NRC and Regulatory Relief for Training for Imaging/ Localization Studies

SNMMI announced on September 19 the receipt of a response from the U.S. Nuclear Regulatory Commission (NRC) addressing a previous request for regulatory relief for training for imaging and localization studies during the COVID-19 Public Health Emergency (PHE). In the response, addressed to SNMMI, the American Society of Nuclear Cardiology (ASNC), the American Society for Radiation Oncology (ASTRO), and the American College of Radiology (ACR), NRC staff stated that the agency was "prepared to consider, on an expedited basis, requests for an exemption from the requirement to obtain the hands-on work experience described in [10 CFR] 35.290(c)(1)(ii)(G)."

The current regulation reads: "Work experience must involve: Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs." On June 11, the SNMMI, ASNC, ASTRO, and ACR sent a formal request that the NRC allow this requirement to be met using virtual technology (video/webinar) and to add this as an already vetted area for regulatory relief when requested by licensees. This request was similar to the NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) subcommittee recommendation for a 1-time modification because of COVID-19. The ACMUI request stated: "In situations when hands-on training (hot lab) is not feasible, then video/webinar observational training may be considered. Similarly, when work experience cannot be met in person, then virtual training may be considered."

The NRC received a similar request from the Certification Board of Nuclear Cardiology, dated June 24, 2020, and has granted that request via a temporary exemption. The exemption allows individuals seeking board certification to fulfill this work experience requirement virtually, rather than hands-on, from January 31, 2020 (when the U.S. Department of Health and Human Services declared a PHE for the United States) through December 31, 2020. Despite the regulatory relief provided by this exemption, a licensee that uses generator systems is advised to provide, as soon as safely possible, hands-on work experience involving the tasks described in 10 CFR 35.290(c)(1)(ii)(G) to its authorized users who obtained this work experience virtually.

SNMMI

Open-Source COVID-19 Medical Image Database

Representatives of the American College of Radiology (ACR), the Radiological Society of North America (RSNA), and the American Association of Physicists in Medicine (AAPM) announced in August the development of the Medical Imaging and Data Resource Center (MIDRC), an open-source database with medical images from thousands of COVID-19 patients. The National Institute of Biomedical Imaging and Bioengineering is funding the effort through a contract to Maryellen Giger, PhD, of the University of Chicago (IL), which will host the MIDRC. The effort will be led by the 3 associations, with Etta Pisano, MD, and Michael Tilkin, MS, taking the lead for the ACR; Curtis Langlotz, MD, PhD, and Adam Flanders, MD, for the RSNA; and Giger and Paul Kinahan, PhD, for the AAPM.

"The MIDRC database will provide a critical tool to help the medical imaging community, doctors, and scientists better understand COVID-19 and its biological effects on humans," said Pisano. "This knowledge, and the technological advancements the registry can enable, will ultimately help providers save lives."

Funded under the National Institutes of Health special emergency COVID-19 process, the MIDRC will create an open-access platform to collect, annotate, store, and share COVID-related medical images. The MIDRC will leverage existing data collection efforts to upload more than 10,000 COVID-19 thoracic radiographs and CT images, including many from the ACR COVID-19 Imaging Research Registry and the RSNA International COVID-19 Open Radiology Database. This will allow researchers from around the world to access images as well as clinical data to answer COVID-19 questions. The MIDRC will include 5 infrastructure development projects and oversee 12 research projects, including ~20 university labs, in support of solutions to the COVID-19 pandemic. The MIDRC will initially focus on COVID-19 but will work to expand services to provide imaging data and artificial intelligence pipelines to aid in the fight against other diseases.

"This dedicated team of research scientists, engineers, and imaging professionals will produce new tools for the detection, diagnosis, and prognosis of COVID-19 by aggregating massive amounts of imaging and other clinical data from COVID-19 patients," said Langlotz. "We look forward to linkages with other national data repositories to enable a comprehensive analysis of COVID-19 disease and its imaging manifestations."

American College of Radiology

NCI, Cancer Research UK Launch Cancer Grand Challenges

The National Cancer Institute (NCI) announced on August 27 that it will partner with Cancer Research UK to fund Cancer Grand Challenges, an international initiative to address profound and unanswered questions in cancer research. Through this effort, NCI and Cancer Research UK will seek novel ideas from multidisciplinary research teams from around the world that offer the potential to make bold advances in cancer research and improve outcomes for people affected by cancer. The new partnership builds on

Cancer Research UK's Grand Challenge initiative, which is currently funding 7 international teams of researchers across 9 countries. Cancer Research UK is the world's largest independent cancer research charity. Cancer Grand Challenges will foster a highly competitive process designed to stimulate scientific creativity of the highest order.

"This new partnership leverages the expertise of the world's leading funders of cancer research in a bold effort to identify and pursue innovative ideas that address major challenges in understanding cancer," said NCI Director Norman E. "Ned" Sharpless, MD. "We're thrilled to join Cancer Research UK in this unique collaboration to support novel cancer research on a global scale."

