NRC Seeks Comment on Protection Regs

The Nuclear Regulatory Commission (NRC) announced on April 27 that it would seek public comment on regulatory issues and options for potential changes to achieve greater alignment between its existing radiation protection regulations and the 2007 recommendations of the International Commission on Radiological Protection (ICRP; Publication 103). In a press release, the NRC noted that the ICRP recommendations propose "measures that go beyond what is needed to provide adequate protection" and that "the NRC believes that the agency's current regulations continue to provide adequate protection of health and safety of workers, the public, and the environment." In a Staff Requirements Memorandum dated April 2, the NRC directed its staff to engage stakeholders and interested parties on the benefits and burdens of any potential regulatory changes based on the ICRP recommendations.

NRC staff will use public comments over the next 2–3 y to develop a technical basis for potential rulemaking for presentation to the Commission. The staff will consult with state regulatory agencies, the Conference of Radiation Control Program Directors, the Interagency Steering Committee on Radiation Standards, other federal agencies, and other organizations while developing the technical basis. "The Commission is concerned about the potential impact of effectively lowering the occupational dose limit to 2 rem [from the current 5 rem] per year," the memorandum noted. "In developing the technical basis for rulemaking, the staff should examine how lower dose limits have affected the medical and industrial sectors in countries that have implemented them."

Possible changes to both material- and reactor-based radiation protection regulations are outlined by the NRC staff in a 34-page document available on the NRC Web site at: www.nrc.gov/reading-rm/doc-collections/commission/secys/2008/secy2008-0197/2008-0197scy.pdf. The Commission's Staff Requirements Memorandum is available at: www.nrc.gov/reading-rm/doc-collections/commission/srm/2008/2008-0197srm.pdf.

The NRC is currently developing a dedicated Web site for public comments on this issue. Comments may also be submitted by e-mail to Regs4RP.Resource@nrc.gov.

Nuclear Regulatory Commission

SNM and CMOD Session on Radiopharmaceuticals

SNM and the International Partnership for Critical Markers of Disease (CMOD) organized a special joint session on the evening of May 1, at the National Institutes of Health in Bethesda, MD. Peter Libby, MD, cofounder of CMOD, and Michael M. Graham, PhD, MD, president-elect of SNM, welcomed the group to a special session examining U.S. Food and Drug Administration (FDA) requirements for manufacturing PET radiopharmaceuticals.

"We are delighted to bring everyone together tonight to facilitate discussion among various stakeholders—including pharmaceutical developers, regulatory agencies, the imaging community, and others," said Graham. "In conversations with these partners, we continue to hear that there is a real need in the community for information about issues of current good manufacturing practice [cGMP]; chemistry, manufacturing, and control [CMC]; and associated regulatory issues for the manufacturing of PET radiopharmaceuticals. SNM's new centralized IND provides to the community an opportunity to enable the implementation of investigational and approved PET imaging in multicenter clinical trials."

Invited speakers surveyed the regulatory history of PET, reviewed current guidelines for radiopharmaceutical compounding, and discussed challenges and opportunities from both the commercial and academic perspectives. Invited speakers also addressed the critical necessity of developing new tracers and radiopharmaceuticals in compliance with FDA's current cGMP and CMC regulations. Sally Schwarz, from Washington University (St. Louis, MO), provided a detailed overview of the requirements of U.S. Pharmacopeia (USP) General Chapter <823>, "Radiopharmaceuticals for Positron Emission Tomography: Compounding," and the proposed draft §212.5 (b) FDA rule. Eldon Leutzinger, PhD, chemistry team leader at FDA in Rockville, MD, presented an overview of the current draft FDA regulations issued in 2005.

"We are so pleased that CMOD and SNM were able to put together this in-depth and engaging joint session," said Thérèse Heinonen, DVM, executive director of CMOD. "With the topics of PET manufacturing, regulatory compliance, and pharmaceutical development of critical importance to both our organizations, teaming up seemed like a natural fit."

"It was really a team effort," added Graham. "That is how we approach our collaboration with various partners—as a joint effort that brings together multiple partners. SNM's goal is to provide a framework and a forum for these discussions to occur."

Because of the ongoing need to address standardization and harmonization across imaging sites, SNM plans to host a number of Webinars later in 2009 on compliance with USP Chapter 823 and draft FDA guidelines. CMOD and SNM will also host a joint session at the CMOD annual meeting in October. A file of the talks presented at the May 1 meeting is available for download at www.snm.org or www.cmod.org.

