initiation of a Small Business Innovation Research grant targeted at these issues. Seven applications were received that will be reviewed for funding in 2005.

(Mathew L. Thakur, PhD, SNM President)

SNM wants to promote a unified voice for this plan, which, when implemented, will assure our nation of a stable and secure supply of radionuclides for future generations.

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(Continued from page 22N)

The NRPE plan calls for the continuous monitoring of radionuclide needs of researchers and clinicians and the establishment of an education program to ensure that the next generation of nuclear and molecular imaging professionals are trained and available to support the nation’s critical needs. The plan also asks for upgrading the capability of MURR and other existing facilities that produce radionuclides and stable isotopes.

Briefly, here are the proposal’s 5 specific goals, its timeline, and the requested appropriations. In fiscal year 2006, $6.3 million would be needed for upgrading MURR from 10 to 20 MW and to support the work of a select committee, which will be formed to define the optimal operating characteristics for a cyclotron production facility. The next year, approximately $29–$39 million would be used to begin installation of a new cyclotron, which would be completed by 2010.

For fiscal years 2008–2010, $3 million would be used each year to fund research and development of small-energy cyclotron targets, to research radionuclide production capability, and to pay for operating costs of the new cyclotron. In fiscal years 2010–2015, $4 million will be used each year for research and development funding for Oak Ridge National Laboratory to upgrade processing hot cells for a stable supply of alpha-emitting radionuclides for therapeutic applications and to produce alpha emitters for therapeutic uses. In fiscal year 2016, approximately $5 million would fund an isotope separator to produce enriched stable isotopes that are required as target material for production of both reactor-produced and cyclotron-produced radionuclides.

Radionuclides are part of the foundation supporting today’s applied molecular/nuclear technology. The very duality of purpose of molecular/nuclear medicine—offering both noninvasive diagnostic methodology and a powerful therapeutic modality—drives the exploration and development of new radiopharmaceuticals. Radiopharmaceutical research leads to a better understanding and improved or early diagnosis of human diseases and to the development of effective treatments and the monitoring of the effectiveness of existing ones. For these reasons, SNM is committed to gaining support for this program and to promoting it at the federal level.

Many thanks go to the individuals who served on the NRPE Task Force, including Michael J. Welch, PhD, chair; Richard C. Reba, MD; Barbara Y. Croft, PhD; David Hill, PhD; Robert F. Carretta, MD; Alan R. Ketring, PhD; Peter T. Kirchner, MD; Edward B. Silberstein, MD; Wynn A. Volkert, PhD; D. Scott Wilbur, PhD; Iain Trevena, PhD; and Roy Brown, PhD. SNM also thanks Martin Brechbiel, PhD, Suresh Srivastava, PhD, and John Pantaleo for their technical contributions and Daniel Sullivan, MD, for his support. Our thanks also go to the leadership of organizations who thoughtfully supported this program of national importance.

Mathew L. Thakur, PhD
President, SNM

Erratum
March 2005 Newsline

The subhead, “Goal: Membership in SNM Will Be Viewed as Essential by All With an Interest in the Field of Nuclear Medicine and Molecular Imaging,” was inadvertently omitted in the SNM Leadership Update. A corrected version appears in the Newsline section of the SNM journals Web site at http://jnm.snmjournals.org/cgi/reprint/46/24N.
CMS Activates CPT Codes, Discontinues G Codes for PET

The Centers for Medicare & Medicaid Services (CMS) announced in February activation of the adoption of Current Procedural Terminology (CPT) codes for PET procedures, essentially discontinuing previously used G series Healthcare Common Procedure Coding System (HCPCS) codes. This change will be implemented April 4, will be retroactive to January 30, and will activate 3 cardiac, 2 brain, and 6 (new this year) tumor PET CPT codes for patients covered by CMS programs.

SNM President Mathew L. Thakur, PhD, hailed this action as “the first in a series of steps toward a more uniform coding system for all PET procedures.” He said, “SNM has long believed that the continued use of G series HCPCS codes is administratively burdensome, creating complicated charge description masters and often requiring different codes for different payers for the same study.” SNM has strongly advocated the use of CPT codes and submitted recommendations in a series of letters to CMS representatives. “CPT codes describe the PET procedures based on the resources used,” agreed SNM President-Elect Peter S. Conti, MD, PhD. G codes primarily represent the indications for the uses of PET in patients for oncologic, cardiac, and neurologic diseases, whereas CPT codes represent the procedures themselves and are not tied to a specific indication. Conti, who chairs the SNM PET Center of Excellence, also noted, “While this action directly impacts physicians and physician offices, the policy decision affects all providers of PET services.”

