

Restored Funding for Nuclear Medicine Research

On December 26, President Bush signed an omnibus appropriations package for fiscal year 2008. The bill contains more than \$411 million for biological research at the Department of Energy (DOE) Office of Science, including \$31.5 million for medical applications and measurement science. This is an increase of \$17.5 million (pending small overall cuts) for basic nuclear medicine research to be awarded through competitive grant solicitations.

For almost 60 years, DOE has supported basic nuclear medicine research that has helped in the development of new technologies and treatments. Since the program was cut in fiscal year 2006, many important projects related to radioisotope-based science have been abandoned, and long-term innovation in the field has been jeopardized. The Senate Energy and Water Appropriations Committee report included \$34 million for the DOE Office of Science/Office of Biological and Environmental Research Medical Applications and Measurement Science program for fiscal year 2008, restoring \$20 million explicitly for nuclear medicine research. However, the House version of energy appropriations did not address funding for basic research. The final bill, after a Senate-House Conference, included \$17.5 million for nuclear medicine research.

SNM leaders and members have been vocal advocates for restoring this funding. After the bill was signed, SNM leadership issued a statement expressing thanks to members whose interactions with legislators through phone calls, sign-on letters, and constituent visits were instrumental in this effort.

SNM

Canadian Reactor Restarts

Under pressure from the Canadian government and through a special en-

forcement allowance from the country's nuclear regulatory agency, Atomic Energy of Canada, Ltd. (AECL) announced on December 13 that it would restart a nuclear reactor shut down for almost 1 month. The shutdown caused widespread shortages of ^{99m}Tc , the most commonly used nuclear medicine radioisotope, and sparked discussions in the United States about the need for redundancy and back-up in radionuclide supplies. The reactor restarted on December 16. At Newsline press time in January, both U.S. and Canadian media reported lingering patient backlogs from the shortages.

As reported in the January issue of *JNM's* Newsline, AECL shut down its Chalk River, Ontario, National Research Universal (NRU) reactor on November 18 for what was initially described as 5 days of routine maintenance. MDS Nordion, which manages wholesale marketing and distribution of radioisotopes from the reactor, alerted customers almost 2 weeks later to a more serious interruption in the supply of ^{99}Mo used in the manufacture of ^{99m}Tc generators. By the end of the first week of December, the Canadian government was responding to reports from medical providers from around the world whose patients would be affected by the shortages.

On December 12, the Canadian government passed legislation allowing AECL to bypass the Canadian Nuclear Safety Commission (CNSC) order for an indefinite stoppage at the facility, issued after a discovery that the facility had been functioning without a requisite emergency power system. In describing the restart initiative, Canadian Prime Minister Stephen Harper criticized CNSC leadership for not allowing the reactor to restart earlier. The events surrounding the shutdown resulted in the December 31 resignation of Michael Burns, chair of the AECL board.

The emergency legislation allowed AECL to operate the NRU for 120 days

(i.e., until mid-April) without the approval of the CNSC, as long as AECL is "satisfied that it is safe to do so." Federal Health Minister Tony Clement visited the Chalk River Laboratories on December 22 to thank AECL staff for their efforts in resuming production. Clement noted that Health Canada would work with an ad hoc expert committee to identify alternative sources of isotope supply, alternative isotopes to use, and possible alternative therapies that could be approved on an emergency basis to meet patient needs until the supply was fully restored. "As the radioisotope shortage has evolved, Canadians can feel reassured by the swiftness with which health care professionals have worked together to address the urgent needs of patients. Until the shortage is alleviated, I will spare no effort in working with all of our partners to minimize treatment delay, and I would like to take this opportunity to thank all health care professionals for their creativity and spirit of sharing during this difficult period," Clement said.

The CNSC announced in late December that it will review "lessons learned" in the NRU shutdown, including "the performance of CNSC staff over the period leading up to and pursuant to the decision to renew the NRU license."

