Review Panel Recommends NRC Licensing Changes

The U.S. Nuclear Regulatory Commission (NRC) Independent External Review Panel on March 18 issued a summary of recommended changes to the commission's process for granting licenses to possess radioactive materials. These changes were said to be "aimed at eliminating vulnerabilities that could be exploited by terrorists or other adversaries." The panel was chartered in October 2007 as part of the NRC response to a Government Accountability Office report that identified vulnerabilities in the agency's materials licensing process.

"Security of radioactive materials is of primary importance to the NRC," said Commission Chair Dale E. Klein in a public briefing on the release of the recommended changes and accompanying report. "We welcome the panel's recommendations as part of our continuing effort to strengthen our licensing process."

The panel's report contains a series of observations and recommendations for the NRC and its 34 Agreement States including but not limited to:

(1) Suspending the "good faith presumption" that new applicants or licensees seeking significant increases in their possession limits for radioactive materials are honest; performing site visits to a new applicant's facilities before issuing a license; and conducting background checks on key personnel.

(2) Reviewing publicly available licensing guidance to identify and remove information that might be helpful to an adversary seeking to exploit the process.

(3) Integrating the NRC Web-Based Licensing System and the National Source Tracking System, both now under development, and including a mechanism through which licensees and vendors can enter real-time information on transfers of radioactive materials.

(4) Developing detailed physical security requirements for licensees who possess risk-significant radioactive materials.

(5) Giving security equal billing with health and safety when training NRC or Agreement State licensing officers, so that license reviewers are trained to recognize a malevolent applicant.

The panel's report is available through the NRC ADAMS document system at www.nrc.gov/reading-rm/adams/web-based.html by entering access number ML080700957.

Nuclear Regulatory Commission

Bilingual Guide to Nuclear Medicine Procedures

SNM recently released *A Patient's Guide to Nuclear Medicine Procedures: English–Spanish/Una Guía Para el Paciente Sobre Procedimientos de la Medicina Nuclear: Inglés–Espanol*, a flip-chart book that explains more than 30 common nuclear imaging procedures. "Patient preparation is one of the most important aspects of any nuclear medicine procedure. A patient who understands what to expect, how to prepare, and what the time commitment is for a procedure will be more cooperative, and in this way, improve the final diagnostic or therapeutic quality of the exam," said Juan C. Más, CNMT, RT(N), author of the book. The flip-chart format was designed to be set up in doctors' offices, reception areas, labs, and imaging rooms so that patients can read along in Spanish as medical personnel read from the opposite side.

Chapters such as "Bone Scan," "Myocardial Perfusion Study," and "PET and PET/CT" are tabbed in the flip-chart format for easy access. The guide also comes in a smaller version that fits into a shirt or lab coat pocket and can be used by the physician or technologist for easy reference. "In addition to Spanish speakers, the simplified terms will help English speakers unfamiliar with medical terminology," said Más. "The book will also be an aid to physicians and technologists who are new to the field and haven't had a lot of patient contact."

For information on purchasing copies of the full-size and pocket guide, contact the SNM Service Center at 800-513-6853 or servicecenter@snm.org.

SNM

Ten Million Boomers to Develop AD

On March 18, the Alzheimer's Association (Washington, DC) released a report estimating that 10 million "baby boomers"—1 in 8—in the United States will develop Alzheimer's disease (AD). The report, *2008 Alzheimer's Disease Facts and Figures*, urges immediate federal efforts to address "this looming epidemic that currently has no effective disease-modifying treatments that halt or delay the progression of the disease." Today, as many as 5.2 million Americans are living with AD, and the disease is the seventh leading cause of death in the country and the fifth leading cause for individuals older than 65. The report predicts that in 2 years a half million new cases will have been diagnosed and that by 2050 more than a million cases will be diagnosed each year.

"The information in the *2008 Alzheimer's Disease Facts and Figures* makes it clear the Alzheimer crisis cannot be ignored—not when 10 million baby boomers are at risk for developing this fatal disease," said Harry Johns, president and CEO of the Alzheimer's Association. "Unchecked, this disease will impose staggering consequences on families, the economy, and the nation's health and long-term care infrastructure. We have the opportunity to change the trajectory of this disease now. Today's scientific landscape is rich with possible disease-modifying treatments—but the shrinking

investment in Alzheimer research threatens these breakthroughs."