The CMS action, published as Change Request 3726, is the first of several anticipated clarifying policy statements on eliminating G codes and moving to CPT codes. The memo included the relative value units for physician services (–26) previously assigned to the CPT PET codes by CMS but did not address other reimbursement issues, such as payment for technical services.

The 53-page CMS change request, posted at www.cms.hhs.gov/manuals/pm_trans/R475CP.pdf, lists the code changes. At Newsline press time, CMS was expected to post a related Medlearn Matters provider education article online (www.cms.hhs.gov/medlearn/matters) to provide additional information on this coding issue.

Society of Nuclear Medicine

Media Cover DOE Nuclear Medicine Cuts

Under the banner headline “Nuclear Medicine Funds to Disappear Under Plan,” Newsday writer Jamie Talan reported on March 2 on proposed budget cuts to nuclear medicine research by the U.S. Department of Energy (DOE). The author detailed the cuts, which would eliminate DOE funding of nuclear medicine research at 23 universities and 4 labs, with funding dropping from $37 million to less than $13 million in 2005 and be entirely eliminated thereafter. “We judged that the DOE was not the appropriate place for research on nuclear medicine,” budget office spokesman Noam Nuesner told Newsday. He said the National Institutes of Health (NIH) “would be a better source.” But NIH has also been hit by budget cuts and has been further constrained by increased obligations to support research related to homeland security issues.

The effects, noted Newsday, could be “devastating.” Thomas Budinger, PhD, head of nuclear medicine and functional imaging at the Lawrence Berkeley National Laboratory (Berkeley, CA) noted that his lab would lose more than $2 million in funding for the first year. “I’m struggling now to cover that loss,” he said. “This is a shock to all of us.” Newsday also spoke with Joanna Fowler, PhD, director of Brookhaven’s Center for Translational Neuroimaging and a frequent Journal of Nuclear Medicine and Newsline contributor. She said, “We need funding to take this technology into the future.”

Newsday

NRC to Amend Fees

The Nuclear Regulatory Commission (NRC) announced on February 22 a proposal to amend its regulations for the licensing, inspection, and annual fees it charges applicants and licensees for fiscal year (FY) 2005. The agency is required by Congress to recover for the Department of the Treasury 90% of its appropriated budget through 2 types of fees: hourly fees for NRC services that apply to a specific license and annual fees paid by all licensees (covering generic regulatory expenses and other costs). The total amount to be recovered in FY 2005 is $540.7 million, a portion of which is recouped through annual adjustments.

Under the proposed rule, hourly rates would rise to $198 for the Nuclear Materials and Waste Safety Program. Although some annual fees have been reduced, most material users fees would rise. Categories of licenses and new fees that affect nuclear medicine-related activities include: test and research reactors (nonpower reactors), $54,400; materials users, $4,300; radiographers, $12,800; and gauge users, $2,500.

Nuclear Regulatory Commission
Former DOE Worker Screening Program Expanded

U.S. Secretary of Energy Samuel W. Bodman announced on February 9 the addition of 9 medical screening centers as part of the Department of Energy (DOE) Former Worker Medical Screening Program. Under this expansion, the program will offer all former DOE employees, contractors, and subcontractors free medical examinations to determine whether possible exposure to harmful substances, including radioactive materials, resulted in subsequent illness. The fiscal year 2005 budget provided $12.5 million for the operation of 10 screening centers around the country. The latest action adds the 9 additional sites and creates a toll-free number (888-580-1746) to guide former workers who do not live near a regional center or who prefer to see a personal physician through the program.

New clinics will be established for former employees of the following facilities: Lawrence Berkeley National Laboratory (Berkeley, CA); Lawrence Livermore National Laboratory (Livermore, CA); Sandia National Laboratory (Albuquerque, NM); Ames (Ames, IA); National Nuclear Security Administration (Kansas City Plant; Kansas City, MO); Mound Closure Project (Miami, OH); Fernald Closure Project (Fernald, OH); Brookhaven National Lab (Upton, NY); and the Pinellas Project (Pinellas, FL). Clinics currently serving former workers of the following facilities include: Hanford Project (Richland, WA); Idaho National Lab (Idaho Falls, ID); Nevada Test Site (near Las Vegas, NV); Rocky Flats Closure Project (Golden, CO); National Nuclear Security Administration’s Pantex Plant (near Amarillo, TX); Paducah Gaseous Diffusion Plant (Paducah, KY); Portsmouth Gaseous Diffusion Plant (Portsmouth, KY); Oak Ridge Operations (Oak Ridge, TN); Savannah River Site (Aiken, SC); and the Iowa Army Ammunition Project (Middletown, IA)

U.S. Department of Energy

Research Protection Assurances Simplified

The U.S. Department of Health and Human Services (HHS) on February 9 released a new and simplified mechanism for all research institutions that receive HHS funding or support to obtain an assurance of compliance with HHS regulations for the protection of human subjects. A single Web-based “Federalwide Assurance” (FWA) will replace the several types of assurances under which research institutions had operated in the past. “We are pleased to provide this robust and flexible simplification to our assurance system,” said Bernard A. Schwetz, DVM, PhD, director of the Office for Human Research Protection. “It reduces the burden of regulatory compliance while strengthening the research community’s ability to focus on protections for research subjects.”