The goals of the partnership include identifying important cancer research opportunities, facilitating global collaboration among multidisciplinary researchers to solve these challenges, giving the global teams the freedom and scale to innovate and carry out cutting-edge research, and advancing fundamental biological knowledge and its clinical application to cancer. To gain perspectives from people affected by cancer, a patient committee will offer input and ideas throughout the Cancer Grand Challenges process.

NCI and Cancer Research UK planned to announce the list of new challenges in October 2020. Expressions of interest from research teams for the new challenges are expected to be accepted from October 2020 through April 2021. From these, a small number of teams will be selected to receive pilot funds to develop their ideas into larger, final applications. Those selected to receive pilot funding will be notified in June 2021, and the awards to final teams will be announced in 2022. NCI and Cancer Research UK expect to cofund ~4 awards for each round of Cancer Grand Challenges, with each multidisciplinary team being awarded ~$25 million over 5 years. NCI anticipates that the Cancer Grand Challenges partnership will support 3 rounds of awards, with a new round of challenges announced every other year. NCI plans to use annual funding currently set aside for the Provocative Questions (PQ) initiative and anticipates funding PQ awards and Cancer Grand Challenges awards in alternating years.

The process to determine the Cancer Grand Challenges is conducted through a series of international workshops to receive input from thought leaders from the cancer research community and people affected by cancer. The most compelling ideas generated from these workshops are then reviewed and the final challenges selected. Cancer Research UK launched the Grand Challenge initiative in 2015 and has since overseen 2 rounds of Grand Challenge awards. These awards are currently funding teams focusing on identifying preventable causes of cancer, creating virtual reality maps of tumors, preventing unnecessary breast cancer treatment, studying tumor metabolism from every angle, understanding why cancers grow in some tissues and not in others, finding new ways to tackle inflammation-associated cancer, and manipulating the microbiome to treat bowel cancer.

"Many of the ongoing Grand Challenge awards align with NCI research priorities, and our missions overlap in many ways," said Dinah S. Singer, PhD, NCI Deputy Director for Scientific Strategy and Development. "This initiative will expand opportunities to identify new challenges based on insights from the cancer research community and to further our understanding of cancer. We're looking forward to the new ideas proposed by creative teams from around the world."

See the NCI Cancer Grand Challenges webpage (including the newly announced Grand Challenge areas of focus) at: https://www.cancer.gov/grants-training/grants-funding/cancer-grand-challenges and the Cancer Research UK Cancer Grand Challenges webpage at https://www.cancerresearchuk.org/funding-for-researchers/cancer-grand-challenges.

National Cancer Institute

SNMMI and Partners Host Congressional Briefing

On September 17, SNMMI and its coalition partners, the Medical Imaging & Technology Alliance (MITA) and Council on Radionuclides and Radiopharmaceuticals, Inc., hosted a virtual briefing for Capitol Hill staff with leading physicians to discuss the growing impact of PET and nuclear medicine in cancer treatment, as well as the importance of expanding patient access to these drugs through passage of the Medicare Diagnostic Radiopharmaceutical Payment Equity Act of 2019 (HR 3772).

The briefing included presentations from David Mankoff, MD, PhD, Gerd Muehllehner Professor of Radiology and Vice-Chair for Research of Radiology at the University of Pennsylvania's Perelman School of Medicine (Philadelphia), and Michael Roarke, MD, MS, Chair of the Division of Nuclear Medicine for the Mayo Clinic Arizona Department of Radiology and Medical Director at the Mayo Clinic's Arizona Cyclotron Facility (Phoenix). The event also featured remarks from a prostate cancer patient who provided insights into his experience with nuclear medicine and its positive effect on his treatment pathway.

Congressman Greg Murphy, MD (NC-3), a cosponsor of HR 3772, started the briefing by noting that: "Nuclear medicine is already playing a growing role in diagnosing advanced disease, including prostate and breast cancer. Passage of HR 3772 will give patients and their physicians the tools they need to diagnose life-threatening diseases early, when they are most treatable—a key improvement that will reduce downstream costs and, more importantly, save lives."

Roarke drew on more than 24 years of experience in nuclear medicine to provide an overview of PET technology and its growing influence on the clinical mainstream. Mankoff elaborated on ways in which PET radiopharmaceuticals are used to enhance breast cancer treatment: "Diagnostic PET radiopharmaceuticals are capable of identifying metastatic breast cancer at an earlier stage and can determine if a prescribed treatment is working. Although this information can help guide treatment decisions and improve patient outcomes, patients and their providers continue to encounter severe roadblocks when seeking coverage for these innovative diagnostic approaches."