*Health Canada
Media Resources*

FDA Science and Research Criticized

An investigative report released on December 5 by a subcommittee of the Science Board, which advises the U.S. Food and Drug Administration (FDA), catalogued a lengthy list of shortcomings in technology, science, and research capacities, many of which were attributed to increased demands and inadequate resources. The Science and Technology Subcommittee of the Science Board pulled no punches, stating

that “The FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak,” resulting in an endangered food and drug supply and putting “American lives at risk.”

The 56-page *FDA Science and Mission at Risk* report was called for by FDA Commissioner Andrew von Eschenbach, MD, and, in part, provided documentation supporting the agency’s request for \$2.1 billion in fiscal year 2008, a 5.3% increase. However, the findings in the report suggested the need for additional funding and more focused remedial organizational and scientific efforts. In addition to noting that “FDA’s evaluation methods have remained largely unchanged over the last half century” and “have not kept pace with major advances in medical devices and use of products in combination,” the report concluded that “not only can the Agency not lead, it cannot even keep up with the advances in science.” Among the contributory causes cited were high turnover and poor retention of qualified staff, inadequate information technology infrastructures, and underutilized channels of communication with scientists outside the agency. The full report is available at: www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_00_index.html.

U.S. Food and Drug Administration

NRC Orders Fingerprints, Criminal Histories for Some Licensees

The Nuclear Regulatory Commission (NRC) issued an order on December 5 to almost 1,000 licensees to begin fingerprinting of and criminal history checks on all persons granted unescorted access to certain radioactive materials. The order applies to NRC licensees in industry, academia, and medicine who are licensed to possess “radioactive materials in quantities of concern” from a security perspective. These quantities are essentially equivalent to Category 1 and Category 2 sources as defined in the International Atomic Energy Agency’s Code of

Conduct on the Safety and Security of Radioactive Sources. The order implements requirements contained in the Energy Policy Act of 2005. The agency plans to develop a proposed rule to make the new requirements part of its regulations. The order was issued to implement the requirement while the rule is being developed.

The NRC considers the identities of licensees receiving the order to be “sensitive information” and will not release the names of individuals or institutions. The order applies to licensees in the 16 states, the District of Columbia, Puerto Rico, and U.S. territories where the NRC has regulatory authority. The 34 Agreement States that regulate radioactive materials under agreements with the NRC are expected to issue similar requirements to their licensees in early 2008.

Nuclear Regulatory Commission

NCRP on Radionuclide Therapy Patients

The National Council on Radiation Protection and Measurements (NCRP) announced on November 26 the release of NCRP Report No. 155, *Management of Radionuclide Therapy Patients*, intended for use by physicians, medical physicists, health physicists, administrators, nurses, other professional and medical staff, and patients. The approaches originally suggested in NCRP Report No. 37, *Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides* (1970), were incorporated and updated in the new report. The publication includes recommendations on explaining risks from therapeutic procedures and obtaining adequate, informed patient consent; dose limits for members of the patient’s family; patient confinement in a hospital or skilled-care facility; and patient records, including radionuclide and activity used, treating physician, and contact information.

Section 1 of Report No. 155 includes brief historical items and discusses the basic principles of radiopharmaceutical therapy and brachytherapy. Section 2 deals with basic radiation safety prin-

ciples in a medical facility and includes a description of the radiation safety program, dose limits, and staffing. Section 3 addresses radiopharmaceutical therapy, including both clinical and radiation safety aspects. Section 4 covers brachytherapy. Section 5 includes facility design for both nuclear medicine and radiation oncology installations. Section 6 describes changes in patients’ status, including medical emergencies, and includes guidelines for other situations that may be adapted to specific facility requirements. The report is supplemented by appendices. NCRP Report No. 155 can be purchased in hard- or softcopy formats at <http://NCRPpublications.org>. A 20% discount is available to SNM members for all online purchases by entering the code `snm37155` at checkout.