Almost all federal departments and agencies that conduct or fund human subject research adhere to the Federal Policy for the Protection of Human Subjects, a set of identical regulations adopted by 16 departments and agencies in 1991 that is known informally as the “Common Rule.” The Common Rule is based on the HHS regulations in force since 1974 and requires that federally supported research involving human subjects be covered by an assurance. Common Rule agencies will now have the option of using or directing their grantees to use the HHS FWA rather than operating their own assurance systems. A majority of the agencies are expected to rely on the FWA.

Because of the multiple types of assurances in current use, HHS will allow research institutions to transition to the new system over the next 11 months. By December 31, 2005, all institutions conducting HHS-funded human subjects research must hold an FWA approved by the HHS Office for Human Research Protections (OHRP). For more information, visit the OHRP assurance Web page at www.hhs.gov/ohrp/assurances_index.html.

U.S. Department of Health and Human Services

New NCI Gene Expression Database

Researchers at the National Cancer Institute (NCI) described in a press release on March 1 the creation of the largest open-source gene expression database for normal tissue from human organs. “Genes identified by the database as abnormally active in a particular disease could become potential targets, guiding researchers to better candidates for new drug therapies, immune-based vaccine treatments, and potential biomarkers to help with diagnosis,” explained Javed Khan, MD, chief of the Oncogenomics Section of NCI’s Pediatric Oncology Branch.

“These data give investigators a baseline against which to compare gene expression data obtained from tumor or other disease specimens, and should be a valuable resource for the research community,” said James Jacobson, PhD, acting branch chief of the Diagnostics Research Branch in NCI’s Division of Cancer Treatment and Diagnosis.

The normal organ database will enable scientists and clinicians to compare gene expression results for their own tissue or genes of interest with a baseline standard that represents a generic picture of normal gene activity, organ by organ, in the human body. The new Web site contains expression profiles for 18,927 genes, which include most of the genes known to help with diagnosis, drug therapies, immune-based vaccine treatments, and potential biomarkers to help with diagnosis. The press release accompanying the debut of the site noted that the Human Genome Project has revealed that the total number of human genes (20,000–25,000) is much lower than previously assumed and that only a fraction of these—perhaps 10,000
genes—are actively transcribed in normal cell processes. The new database takes on the important task of “characterizing this essential backdrop.” This is the first publicly available, normal human organ database to draw from so many tissue samples (158) or include samples of tissue from multiple organs and from different parts of the same organs. The very large cDNA microarray has more than 42,000 detectors built into 2 chips using verified cDNA libraries upon which many other researchers currently rely.

To illustrate the kind of useful data that can emerge from using this tool, Khan’s team analyzed 100 samples of neuroblastoma. Despite the fact that the tumor samples were taken from a variety of patients with different stages of cancer, the database kicked back a list of 19 genes that were consistently overexpressed compared with normal brain tissue.


National Cancer Institute

Joint NCI–FDA Fellowship Program Announced

In preparation for the new generation of molecular-based oncology medical products, the National Cancer Institute (NCI), part of the National Institutes of Health, and the Food and Drug Administration (FDA) announced on February 16 the creation of an NCI–FDA Research and Regulatory Review Fellowship program. The program, initiated by the joint Interagency Oncology Task Force, is designed to train a cadre of researchers to bridge the processes from scientific discovery through clinical development and regulatory review of new oncology products. Fellows will work and train primarily at FDA’s offices and laboratories in the metropolitan Washington, DC, area and will learn first-hand about the regulatory requirements that must be built into the early stages of medical product development. “As new therapies are developed using the latest breakthroughs, fast progress requires that researchers understand the safety and effectiveness questions that regulators must ask, and that reviewers understand the critical details of the latest science,” said Acting FDA Commissioner Dr. Lester M. Crawford. “This cross-fertilization of FDA and NCI will be invaluable in helping move the next wave of promising cancer-fighting agents through the development pipeline.”