SNM

WHO amd IAEA Join Forces Against Cancer

The World Health Organization (WHO) and the International Atomic Energy Agency (IAEA) announced on May 26 the launch of the Joint Programme on Cancer Control, aimed at strengthening and accelerating efforts to fight cancer in the developing world. The groundbreaking agreement reflects growing international concern over the global cancer burden and its projected increase. Latest statistics indicate that cancer will continue to be among the leading causes of deaths, with more than 70% of all cancer deaths occurring in low- and middle-income countries.

"In low- and middle-income countries, cancer overwhelmingly affects the poor. This has huge implications for human suffering, health systems, health budgets, and the drive to reduce poverty," said WHO Director-General Margaret Chan, who signed the Joint Programme agreement together with IAEA Director General Mohamed ElBaradei. The Joint Programme will provide the framework through which the 2 organizations can cooperate, building on areas of expertise to create a more coordinated and robust approach to combating cancer in poor countries. In practical terms, this will mean working with Member States to integrate diagnostic and treatment-related activities into each country's cancer control plans, which are based on WHO cancer control guidelines and strategies in each region. Such programs include cancer prevention, early detection, screening, treatment, and palliative care, as well as monitoring of cancer patterns, including cancer registries. Efforts will initially focus on 6 model demonstration sites in Albania, Nicaragua, Sri Lanka, Tanzania, Viet Nam, and Yemen and will also respond to requests for cancer control assessment and program development assistance in low- and middle-income countries.

"The IAEA has long provided radiation technology and expertise to developing countries, but radiotherapy alone cannot halt the growing global cancer crisis," said ElBaradei. "The IAEA Programme of Action for Cancer Therapy was created to integrate diagnostic and treatment-related activities into national cancer control plans. The Joint Programme with WHO underlines our conviction that only through combined effort and collaboration can we bring hope and relief to those whose lives are threatened by cancer."

International Atomic Energy Agency

Reduced Residency Workloads Costly

A study published in the May issue of the *New England Journal of Medicine* (2009;360:2242–2244) and picked up with varying interpretations by scientific and popular media outlets around the world suggested that significant financial costs may be associated with compliance with recommendations for reduced work hours and workloads for resident physicians. Nuckols and colleagues from the University of California at Los Angeles (UCLA) and the RAND Corporation calculated that compliance with recent recommendations from the Institute of Medicine (IOM) would cost U.S. teaching hospitals approximately $1.6 billion each year in additional fees to hire substitute workers.

A press release issued by UCLA and RAND reviewed the findings. "Adopting new restrictions on the work hours of physicians in training would impose a substantial new cost on the nation's 8,500 physician training programs," said Nuckols. "There is no obvious way to pay for these changes, so that's one major issue that must be addressed."

In December 2008, the IOM released *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*, a report calling for revisions to medical residents' workloads and schedules to decrease the chances of fatigue-related medical errors and to enhance the learning environment. Recommendations included requiring time for sleep during prolonged shifts, reducing shifts to 16 h when residents do not have time for sleep, reducing residents' workloads, and increasing the number of days residents must have off. Graduate medical education programs traditionally required residents to work long hours, often more than 100 h/week.

The study by UCLA and RAND looked closely at the original IOM recommendations, particularly at original cost analyses, and weighed potential increases in labor costs against costs-to-society estimates associated with predicted decreases in preventable adverse deaths. They concluded that if the IOM recommendations are adopted, teaching hospitals will need to make up for residents' shorter work hours by either hiring other providers (such as physician assistants) or by expanding the number of residency positions. The authors noted that adding residency slots could help ease physician shortages in some specialties but could lead to oversupply in others. They estimated that residency positions would need to grow by about 8% across the medical specialties to meet the IOM recommendations. "The trainees who are working more than the proposed limits would allow are not necessarily in the specialties where more physicians are needed," Nuckols cautioned. "For example, pediatric residents work a lot of hours, but there is no evidence that there are too few pediatricians." The article also pointed out that only a small percentage of medical errors actually cause injury and that revising work rules could prompt other types of medical errors as the care of hospitalized patients is more frequently handed from one provider to another.

The researchers estimated that adopting the IOM recommendations would cost each major teaching hospital about $3.2 million annually and would be more expensive than the major revision of resident work hours adopted by the Accreditation Council for Graduate Medical Education 6 y ago. Under those rules, a resident should not work more than an average of 80 h/wk, among other limits.