National Council on Radiation Protection and Measurements

NIH Launches Human Microbiome Project

The National Institutes of Health (NIH) announced on December 19 the official launch of the Human Microbiome Project, which will attempt to sequence the collective genomes of all microorganisms present in or on the human body. “The human microbiome is largely unexplored,” said NIH Director Elias A. Zerhouni, MD. “It is essential that we understand how microorganisms interact with the human body to affect health and disease. This project has the potential to transform the ways we understand human health and prevent, diagnose, and treat a wide range of conditions.” Part of the NIH Roadmap for Medical Research, the Human Microbiome Project will award a total of \$115 million to researchers over the next 5 years. Researchers will initially sequence 600 microbial genomes, completing a collection that will total more than 1,000 microbial genomes and providing a resource for investigators interested in exploring the human microbiome. Other microbial genomes are being contributed to the collection by individual NIH institutes and internationally funded projects. A

meeting between international partners was recently convened to discuss forming an international consortium.

In the next phase of the project, research will use comprehensive laboratory technologies to characterize microbial communities present in samples taken from healthy human volunteers. Samples will be collected from 5 body regions known to be inhabited by microbial communities: the digestive tract, the mouth, the skin, the nose, and the female urogenital tract. Demonstration projects will be funded to sample microbiomes from volunteers with specific diseases. This will allow researchers to correlate the relationship between changes in a microbiome present at a particular body site to a specific illness. "We now understand that there are more microbial cells than human cells in the human body. The Human Microbiome Project offers an opportunity to transform our understanding of the relationships between microbes and humans in health and disease," said Alan Krensky, MD, director of the Office of Portfolio Analysis and Strategic Initiatives, which oversees the NIH Roadmap for Medical Research.

Microbiology has focused in the past on the study of individual species as isolated units, making it difficult to develop and inventory all microbes in and on the human body. Because their growth is dependent on specific natural environments, it is difficult to recreate microbe–host interactions in the laboratory. Advances in next-generation DNA sequencing technologies relying on metagenomic sequencing will be used. Instead of isolating each microbe, all DNA within collected samples will be sequenced.

"Our goal is to discover what microbial communities exist in different parts of the human body and to explore how these communities change in the presence of health or disease," said National Human Genome Research Institute Director, Francis S. Collins, MD, PhD, cochair of the Human Microbiome Project Implementation Group. "In addition, we will likely identify novel genes and functional elements in microbial genomes

that will reshape the way we think about and approach human biology."

NIH recently awarded \$8.2 million to 4 sequencing centers to begin building a framework and data resources for the project. One-year awards were given to sequencing centers at the Baylor College of Medicine (Houston, TX), Washington University School of Medicine (St. Louis, MO), the Broad Institute of MIT/Harvard (Cambridge, MA), and the J. Craig Venter Institute (Rockville, MD).

Following the precedents set by other large-scale genomics efforts, data from the Human Microbiome Project will be deposited in public databases, including those supported by the National Center for Biotechnology Information (<http://www.ncbi.nlm.nih.gov/mapview/>), part of the National Library of Medicine. The project also will fund the establishment of a Data Analysis and Coordinating Center, which will provide data access and develop data retrieval tools for the research community.

The Human Microbiome Project also will monitor and support research on the ethical, legal, and social implications of the research. Areas of focus include the clinical and health implications of using probiotics, potential forensic uses of microbiome profiles, bioterrorism and biodefense applications, the application of new technologies from the project, and patenting and privacy issues.

Additional information about the Human Microbiome Project and funding is available at <http://nihroadmap.nih.gov/hmp/> and www.nihroadmap.nih.gov/hmp/grants.asp.