The fellowships are viewed as part of a pilot program and as a possible model for future training programs. The NCI–FDA Research and Regulatory Review Fellowships will consist of 4 different programs, each with its own curriculum: (1) Clinical Oncology Product Research/Review for Oncology Fellows (designed for MDs or MD/PhDs); (2) Clinical Oncology Product Research/Review for Board-Certified Oncologists; (3) Oncology Product Research/Review Fellows (designed for MDs, PhDs or MD/PhDs); and (4) Cancer Prevention Fellows (designed for MDs, PhDs, or scientists with equivalent doctoral degrees).

For more information about the NCI–FDA Research and Regulatory Review Fellowship program, see http://iottraining.nci.nih.gov.

National Cancer Institute

Bone Quality Assessment Meeting Scheduled

The National Institute of Arthritis and Musculoskeletal and Skin Diseases and the American Society for Bone and Mineral Research, with co-sponsors from the National Institute of Biomedical Imaging and Bioengineering and the French Institute of Health and Medical Research, will be offering a scientific meeting and symposium on “Bone Quality: What Is It and Can We Measure It?” on May 2 and 3 in Bethesda, MD. Topics to be covered by internationally recognized experts in the field will include identification of needs and future directions in this area; basic science, clinical, regulatory, and pharmaceutical perspectives; assessment of which established and newly developed methodologies for measurement of bone fragility are ready for inclusion into large clinical trials and ways to facilitate their inclusion; and discussion of “novel” mechanisms to bring together research efforts on bone quality to move the field forward.

For more information, see the meeting Web site at www.asbmr.org/bonequality.cfm.

National Institute of Biomedical Imaging and Bioengineering

Bangladesh Nuclear Medicine Conference

The opening ceremony of the 10th National Conference and International Symposium of the Bangladesh Society of Nuclear Medicine highlighted the ways in which previously out-of-reach medical technologies are being made accessible here and in other developing nations. “Poor people are getting free services from the country’s nuclear medicine centers, and the government is going to set up a new center at Rangamati district to help the poor community of that area get services for free,” said Dr. Abdul Moyeen Khan, MP, Bangladesh Minister for Science and Information and Communication Technology. Kamaluddin Ahmed, a former member of the Bangladesh Atomic Energy Commission (BAEC) and a special guest at the symposium, said, “BAEC is providing services to the people of the country through the Nuclear Medicine Institute as well as its 14 centers. Poor people are getting services free of cost and only a token amount is charged from the other patients, in spite of the fact that these tests and treatment procedures are rather costly because of the expensive instruments and radioisotopes.”

(Continued on page 32N)
He added that many patients who previously might have gone outside the country for nuclear medicine diagnostic and therapeutic procedures now opt to remain in Bangladesh. Experts from Japan, Singapore, and India also attended the symposium, which was held at the Dhaka Sheraton Hotel.

**Society of Nuclear Medicine, Bangladesh**

**Stokes, Lithium Pioneer, Dies**

Peter E. Stokes, MD, a Cornell Medical College endocrinologist and psychiatrist and a pioneer in the use of lithium to treat manic depression, died January 22 at St. Luke’s-Roosevelt Hospital Center in New York City. In addition to his work in psychiatry, Stokes also trained in neuroendocrinology and nuclear medicine.

In 1965, at the Payne Whitney Clinic in Manhattan, Stokes and colleagues began their work on the effects of lithium salts in controlling bipolar disease and manic depression, publishing positive results in *The Lancet* in 1971, a year after U.S. Food and Drug Administration approval. He also published early studies on neurotransmitters, brain deoxyglucose uptake in animal models, and selective serotonin reuptake inhibitors in the treatment of depression.

Stokes was born in Haddonfield, NJ, attended Trinity College, and earned his medical degree from Cornell in 1952. He was appointed an instructor in medicine at Cornell Medical College in 1957 and remained there for his entire career, retiring as an emeritus professor of medicine and psychiatry in 1998.

*New York Times*

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**Outstanding Technologist Award**

- Publication of education-focused articles; and
- Conduct of education-focused research.

The Outstanding Technologist Award seeks to acknowledge an SNMTS member who has demonstrated outstanding service and dedication to the field and who has exhibited commitment to advancing nuclear medicine technology in his or her workplace and through involvement with the Society. Nominees must be involved with the Society at the local, regional, and/or national level and have at least 5 years of experience in nuclear medicine technology. Some of the characteristics that define an outstanding technologists may include:

- Contributing significantly to the profession as a leader;
- Receiving local, national, or international recognition;
- Enhancing the image of nuclear medicine technologists in the workplace, for the Society, and/or elsewhere;
- Mentoring others to make an impact on the field;
- Conducting and publishing original research; and
- Exemplifying excellence in patient care.