The full text *of 2008 Alzheimer's Disease Facts and Figures* can be viewed at www.alz.org.

Alzheimer's Association

Physicians, Physicists Team Up

An international collaboration of medical and high-energy physicists met at a March 27 workshop on the University of Chicago (UC) campus to develop a common technology that would serve dramatically different purposes, including the advancement of time-of-flight (TOF) PET imaging and the investigation of subatomic particles.

The collaboration included Henry Frisch, PhD, a professor of physics at UC, and his colleagues Chin-Tu Chen, PhD, an associate professor in radiology; Chien-Min Kao, PhD, an assistant professor in radiology; and other scientists and engineers from UC, several Department of Energy National Laboratories, the Stanford Linear Accelerator (Menlo Park, CA), the University of Hawaii (Honolulu), and the French atomic energy commission (CEA; Grenoble, France). The meeting was funded in part by the French Embassy and the UC France Chicago Center.

Frisch and Chen share a desire to more precisely measure very short intervals of time, typically a few to tenths of a trillionth of a second. Chen's interest is to use this to provide precise positional measurements for TOF PET. The high-energy physicists, meanwhile, could use the technique to help identify many of the currently anonymous particles produced in their accelerator experiments. "For the bulk of the particles that are made, we only know that a charged particle was created in the high-energy collision. We don't know what kind it is," Frisch said. The most common types of charged particles differ only in their quark content. "It's important because if you can identify the quark content of the particles, then you can look for very specific processes that are rare or forbidden in the 'Standard Model' that is the basis of our present understanding," Frisch added.

Shared resources and expertise will be the key to their success, said Frisch and Chen. Physics students work in Chen and Kao's PET laboratory, helping transfer the Enrico Fermi Institute's engineering capabilities in high-speed, large-scale electronic systems to the needs of medical imaging. Frisch and Chen, along with Simon Swordy, PhD, director of the Fermi Institute and the UC James Franck Professor in Physics, also recently shared the cost of an ultrafast Tektronix sampling digital oscilloscope. The oscilloscope has enabled them to compile a library of the types of signals generated by 2 different particle detectors. This allows them to determine how well certain kinds of electronics can measure the velocity and position of the particles.

"No one has this kind of collection so far," Chen said of the pulse library. Testing the library against different particle detector configurations could cut down PET scan costs while also increasing image quality. "If we have very accurate digital measurements with modern computing and processing chips, we can actually cut down some of the manufacturing costs because we can get rid of some of the boards that were previously required," he said.

Frisch's goal for TOF PET is to achieve a resolution of 1 picosecond. Chen, who is measuring different types of events, would be satisfied with 30 picoseconds. This would provide improved PET scanner resolution in both directions and eliminate the need for expensive computational filtering of background noise. In their first simulations, the strategies that Chen and his associates tested had achieved a resolution of 100 picoseconds. "That was pretty good. That was our first try," Chen said. "We can do a lot better using an improved method for analyzing the data."

University of Chicago

Safety of FDA Approval Speed Questioned

Researchers from Harvard University (Boston, MA) reported in the March 27 issue of the *New England Journal of Medicine* (Carpenter et al.; 2008;358:1354–1361) on a study examining safety issues associated with implementation of the Prescription Drug User Fee Act (PDUFA) of 1992, which imposes deadlines for the completion of drug reviews by the Food and Drug Administration (FDA). The authors noted that critics have suggested that these deadlines may result in rushed approvals and that "the user-fee program makes the agency too dependent on the industry it regulates" and may have led the FDA to "focus disproportionately on the needs of the manufacturers that now fund more than half of its drug review budget and staff." The study first assessed the statistical association between the PDUFA deadlines and the timing of FDA drug approval for all new molecular entities approved between 1950 and 2005. To determine whether these deadlines were associated with subsequent safety problems, the authors focused on drugs submitted since January 1993, when the deadlines were imposed. They found that initiation of the PDUFA requirements resulted in a concentration of the number of approval decisions in the weeks immediately preceding the deadlines. Since 1993, the 97 drugs approved near the FDA deadline had a subsequent 14% rate of severe safety problems, compared with 3% for 216 drugs not approved near the deadline. Drugs approved in the 2 months before their PDUFA deadlines were more likely to be withdrawn for safety reasons, more likely to carry a subsequent black-box warning, and more likely to have 1 or more dosage forms voluntarily discontinued by the manufacturer than drugs approved before this 2-month window. They concluded that "PDUFA deadlines have appreciably changed the approval decisions of the FDA" and that drugs approved immediately before deadline are more likely to have safety problems in clinical use.