National Institutes of Health

IAEA Designates Nuclear Trafficking a Global Challenge

The illicit trafficking of nuclear material and the potential threat it poses continue to be issues of international concern, and steps to establish effective technical and administrative systems to prevent the unauthorized movement of nuclear and other radioactive materials

must continue to be taken, according to a final report from an International Atomic Energy Agency (IAEA)–organized conference held November 19–22 in Edinburgh, Scotland. More than 300 delegates from 60 states and 11 international organizations at the Illicit Nuclear Trafficking: Collective Experience and the Way Forward conference acknowledged the IAEA's Illicit Trafficking Database (ITDB) as a critical tool against nuclear trafficking, providing valuable information on "weaknesses and vulnerabilities" that can be exploited to acquire such material. Conference consensus findings indicated the importance of halting the illicit movement of nuclear material, equipment, and technologies. Conference findings also stressed the role of international cooperation in understanding the circumstances of trafficking events, patterns, and trends and in strengthening the compilation of information in systems such as the ITDB.

Recommendations made by the conference included: continuing the development of new technologies for hard-to-detect fissile materials, sharing new technologies with states that lack them, taking into account unguarded borders in the need to increase the sophistication of detection capabilities, formulating effective communication strategies to inform the public, and convening a conference in 2010 to assess progress.

International Atomic Energy Agency

National Biodefense Science Board Named

U.S. Department of Health and Human Services Secretary Mike Leavitt announced on December 17 the names of members of the newly formed National Biodefense Science Board (NBSB). The NBSB will provide expert advice and guidance on scientific, technical, and other matters of special interest regarding activities to prevent, prepare for, and respond to adverse health effects of public health emergencies resulting from current and future chemical, biological, nuclear, and radiologic agents. "This board will

play an important role in ensuring that our nation is well-prepared to prevent and respond to public health emergencies,” Leavitt said. Authorized by the Pandemic and All-Hazards Preparedness Act, the board held its first meeting on December 17 and 18 in

Washington, DC. Members include: Patricia Quinlisk, MD, MPH, Chair; Ruth L. Berkelman, MD; Stephen V. Cantrill, MD; Roberta Carlin, MS, JD; Albert J. Di Rienzo; Kenneth L. Dretchen, PhD; John D. Grabenstein, RPh, PhD; James J. James, Brigadier

General (Ret), MD, DrPH, MHA; Thomas J. MacVittie, PhD; John S. Parker, MD, Major General (Ret); Andrew T. Pavia, MD; Eric A. Rose, MD; and Patrick J. Scannon, MD, PhD.
U.S. Department of Health and Human Services

(Continued from page 35N)

already participating in quality assurance and quality improvement (QI) activities. For example, the diplomate may survey patients about the quality of services or technologists about the strengths and weaknesses of the physician staff; hold follow-up conferences in which errors in interpretation are discovered or request formal independent second interpretations of a percentage of cases; have his or her practice independently inspected and accredited by an outside organization; or have processes in place to improve report signing times and decrease errors in reports. The main difference between PPA and QI activities is that the former are at the individual physician level rather than the departmental level. For each 3-year cycle, the diplomate will pick an area for improvement, measure baseline data, formulate an improvement plan, and then remeasure to document any improvement. Depending on the results, at the end of a 3-year cycle, the diplomate may decide to move on to another project or repeat the same project if additional improvement is possible. Part IV of MOC has been discussed frequently in Newsline, and information about Part IV can also be found on the ABNM Web site.

To inform SNM members of the new MOC requirements, Newsline has published monthly articles on MOC since

March 2007. These articles can be viewed in full on the ABNM and SNM LLSAP/MOC Web sites.

March 2007—New MOC Requirements in Effect

April 2007—ABMS Requires Lifelong Learning

May 2007—MOC Featured at Annual Meeting

June 2007—What is “My MOC”?

July 2007—Self-Assessment Credit: What SNM is Doing to Help

August 2007—Maintenance of Certification for ABNM Diplomates

September 2007—Part IV of MOC: What Is It?

October 2007—Part IV of MOC: How Will It Evolve?

November 2007—MOC Part IV: Practical Issues

December 2007—MOC: Frequently Asked Questions

January 2008—MOC Fees: An Inconvenient Truth

The majority of diplomates, including those with lifetime certificates, who are actively practicing nuclear medicine are participating in MOC. In the coming year, the ABNM will publish a list of milestones that must be met in order for the ABNM to classify a diplomate as actively participating in MOC. ✨