Applications for both awards are now being accepted and must be received at SNM headquarters by April 15 to be considered for 2005. For more information and application materials, see www.snm.org/grants.
“Positherapy”: $^{18}$F-FDG in Breast Cancer

Moadel et al. from the Albert Einstein College of Medicine (Bronx, NY) reported in the February 1 issue of Cancer Research (2005;65:698–702) on continued research into targeted breast cancer therapy with $^{18}$F-FDG, a technique the group has termed “positherapy.” In previous work, the authors demonstrated the therapeutic potential of positrons in malignancy at the cellular level (Breast Cancer Res. 2003;5:R199–R205). The current article reports on tumor growth rate and survival after $^{18}$F-FDG therapy in a mouse breast cancer model. Tumor-bearing mice were treated with a dose of the radiotracer equivalent to the maximum tolerated dose for humans. The treatment resulted in significant prolongation of survival and decrease in tumor growth rate in comparison with nontreated controls. Substantial differences in distribution of glucose transporters (GLUT) 1, 4, and 8 in tumor masses were observed, with GLUT1 localizing mainly in necrotic areas and expressed mostly at the cell membrane, indicating that GLUT1 was probably the most responsible for cellular uptake. The authors concluded that “these results are important for the development of positherapy with $^{18}$F-FDG for refractory metastatic breast and other cancers.”

Cancer Research

Initial Treatment with $^{131}$I-Tositumomab

Evidence of the effectiveness of $^{131}$I-tositumomab therapy continues to accrue, as the results of clinical trials are assessed and as elapsed time provides perspective on survival and quality of life. Results of a multiinstitutional study were published in 2 journals in February. In the February 3 edition of the New England Journal of Medicine (2005;352:441–449), an article by Kaminski from the University of Michigan Medical Center (Ann Arbor) and others detailed a trial in which a single course of $^{131}$I-tositumomab therapy was used as initial treatment for patients with stage III or IV follicular B-cell lymphoma. The study included 76 patients who received a dosimetric administration of tositumomab and $^{131}$I-labeled tositumomab and 1 week later received the therapeutic dose. Of these patients, 75% (57) showed a complete response, with 40 of these responders remaining in remission for 4.3–7.7 years. Some response was noted in all but 5% of patients treated, and the 5-year progression-free survival for all patients was 59%, with a median progression-free survival of 6.1 years. Hematologic toxicity was moderate, but no transfusions or hematopoietic growth factors were required, and no cases of myelodysplastic syndrome were reported. The authors concluded that “a single 1-week course of $^{131}$I-tositumomab therapy as initial treatment can induce prolonged clinical and molecular remissions in patients with advanced follicular lymphoma.”

The editors of The New England Journal of Medicine hailed the treatment in a separate commentary as a “hot new treatment for lymphoma.”

In an article e-published ahead of print on February 24 in Blood, many of the same authors reported on the occurrence of treatment-related myelodysplastic syndromes and acute myeloid leukemia after initial therapy with $^{131}$I-tositumomab in patients with non-Hodgkin’s lymphoma (NHL) and compared these results with those from patients with NHL who had previously undergone treatment(s) with other regimens. Bennett from the University of Rochester School of Medicine (NY) and others outlined the aggregated results from 7 studies including 1,071 patients (995 with relapsed/refractory low-grade NHL with a median of 3 prior treatment regimens) and 76 patients with previously untreated low-grade follicular NHL. A single dose of tositumomab, followed 1 week later by the radiolabeled tositumomab, was administered. Median follow-up was 6 years after diagnosis and 2 years after radioimmunotherapy (RIT) in previously treated patients and 4.6 years after RIT for previously untreated patients. Treatment-related myelodysplastic syndromes and/or acute myeloid leukemia were reported in 35 of the 995 previously treated patients, but only 13 of these were confirmed to have developed these conditions after RIT, an incidence consistent with the prior chemotherapy regimens of these patients. During a median follow-up period of almost 5 years, no cases of treatment-related myelodysplastic syndromes or acute myeloid leukemia were re-
ported in the group of 76 patients receiving the \(^{131}I\)-tositumomab as initial therapy for NHL.

*The New England Journal of Medicine Blood*

**Long-Circulating Liposomes as Delivery Agents**

Oku and Namba from the University of Shizuoka (Japan) reported in the February issue of *Methods in Enzymology* (2005;391:145–162) on the use of glucuronate-modified, long-circulating liposomes as effective antitumor drug carriers in therapy. The survey article included data previously reported by the authors’ research group on antineovascular therapy by use of radiotargeted long-circulating liposomes (*J Control Release*. 2004; 100:41–52) and noted the benefits of monitoring localization and accumulation using PET techniques. The focus of the current article was on characteristics, in vivo trafficking, and usage in cancer therapy of glucuronate-modified liposomes, which bind to macrophage-like cells in vitro and passively accumulate in tumor tissue. This technique carries significant promise of reducing many of the side effects usually associated with the delivery of some anticancer agents.