Sue Bunning, MITA Industry Director of Molecular Imaging & PET, closed the briefing with an overview of Medicare's current reimbursement policy and the ways in which it undermines patient access to innovative radiopharmaceutical diagnostics: "Unfortunately, the Centers for Medicare and Medicaid Services currently treat PET radiopharmaceuticals, including the drugs needed for diagnostic scans, as part of the packaged cost of the procedure in the hospital outpatient setting. This structure disincentivizes the utilization of many radiopharmaceuticals for Medicare patients, leading to limited patient access and stifled innovation. The Medicare Diagnostic Radiopharmaceutical Payment Equity Act of 2019 represents a legislative solution that would address structural flaws in the current payment methodology and grant greater access to life-saving PET diagnostic radiopharmaceuticals for patients."

SNMMI

SNMMI 2020–2022 Wagner–Torizuka Fellowship Recipients

SNMMI announced on September 28 the recipients of the 2020–2022 SNMMI Wagner–Torizuka Fellowship. This 2-year award, founded in 2008 by the late Henry N. Wagner, Jr., MD, and the late Kanji Torizuka, MD, PhD, is designed to provide extensive training and experience in the fields of nuclear medicine and molecular imaging for Japanese physicians in the early stages of their careers. "SNMMI is pleased to sponsor the Wagner–Torizuka Fellowship in support of the worldwide advancement of nuclear medicine and molecular imaging. The program has provided invaluable experience for many rising nuclear medicine and molecular imaging professionals over the years, equipping them to make significant contributions to the field in Japan," said Satoshi Minoshima, MD, PhD, past SNMMI president and chair of the SNMMI Awards Committee.

The 2020–2022 fellows, each receiving an annual stipend of $24,000, are: Masatoshi Hotta, MD, National Center for Global Health and Medicine (Tokyo, Japan), whose research interests include PET/CT and SPECT/CT and the roles they play in image-based treatment planning and dosimetry for theranostics. He is a visiting researcher in the Department of Molecular and Medical Pharmacology in the Ahmanson Translational Theranostics Division at the David Geffen School of Medicine at the University of California, Los Angeles, under the supervision of Johannes Czernin, MD; Yuichi Wakabayashi, MD, PhD, National Institutes of Health (NIH; Bethesda, MD), whose research focuses on utilization of PET/CT to localize and quantify specific proteins in the living brain. He is continuing his studies at the NIH Molecular Imaging Branch of the National Institute of Mental Health under the supervision of Robert Innis, MD, PhD; and Keiichiro Kuronuma, MD, PhD, Nihon University Hospital (Tokyo, Japan), whose current research interests include PET imaging using ^{18}F-flurpiridaz and artificial intelligence technology in medicine. He will study in the Department of Imaging at Cedars–Sinai Medical Center in Los Angeles, CA, under the supervision of Daniel S. Berman, MD.

The SNMMI Wagner–Torizuka Fellowship program, sponsored by Nihon Medi-Physics Co., Ltd. (Tokyo, Japan), has successfully graduated 30 fellows since its inauguration in 2008. Applications and information about requirements for the 2021–2023 SNMMI Wagner–Torizuka Fellowship are available at www.snmmi.org/grants. Applications are due by January 31, 2021. For more information about these and other scholarships, visit www.snmmi.org/grants or contact the SNMMI Development Department at Grants&Awards@snmmi.org.

SNMMI

New Nanoparticles from IAEA Coordinated Research Project

In a September 1 article on the website of the International Atomic Energy Agency (IAEA), the agency reported on the development of 2 new nanoparticles that "hold promise for a new generation of nanosized radiopharmaceuticals" for therapy. The research has been conducted under the aegis of an IAEA Coordinated Research Project (CRP). The Nanosized Delivery Systems for Radiopharmaceuticals (F22064) project involved scientists from 12 countries, who developed more than 40 new polymeric nanoparticles using chemical synthesis and/or radiation technology. The aim was to provide significant improvement in delivery of therapeutic radiopharmaceuticals through the use of nanotechnology.

The scientists experimented with different base structures, such as nanogels, proteins and inorganic nanoparticles, and different targeting agents.

The project closed in October 2019. The findings of the CRP were published throughout the duration of the project in 76 scientific journals. The IAEA CRP project page (https://www.iaea.org/projects/crp/f22064) indicates that "The participants agreed that the report to be kept confidential among the participants and not to be shared publicly. As soon as the participants announce their willingness for public access, the scientific secretary will initiate publishing the report as a 'working material'." Preliminary published joint recommendations for future work included: (1) initiation of a new CRP for completion of preclinical studies of selected nanoconstructs (with a focus on ^{68}Ga, ^{177}Lu, and ^{198}Au); initiation of a new CRP on a selected nanoconstruct from this CRP F22064 (MGF ^{198}AuNPs), with completed preclinical results; initiation of an IAEA publication on "Development of radiolabeled nanoparticles for theranostic applications" as an outcome of CRP F22064; preparation of an IAEA publication on "Guidelines on the development of human tumor models for preclinical studies of radiopharmaceuticals"; and initiation of a new activity on clinical evaluation of chemical- and radiation-produced ^{99m}Tc-nanocolloids for sentinel node scintigraphy.

IAEA