A *Wall Street Journal* article by Keith J. Winstein on March 27 covered the results of the Harvard study and noted that FDA officials were contest-

ing the findings. The FDA said its own database of drug approval times did not match those of the Harvard team and questioned the accuracy of the research database. "We just are unable to replicate the numbers," said Clark Nardinelli, an FDA economist, noting that the agency planned to send a detailed letter of response to the *New England Journal of Medicine*. In an interview, the Harvard group's lead researcher told Winstein that it was impossible to say in any specific case whether a rush to approval led to inadequate vetting of safety. "You can't point to any single case and say, well, an extra 2 months would have made the difference," Carpenter said, adding that "Congress would be much better off relying less upon these deadlines and relying more on a big increase in full-time employees."

New England Journal of Medicine
Wall Street Journal

Pitt Receives Gates TB Grant

The University of Pittsburgh (PA) Center for Vaccine Research announced on March 19 the receipt of an $11.4 million grant from the Bill & Melinda Gates Foundation (Seattle, WA) to develop new strategies to control tuberculosis (TB), which kills almost 2 million people per year worldwide. The grant will enable Pitt researchers to use multiple imaging technologies, including PET and PET/CT, to study TB to shorten and simplify its course of treatment. "One of the most challenging issues in treating TB and stopping its spread is the length of time it takes to adequately stem the infection," said JoAnne Flynn, PhD, principal investigator of the grant and professor of microbiology and molecular genetics at the University of Pittsburgh School of Medicine. "Current drugs are available, but we don't fully understand how or why they work. TB treatment must be continued for at least 6 months to be effective, placing an undue burden on those who are infected—often from the poorest and most disadvantaged countries.... Current medications for TB were developed more than 3 decades ago. To create significantly shorter and simplified approaches to treatment, we must improve our understanding of this disease and how current drugs are localized at the site of infection."

To understand more about the basic biology of TB, Flynn and colleagues will use PET/CT studies in nonhuman primates to follow the progression of the disease over time and analyze changes in tissue and responses to specific drugs. They will use radionuclide-based and fluorescent imaging, as well as mass spectrometry, to develop imaging probes and techniques to precisely locate bacteria associated with TB and to explore underlying factors responsible for slow drug metabolism.

"By applying the tools of modern medicine to TB, we hope to lay the groundwork for real-time measurements of TB drug efficacy in clinical trials and develop new targeted therapies that will considerably shorten the length of treatment," said Flynn.

Coinvestigators on the grant include Clifton Barry, III, PhD, National Institute of Allergy and Infectious Diseases (Bethesda, MD); Richard Caprioli, PhD, and Michelle Reyzer, PhD, Vanderbilt University (Nashville, TN); David Russell, PhD, and Warren Zipfel, PhD, Cornell University (Ithaca, NY); Kim Janda, PhD, and Tobin Dickerson, PhD, The Scripps Research Institute (La Jolla, CA); Benjamin Davis, PhD, Oxford University (UK); Chet Mathis, PhD, Jonathan P. Carney, PhD, and Brian J. Lopresti, BS, University of Pittsburgh; and Veronique Dartois, PhD, Novartis Institute of Tropical Disease (Singapore).

University of Pittsburgh Center for Vaccine Research

Medical Tests Trigger Problems at the Border

On March 5 the Southgate, MI, *News-Herald* published an account of a Michigan man who was detained at the U.S./Canadian border after undergoing nuclear medicine diagnostic tests.