*Methods in Enzymology*

**PET in Follow-Up of Hepatic Tumor Ablation**

Blokhuis et al. from the VU Medical Center (Amsterdam, The Netherlands) reported in a late-year supplement to the *Scandinavian Journal of Gastroenterology* (2004; 241[suppl]:93–97) on the use of \(^{18}F\)-FDG PET and CT in long-term follow-up of patients who had undergone radiofrequency ablation of primary and secondary liver tumors. The study included 15 patients, of whom 1 had been diagnosed with primary liver tumor and the remaining 14 had been diagnosed with hepatic metastases from breast (1), ovary (1), renal cell (1), and colorectal (11) carcinoma. Each patient underwent CT imaging before and after ablation and at regular intervals, and 11 patients underwent PET scanning at regular intervals. The mean follow-up period was 16.8 months. Positive uptake, which defined tumor recurrence in the study, was seen in 4 of the 11 patients evaluated with PET at a mean period of 6.8 months. At CT evaluation, tumor recurrence was observed in these patients but at a mean time of 9.8 months. The authors concluded that “the use of PET in combination with CT scan at follow-up may lead to earlier detection of tumor recurrence than contrast-enhanced CT alone.”

*Scandinavian Journal of Gastroenterology*

**PET and Aspects of Cerebral Blood Volume**

Ito et al. from the Akita Research Institute of Brain and Blood Vessels (Japan) and Tohoku University (Sendai, Japan) recently published 2 reports in the *Journal of Cerebral Blood Flow and Metabolism* on the use of PET to measure aspects of cerebral blood volume (CBV). In the first, e-published ahead of print on February 16, the group described \(H_2^{15}O\) and \(^{11}CO\) PET assessment of changes in the arterial fraction of human CBV during hypercapnia and hypocapnia. Their results indicated that alterations in CBV during these conditions are caused by changes in arterial blood volume with no accompanying changes in venous or capillary blood volumes. In the March issue of the same journal (2005;25: 371–377), the authors compared PET measurement of changes in cerebral blood flow and oxygen metabolism during neural activation with blood oxygenation level-dependent (BOLD) contrast measured by functional MRI. \(C^{15}O, \,^{15}O_2,\) and \(H^{15}O\) PET studies were performed on volunteers both while executing a right-hand motor task and at rest, followed by functional MRI studies to measure the BOLD signal under the same 2 conditions. A significant positive correlation was seen between changes in the cerebral blood flow and the BOLD signal, and a significant negative correlation was observed between changes in the cerebral oxygen extraction fraction and the BOLD signal. The authors concluded that “this supports the assumption on which BOLD contrast studies during neural activation are based.”

*Journal of Cerebral Blood Flow and Metabolism*

**PET/CT in RT Planning for Non–Small Cell Lung Cancer**

\(^{18}F\)-FDG PET/CT and CT alone were compared in modeling of radiotherapy planning for patients with CT-staged N2–N3M0 non–small cell lung cancer (NSCLC) in a study by van der Wel et al. from the Maastro Clinic (Maastricht, The Netherlands) published in the March 1 issue of the *International Journal of Radiation Oncology, Biology, Physics* (2005;61: 649–655). The study included 21 patients. Two 3-dimensional conformal treatment plans were devised for each patient, one with CT-based and the other with PET-based planning target volumes, both designed to deliver 60 Gy in 30 fractions. Dosimetric factors were calculated, and tumor control probabilities were estimated. The authors found that the average gross tumor volume of nodes was lower on PET/CT than on CT (9.9 ± 4.0 and 13.7 ± 3.8 cm, respectively) and that all dose-volume characteristics for the esophagus and lungs decreased in favor of PET/CT. For the same toxicity levels of the lung, esophagus, and spinal cord, the dose could be increased from 56.0 ± 5.4 Gy with CT planning to 71.0 ± 13.7 Gy with PET planning. Because the information provided by PET/CT not only reduced the risk of volume and location error but also allowed significant radiation dose escalation, the tumor control probability was raised. The authors concluded that “the results of
this modeling study support clinical trials investigating incorporation of FDG-PET information in CT-based radiotherapy planning.”

