Reminder: USP General Chapter <825> Effective December 1

On June 1, the U.S. Pharmacopeia (USP) published General Chapter <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging. This provides uniform minimum standards for designated activities for sterile and nonsterile radiopharmaceuticals for humans and animals that occur as part of state-licensed activities. Immediately following the inception of the current standards outlined in General Chapter <797>, nuclear medicine and nuclear pharmacy interests had reported that radiopharmaceuticals were underserved by the founding chapter and that specific standards based on the unique characteristics of radiopharmaceuticals were needed. This concern was addressed by the USP with inclusion of standards for compounded sterile radiopharmaceuticals in subsequent revisions of <797> and ultimately in this new General Chapter <825>. In a press release in June, SNMMI commended the USP for this effort to provide a reasonable and rational basis for protection of patients from unsafe practices.

The chapter will become official on December 1, 2019, and as of that date, affected users are expected to meet its requirements. Ensuring compliance with the requirements is the responsibility of regulators such as the U.S. Food and Drug Administration, states, and other government authorities. USP has no role in enforcement. SNMMI recommended in August that nuclear medicine community members review and compare the practices and procedures in place in their facilities against the requirements of the new USP chapter. Items such as facility design, competency of staff, and infection control practices are critical and may need attention and review.

The new chapter features sections on the importance of keeping an appropriate environment during preparation of radiopharmaceuticals, including clean room regimes, hygiene, cleaning equipment, labeling, and air particulate matter monitoring. The chapter also details facilities and engineering controls, personnel training and qualifications, and procedural standards for processing radiopharmaceuticals in nuclear pharmacies, nuclear medicine areas in hospitals and clinics, and other health care settings that use radiopharmaceuticals. For sterile radiopharmaceuticals, these standards balance aseptic handling practices with radiation protection practices to describe appropriate strategies to maintain patient safety while also ensuring the safety of individuals performing these activities. For additional information on the new chapter, see answers to frequently asked questions at https://www.usp.org/frequently-asked-questions/radiopharmaceuticals.

SNMMI

NM Radiation Safety Training in Africa

The International Atomic Energy Agency (IAEA) hosted a Regional Training Course on the Prevention of Accidents and Incidents in Nuclear Medicine from July 22–26 at its headquarters in Vienna, Austria. Planned to promote adherence to the IAEA Safety Standards and to other relevant guidelines, the week-long training course was organized through an ongoing regional technical cooperation project and was attended by 21 professionals from Algeria, Kenya, Mauritius, Morocco, Namibia, Tunisia, Uganda, United Republic of Tanzania, Zambia, and Zimbabwe.

The number of nuclear medicine facilities in Africa has increased from 57 to 74 over the last decade, according to the IAEA Nuclear Medicine Database. A press release from the IAEA highlighted the fact that the increase in access to nuclear medicine services has helped many patients and at the same time emphasizes the importance of minimizing and mitigating the risks of accidental radiation exposure to patients, medical staff, or the public during such procedures.

The course was organized as an interactive learning experience and included didactic lectures, facilitated discussions, hands-on exercises, and a visit to the nuclear medicine department of Vienna's Allgemeines Krankenhaus. Information provided during the training included both theoretical and practical recommendations to reduce errors and accidents in the application of nuclear medicine. The course encouraged consideration of all possible causes and sources of accidents.

"This training will help us to put into place safety systems, by promoting awareness of the potential for accidents and by providing the necessary tools to evaluate patient safety in our medical facilities," said Skander Rahabi, MD, nuclear medicine physician from CHU de Bab El Oued Hospital (Algiers, Algeria). Among other exercises, the participants delivered presentations of errors in their facility and worked to develop action plans on the basis of the training course's material.

International Atomic Energy Agency

Brexit and Nuclear Medicine

On August 1 organizations responsible for the procurement and use of medical radioisotopes in the United Kingdom urged new Prime Minister Boris Johnson to provide assurances about supply and costs ahead of a potential no-deal Brexit. Leaders from the Royal College of Radiologists, the British Nuclear Medicine Society, and the UK Radiopharmacy Group issued a joint letter to Johnson asking him to address specific questions about supply contingencies for these vital medical products.

The letter's authors estimated that ~1 million National Health Service (NHS) procedures, both diagnostic and therapeutic, use radioisotopes in the UK each year. The majority of these are made in nuclear reactors outside the UK, with much of the supply coming from nearby reactors in the European Union, including Belgium and The Netherlands. Although

the group indicated that they were encouraged by work being undertaken by officials and industry to map and test supply lines for radioisotopes, they added "we remain apprehensive about supplier readiness and the impact shipment changes and/or delays are likely to have on hospital planning and expenditure, and ultimately, on patients." Radioisotopes currently enter the UK via road and air freight, with most coming through the Channel Tunnel. In the event of a no-deal Brexit and increased road transport delays, suppliers have been asked by the UK government to ensure that they can fly in all of their consignments. Despite some trial runs of air freight transport of radioisotopes earlier this year, nuclear medicine professionals remain concerned about whether the UK trucking industry has enough specifically licensed drivers to cover changes or delays to shipment timings from airports to hospitals. The letter writers also noted that increased transport costs for flying radioisotopes in will be passed on to hospitals. They estimate that in the event of leaving the European Union with a deal, delivery costs will go up 15% but that this figure would rise to as much as 30% in the event of no deal.