On February 21, William Duran, a former police commissioner of Wyandotte, MI, underwent myocardial perfusion stress imaging at the Brownstone (MI) township office of Dearborn Cardiology. Later, he made a routine border crossing with his wife for dinner at a restaurant in Windsor, Ontario. The return trip through U.S. border security was anything but routine. "We got up to being the third vehicle back coming out of the tunnel, when all of the gates came down," Duran told the *News-Herald*. "We then noticed all of the customs guys coming back to each vehicle with some kind of handheld detector and going around the vehicles. We kind of joked and said, 'We're going to see something going on here.' We thought it was kind of interesting—until they got to my truck. They moved all the other vehicles through the gates, and we were the lone vehicle, which made us feel worse. They all came around our vehicle. We were somewhat surrounded. One guy was on the radio saying they had shut down the bridge and tunnel. He kept saying, 'We have the vehicle. We have the vehicle.'"

The Durans' passports were collected, and the couple was questioned. Among the questions was whether either had undergone a medical test. Duran's affirmative reply led to additional questions and scrutiny of the vehicle. The Durans were asked to drive their truck through another set of sensing equipment. "From their reaction, we set that detector off," he told the *News-Herald*. "Then they had us take our vehicle to the impound-teardown area. I was nervous that they were going to tear down my truck." The couple was then escorted into a customs building for additional questioning. "The guy came in with a handheld detector and set it down on a counter 6 or 8 feet away, and it went off. My wife and I both heard it. He said, 'You didn't have a PET scan today, did you?' and I said no. He said, 'Good. It wasn't in the database.' I said, 'What database?'" The question went unanswered.

The border officials questioned the Durans, asking them for details of their activities in Canada. "They asked me if I had any medical paperwork with me a couple of times. I said no," said Duran. "I asked why we didn't set it off

going into Canada, and he said they don't check for that. . . .I said to the guy that had the handheld detector, 'I'm sorry. If I had known this, I'd have gone to dinner the next day.' He said, 'No. It might take 30 days before you don't set it off.'"

After being detained for more than an hour, the Durans were released along with their passports. On February 22, Duran returned to the cardiology offices to tell physicians and staff about his experiences at the border. According to the *News-Herald* report, a sign is now in place at the offices "informing patients of what could happen if they travel after certain tests."

Duran reflected on the experience, noting that his law enforcement background probably helped and that individuals who become agitated or anxious when detained might not fare as well in similar situations. "I'm assuming they could hold you for a whole lot longer," he said.

The News-Herald

(Continued from page 24N)

urging every program director to respond to this survey now. This input is vital if we are to properly train the molecular imaging physicians of the future.

A special session for NMPDs will be offered at the 2008 SNM Annual Meeting in New Orleans, LA, on Sunday, June 15, from 11:30 AM to 12:30 PM. Program directors are invited to join the MI Education Task Force after this session for lunch from 12:30 to 2:00 PM to continue the discussion. These meetings will offer another opportunity for NMPDs and other interested individuals to provide feedback on the curriculum.

Darlene Metter, MD
Chair, Nuclear Medicine Program Directors
Chair, Nuclear Medicine Residency Review Committee
Member, MICoE Education Task Force

(Continued from page 24N)

It is appropriate for boards to take leadership in addressing the public's concerns about the quality of health care. The ABNM mission statement states: "The Board establishes the standards for training, initial certification, and maintenance of certification for physicians rendering nuclear medicine services, thereby helping patients obtain high-quality health care." Boards are expected to act in the best interest of the public. The primacy of the public's interest and the autonomy to act in the public's interest are necessary to maintain the public's trust. Without that trust, the profession would not be allowed to self-regulate. Many physicians do not keep in mind this important distinction when thinking about boards and their specialty societies. In contrast to boards, specialty societies act in the best interest of their members. The members of the society elect their leadership and determine the policies of their society. For boards, the agenda is largely set in response to the needs of the public.

Note: At the SNM Annual Meeting in New Orleans, LA, the following continuing education sessions on MOC will be offered: "MOC Overview and New Developments," June 14, 4:30–6:00 PM; and "MOC Practice Performance Assessment," June 16, 4:30–6:00 PM. For details, see the SNM Online Meeting Planner at www.snm.org/am. Click on "Attendees."

Henry D. Royal, MD
Executive Director, ABNM