*International Journal of Radiation Oncology, Biology, Physics*

**Novel Analogs for PET- and SPECT-Aided RT**

Ginj et al. from the University Hospital Basel (Switzerland) reported in the February 1 issue of *Clinical Cancer Research* (2005;11:1136–1145) on preclinical evaluation of novel octreotide analogs with broad human somatostatin receptor (sstr) profiles for PET and SPECT imaging to refine targets in radiotherapy. The authors studied 2 promising synthetic octreotides: [1,4,7,10-tetraazacyclododecane-1, 4, 7, 10-tetraacetic acid (DOTA),1-Nal3, Thr8] octreotide (DOTA-NOC-ATE) and [DOTA, BzThi3, Thr8]-octreotide (DOTA-BOC-ATE), each labeled with both “cold” and radioactive 111In. The properties of these analogs were compared with those of the more familiar 111In-DOTA-TOC, which shows affinity only to human sstr2. The authors found that both analogs showed high affinity to human sstr2, sstr3, and sstr5, with lesser but notable affinity to sstr4, and were internalized much more efficiently than was 111In-DOTA-TOC. Biodistribution studies in rats showed high (twice that of 111In-DOTA-TOC) and specific uptake of both novel analogs in tumor and in sstr-expressing normal tissue, with significantly lower renal uptake. The authors concluded “these data suggest that the novel radiodeptides are superior to 111In60Y-DOTA-TOC and show great promise for the clinical application in the imaging of sstr-positive tumors and their targeted radiotherapy.”

*Clinical Cancer Research*

**PET in Parkinson’s Response to Apomorphine**

Hosey et al. from the National Institutes of Health (Bethesda, MD) and scientists from Rush University Medical Center (Chicago, IL) and the University of Amsterdam (The Netherlands) reported in the January/February issue of *Clinical Neuropharmacology* (2005;28:18–27) on the use of 18F-FDG PET and 18F-FDG PET and Cardiac Hemodynamics in Adenosine Infusion

In an article published in the February 1 issue of the *Journal of the American College of Cardiology* (2005;45:553–558), Mishra et al. from the Harvard Medical School (Boston, MA) reported on the use of 13N-ammonia PET to elucidate the relationship between myocardial blood flow and peripheral hemodynamic effects during intravenous adenosine infusion. The study included 348 individuals with no evidence of obstructive coronary artery disease. Each patient underwent 13N-ammonia PET imaging at rest and during a 6-minute adenosine infusion. The authors found that during the infusion, heart rate increased and mean arterial pressure decreased, and that neither of these measures correlated well with hyperemic myocardial blood flow or coronary vascular resistance. They concluded that changes in cardiac hemodynamics during intravenous adenosine infusion are generally poor predictors of changes in myocardial blood flow or coronary vascular resistance during peak hyperemia and “should not be used to assess the effectiveness of vasodilator stress in myocardial perfusion imaging.”

*Journal of the American College of Cardiology*

**PET Measures of Altered Cerebral Glucose Metabolism in Alzheimer’s**

Holthoff et al. from the Dresden University of Technology (Germany) reported in the February 15 issue of *Biological Psychology* (2005;57:412–421) on PET measures of altered cerebral glucose metabolism in patients...
with early Alzheimer’s disease (AD). The study included 53 patients with early AD (17 with apathy; 10 with clinical depression; and 26 with neither of these symptoms) who underwent 18F-FDG imaging. Apathy was found to be associated with significant decreases in left orbitofrontal regions when compared with patients free of apathy. Depression was associated with hypometabolism in dorsolateral prefrontal regions. The authors concluded that “these findings support the notion that different functional circuits underlie apathy and depression in early AD.”

**PET Identifies Spinal Cord Compression in Melanoma**

In the March issue of the *European Journal of Surgical Oncology* (2005; 31:197–204), Franken et al. from the Royal Prince Alfred Hospital (Camperdown, Australia) described a study designed to evaluate the utility of 18F-FDG PET in identifying spinal cord compression in patients with metastatic melanoma. The study included records of 1,365 PET studies from patients with melanoma. Of these, 50 were identified as being at risk of spinal cord compression, and 35 of these were reviewed with MR imaging and CT to confirm or refute the diagnoses. In 9 patients, compression of the spinal cord or adjacent neurologic structures was confirmed, with 8 patients undergoing immediate treatment. The authors concluded that PET can detect imminent, unsuspected spinal cord compression in patients with metastatic melanoma and that “immediate anatomical imaging of the spine is recommended in patients who have evidence of spinal cord compression on PET.”