Royal College of Radiologists

Updated NRC ^{68}Ge/^{68}Ga Generator Guidance

On July 25 the Nuclear Regulatory Commission (NRC) released updated licensing guidance on ^{68}Ge/^{68}Ga pharmaceutical-grade generators. In a letter to NRC licensees accompanying the new guidance, NRC leaders noted that at the time of the last update under Title 10 Code of Federal Regulations (CFR) 35.100 in 2017, the only ^{68}Ge/^{68}Ga generator approved by the U.S. Food and Drug Administration and available on the market was the Eckert and Ziegler GalliaPharm generator. Licensing guidance has been revised to reflect the fact that other ^{68}Ge/^{68}Ga generators are becoming commercially available. The new guidance eliminates reference to any specific generator manufacturer or product.

All sections of the guidance apply to both medical licensee and commercial nuclear pharmacy licensees unless otherwise specified. This guidance does not apply to licensees or applicants that will receive unit or bulk doses of ^{68}Ga radiopharmaceuticals. These licensees and applicants will be regulated under 10 CFR 35.200.

In an informational release, SNMMI reminded licensees that they must continue to provide financial assurance in amounts described in the NRC July 2016 exemption memorandum, pursuant to NRC Decommissioning Funding Plan requirements. Licensees with 1 or 2 ^{68}Ge/^{68}Ga generators (50–100 mCi of material) must provide for financial assurance for decommissioning in the amount of $225,000. Licensees with more than 2 generators (>100 mCi) must provide financial assurance for decommissioning in the amount of $1,125,000. The guidance also includes revised breakthrough reporting requirements ("multiple" failures) in addition to other licensee commitments. The guidance does not address the requirements for shipping an expired generator back to the manufacturer. To ship a generator by air, the licensee must have documented function-specific training and comply with International Air Transport Association guidelines as well as U.S. Department of Transportation regulations (10 CFR Part 71).

The full updated guidance is available on the NRC Medical Uses Licensee Toolkit at: http://www.nrc.gov/materials/miau/med-use-toolkit.html.

U.S. Nuclear Regulatory Commission
SNMMI

CMS Issues 2020 Payment Rules

The Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2020 Medicare Physician Fee Schedule (MPFS) and Hospital Outpatient Prospective Payment System (HOPPS) proposed rules on July 29. MPFS is used by CMS to reimburse physician services and includes resource costs associated with physician work, practice expense, and professional liability insurance. CMS uses the HOPPS to reimburse for hospital outpatient services. The HOPPS was created to minimize beneficiary copayments in response to rapidly growing Medicare expenditures for outpatient services and large copayments being made by Medicare beneficiaries. Outpatient services covered belong to an Ambulatory Payment Classification (APC) group. Each group of procedures (i.e., codes) within an APC is presumed to be "similar clinically and with regard to resource consumption."

In this rule, CMS described changes to payment provisions and to policies for implementation of the fourth year of the Quality Payment Program and its component participation methods: the Merit-Based Incentives Payment System and Advanced Alternative Payment Models. A press release issued by SNMMI on August 2 highlighted the following: (1) With the budget neutrality adjustment to account for changes in relative value units, as required by law, the proposed CY2020 MPFS conversion factor is $36.09, a slight increase from the CY2019 factor of $36.04. (2) CMS is proposing to decrease values for 41 radiology and nuclear medicine–related codes. SNMMI provided additional information about code-specific changes in the weeks after the 2020 payment rules were announced. (3) CMS did not address appropriate use criteria (AUC) or clinical decision support related to advanced diagnostic imaging services in the 2020 proposed rule. CMS published a separate AUC claims processing guidance transmittal on July 26, with additional information on the applicable Healthcare Common Procedure Coding System modifiers and G codes. The clinical decision support requirements for advanced imaging services are still scheduled to go into effect on January 1, 2020.

In the CY2020 proposed rules, CMS also included proposals that would advance its "commitment to increasing price transparency," such as requiring that hospitals make public their "standard charges" for all items and services provided. CMS proposes to continue paying for drugs and therapeutic radiopharmaceuticals at average sales price + 6%, as set forth in the CY 2010 Medicare Hospital Outpatient

Prospective Payment System and Ambulatory Surgical Center (ASC) Payment System final rule.

In addition, the agency proposes an increased threshold payment for therapeutic radiopharmaceuticals of $130, where CMS will package those that are priced ≤$130 into the APC payments and pay separately for those that exceed this threshold amount. CMS proposes no new changes to the APC structure for imaging codes.

In the Physician Outpatient Office Visit Proposed Rule, CMS adopted the Common Procedural Terminology guidelines to report office visits based on either medical decision making or physician time. The agency also adopted the Relative Value Scale Update Committee (RUC) work recommendations for office visit codes. The work value increases represent $3 billion in redistributed spending, resulting in a 3% reduction in the conversion factor. In addition, the RUC physician time recommendations were adopted. Coupled with the work value increases and some modifications in direct practice costs, these changes will lead to an additional $2 billion in redistributed spending, resulting in an additional 2% across-the-board reduction.

The comment period for the proposed rule expired on September 27.

SNMMI
Centers for Medicare & Medicaid Services

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MD; Simin Dadparvar, MD; and Justin Peacock, MD, PhD, Nuclear Medicine Residents Organization president, for their work in planning the ACNM program.

The SNMMI Mid-Winter and ACNM Annual Meeting will be held at the Marriott Tampa Waterside, newly redesigned in 2019. The hotel is located directly on Tampa Bay and just steps from the downtown area, including the Riverwalk, Florida Aquarium, and Sparkman Wharf.

We hope that you plan to join us for the outstanding learning offerings, worthwhile networking events, and warm weather. To register or learn more about the meeting, visit www.snmmi.org/mwm.