"Residency programs already have picked much of the low-hanging fruit by reducing the noneducational duties placed on residents," Nuckols said. "Further changes will require that

hospitals hire professionals with high levels of training, such as nurse practitioners and physicians, and that will be expensive."

University of California at Los Angeles

SNM Clinical Trials Network Support Grows

On May 14, the SNM Clinical Trials Network, an initiative designed to address the need for streamlined drug discovery through the integration of imaging biomarkers into multicenter clinical trials, announced the addition of Genentech, Inc., as a supporter. SNM launched the Clinical Trials Network in late 2008 to facilitate more cost-effective drug development through the integration and standardization of imaging biomarkers into phase 1, 2, 3, and 4 therapeutic clinical trials. As part of this initiative, the society continues to bring together pharmaceutical developers, the imaging community, biomarker manufacturers, and regulatory agencies to address critical needs for biomarkers in multicenter trials. A formal introduction to the Clinical Trials Network was held at a 2-d workshop in Clearwater Beach, FL, in February, and educational sessions about the network were presented in June at the 56th SNM Annual Meeting in Toronto, Canada.

"We are gratified to have Genentech—a pioneer in the field of developing targeted therapeutics—join us in this important endeavor, which we hope will broaden the scope and effectiveness of today's medical practice and lead to improved patient care in the near future," said Peter S. Conti, MD, PhD, cochair of the SNM Clinical Trials Network. "We are pleased that such an innovative corporate leader supports our mission of advancing molecular imaging and therapy."

More information about the SNM Clinical Trials Network, including latest news about participants, is available at: www.snm.org/clinicaltrials.

SNM

Gerald Denardo, MD, Retires

Gerald DeNardo, MD, professor emeritus of internal medicine and radiology at the University of California (UC), Davis, recently notified friends and colleagues of his retirement from his UC position to pursue a range of personal and professional interests. With his wife, Sally J. DeNardo, MD, he pioneered the federally funded radioimmunotherapy (RIT) program at UC Davis. Gerry's long career has paralleled that of clinical nuclear medicine, from early scintigraphy studies to sophisticated combined molecular imaging and therapy. In 1985 the DeNardos treated their first patient with non-Hodgkin lymphoma—the first in the United States to undergo RIT for lymphoma. "Our program has generated a series of novel nanomolecules and related platforms and insights with considerable potential," he said. "For about 50 years, I've had a thrilling ride, growing, building, learning much and translating from bench to bedside with the help of many others." His work has been marked by ingenuity, inventiveness, and consistent compassion and good humor. Both the DeNardos have received wide acclaim and honors for their work, including the 2000 Cassen Award from SNM. The Newsline editor congratulates Gerry on his extraordinary career and looks forward to hearing about his new and diverse endeavors.

Conrad Nagle, MD
Editor, JNM *Newsline*

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The SNM Clinical Trials Network is seeking to register more than 200 sites and is beginning to qualify registered sites using SNM's successful phantom imaging program. We intend to standardize image acquisition capabilities at a large number of sites so that they will be able to efficiently incorporate quantitative imaging of biomarkers into therapeutic clinical trials. The network is also in the process of registering radiopharmaceutical production sites—both commercial and academic—that can supply the necessary radiopharmaceuticals. The first agent to be produced in this uniform manner will be ^{18}F-FLT.

Finally, it is becoming increasingly clear that we, the nuclear medicine community, need to publish a series of high-quality papers examining cost effectiveness and comparative effectiveness in order to appropriately inform the rest of the world—referring physicians, regulatory agencies, CMS, and insurers—that molecular imaging procedures should be more widely utilized. To accelerate this effort, I intend to create a task force in the upcoming months to develop high-quality, comparative effectiveness studies. A unique opportunity has been presented by President Obama's directive that the Institute of Medicine define the ways in which it will spend $1.1 billion on such studies as part of the stimulus package. This is a great opportunity to develop high-quality retrospective, metaanalysis, and prospective studies and should be particularly attractive to young medical professionals. This is an area that you will be hearing more about in the months to come.

It is my hope that the students and young physicians and scientists we assist and the initiatives we undertake will one day usher in more capable and cost-effective imaging techniques and practices in laboratories and clinics around the world. It is a future that looks increasingly achievable because of the initiatives we are undertaking today.

Michael M.Graham, PhD, MD
SNM President