**99mTc-MDP and Bone Mineral Density Measurements**

Campbell et al. from the Royal Perth Hospital (Australia) reported in the spring issue of the *Journal of Clinical Densitometry* (2005;8:14–17) on the effect of 99mTc-methylene diphosphonate (99mTc-MDP) on bone mineral density (BMD) measurements in the lumbar spine and neck of the femur. The study included 20 patients who underwent dual-energy X-ray absorptiometry with a Hologic QDR4500 scanner before and after injection of the radiotracer. A group of 30 volunteers underwent similar sequential imaging and assessment with the injection of the radioisotope. No significant change in BMD measures were detected after 99mTc-MDP injection for either measurement site, and comparison with the control group showed that the precision of the readings was similar in both groups. The authors concluded that “this study has shown that any effect produced by a typical bone scan dose of 99mTc-MDP is small in comparison with the intrasubject variance when estimating BMD” and when using the scanner in this study.

*Journal of Clinical Densitometry*

**99mTc-Sestamibi in Radioguided Parathyroidectomy**

In the March issue of the *European Journal of Surgical Oncology* (2005;31:191–196), Rubello et al. from the Istituto Oncologico Veneto (Rovigo, Italy) evaluated the efficacy of low-dose 99mTc-sestamibi administration for radioguided parathyroid surgery in patients with primary hyperparathyroidism. The study included 300 such patients, who underwent preoperative 99mTc-sestamibi subtraction scintigraphy and high-resolution ultrasonography. Of these patients, 211 were scheduled for minimally invasive radioguided parathyroidectomy and 89 were scheduled for traditional bilateral neck exploration. 99mTc-sestamibi was injected 10 minutes before intraoperative radio-localization, and rapid parathyroid hormone assays were performed. Of the patients who underwent minimally invasive radioguided parathyroidectomy, 207 were successfully treated for a solitary parathyroid adenoma (PA) through a 2–2.5-cm skin incision. Radioguided surgery was less successful in the second group, especially in patients with 99mTc-sestamibi–avid nodules. Even in these patients, however, the combination of radioguided surgery and rapid parathyroid hormone assay was helpful in the management of multigland disease. The authors concluded that “low-dose 99mTc-sestamibi administered a few minutes before surgery is sufficient for minimally invasive radioguided parathyroidectomy in patients with high likelihood of a solitary
PA and without concomitant $^{99m}$Tc-sestamibi–avid thyroid nodules.”

European Journal of Surgical Oncology

$^{11}$C-WAY PET and Chronic Fatigue Syndrome

Cleare et al. from the Institute of Psychiatry and Guy’s, King’s and St Thomas’ School of Medicine (London, UK) reported in the February issue of Biological Psychiatry (2005; 57:239–246) on a study assessing brain 5-HT1A receptor binding potential using PET $^{11}$C-WAY-100635 in patients with chronic fatigue syndrome (CFS). The study included 10 medication-free patients, who fulfilled consensus criteria for CFS and had no diagnosed psychiatric illness, and 10 healthy individuals. The authors found that the patients with CFS showed a marked reduction in 5-HT1A receptor binding potential compared with control individuals, a difference that was especially visible in the hippocampus. They noted that this decrease is not necessarily a primary feature of CFS but may be related to underlying pathophysiology or may be secondary to other processes, such as previous depression or biological changes associated with CFS.

Biological Psychiatry

NOTIFICATION OF PROPOSED BYLAWS CHANGE

March 15, 2005

Members of the Society of Nuclear Medicine:

The following Item represents a proposed amendment to the SNM Bylaws based on the request of SNM members and the House of Delegates. This change was presented to the House of Delegates at the recent mid-winter meeting in Tampa and is now being distributed to the membership. Its approval will be voted on by the House of Delegates in June 2005.

The proposal would add a new section to Article III (Membership) to create an additional designation for members, i.e. Life Member. This designation would not replace the existing membership classifications but would rather give special recognition to members who have met certain criteria, determined by the Board of Directors.

Sincerely,

Warren Moore, MD
Chair, Committee on Bylaws

ITEM 1

ADD to ARTICLE III

Section 2: Life Membership

Members of the Society in any membership classification who have made special contributions and commitments to the Society may be designated by the Board of Directors as Life Members. Criteria for eligibility and selection procedures shall be determined by the Board. Life Members shall retain all rights, privileges, and responsibilities of their membership classification and shall have such additional privileges and recognition as are granted by the Board, consistent with the Bylaws.

RATIONALE: A mechanism is desired to recognize and reward individuals who have made specific contributions to the Society including monetary contributions and a commitment to be involved in the furtherance of the mission of the Society. Life membership may have a different dues structure and certain limited privileges, such as VIP registration, as determined by the Board. Life Membership is an additional designation, which members may seek in addition to their primary membership classification.

Existing Sections 2 and 3 of Article III would be renumbered as Sections 3 and 4 respectively but would not be changed in any other way.