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May Ma, Office of Administration
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U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: (Docket ID NRC-2018-0230, 83 FR 54380); "*Training and Experience Requirements for Different Categories of Radiopharmaceuticals*;" comments of the American College of Radiology

The American College of Radiology (ACR)—a professional organization representing more than 38,000 public safety.

The controversial concept under NRC consideration of a tailored, radionuclide-specific, "limited-scope AU" pathway for uses under 10 CFR Part 35, Subpart E featuring less comprehensive T&E requirements for clinicians without NRC-recognized board certification is generally opposed by the pertinent stakeholder community and ha-3.037m..8(y)3.4(4 Tc 0.f(h)-0.r)8.ud.t014Ul(h)-2(e)-3(rally)]TJ08.109 Tw 3.717 0 Td(1TJ-0.0

provide these uncommonly used therapies would introduce unacceptably higher levels of risk and significantly decrease public trust in NRC's ability to adequately oversee these materials. More important to U.S. patients and their families, the limited-scope AU concept could foster an environment of financially-motivated utilization, conflicting with the broadly accepted standard of cancer care of a multidisciplinary team of subspecialized experts working collaboratively to provide the right treatment, at the right dose, at the right time.

Radiopharmaceutical therapy is a critically important tool in the clinical cancer care armamentarium when used appro (o304lie 0)5j-0.001 [illegible]

from the traditional nuclear medicine, radiation oncology, and diagnostic/nuclear radiology pipelines. Current AU eligibility prerequisites—implemented during the major Part 35 reform in 2002 and revised in 2005—have become permanently engrained elements of the related ACGME-approved training programs. NRC's regulations, in combination with existing ABR, ABNM, and AOBR certification and maintenance of certification requirements, are essential for ensuring health and safety of patients, personnel, and care-giver safety in the U.S.

Any significant regulatory paradigm changes would be costly and severely disruptive to existing training programs, as well as to the NRC and Agreement States. Changes to AU T&E are unlikely to result in a significant surge of new NRC and Agreement State licenses. It would be a more efficacious allocation of NRC's limited resources to continue with the current AU T&E requirements in 10 CFR 35.390, refocus on more impactful priorities of NRC's medical team and the licensee community, and avoid any controversial rulemaking activities designed to effectively reduce the comprehensiveness of AU T&E requirements for those without NRC-recognized board certification.

2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.

Yes, the current AU T&E requirements defined in 10 CFR 35.390 provide reasonable assurance of adequate protection of public safety, as evidenced by the low numbers of abnormal occurrences and other

quickly, which is important for new agents.[3] Time has proven that this approach had the intended effect of allowing 10 CFR 35.390 to persist reasonably well as the boards and programs have had

Regardless of specific radiation-related physical factors such as nature of the emission, energy level(s) of the emission(s), or half-life, there is an underlying public fear of radiation. All radiation has the potential for mishandling and untoward events that may require special knowledge, skills and tools for handling, and widespread availability of the agents raises potential local, regional and national security concerns. Pre-

previously concluded that utilization drivers of radiopharmaceutical therapy are multifactorial and involving mostly considerations outside of NRC's purview (such as referring clinicians' self-interests, financial/reimbursement considerations, availability of non-radiation-emitting and often equally effective treatment options, general fear of radiation exposure, etc.). The ACR and other likeminded stakeholders have previously recommended that NRC collect comprehensive AU data from all states over an extended period of time to explore AU trends—an ongoing, multi-year AU data collection mechanism would be helpful for informing a variety of issues under current and future NRC

need to invest in additional targeted enforcement/monitoring efforts, Information Notices, guidance revisions, and workshops/meetings to educate and closely monitor non-expert AUs. Inspections would need to be more focused on those licensees that rely on limited scope AUs to perform 35.300 uses. Agreement State agencies would be bogged down in the same regulatory revision activities and implementation issues as NRC. Per statutory mandate, the increase in NRC's efforts and resources would require a commensurate increase in annual fees, which would have an adverse effect on the licensee community and, ultimately, patient access.

4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?

For reasons previously mentioned, the ACR opposes the idea of a new limited-scope AU status for nominally-trained clinicians who do not meet the 700 hour alternate pathway or the NRC-recognized board certification standard, and we strongly recommend that NRC not initiate a rulemaking to implement such a concept. Additionally, any reduction in T&E would undermine the NRC's existing alternate pathway.

Regardless of energy level or specific emission(s), nuclear materials are inherently different from antineoplastic agents used in chemotherapy and other hazardous materials used elsewhere in medicine for a variety of reasons (e.g., radiation dose/physics, allied health professionals involved, general public fear of radiation, security interests, etc.). The notion that alpha and/or beta emitting agents have minimal risk and require limited training and experience is evidence of a certain naiveté regarding the properties of the agents and suggests a lesser degree of care necessary in management. Issues such as spills, residual activity in tubing and syringes, unused material and care in handling, etc., require knowledge and skills acquired through years of training and experience and a culture of safety among primary providers and staff. Patients and the U.S. population at large have an inherent fear of radiation and expect that individuals authorized to use unsealed materials requiring a written directive have extensive background and expertise in radiation safety and nuclear materials.

5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?
a. Describe what the requirements should include:
i. Classroom and laboratory training—What topics need to be covered in this training requirement? How many hours of classroom and laboratory training should be required? Provide the basis for the number of hours. If not hours, explain how this training should be quantified. [Note: The topics

NRC's current AU T&E paradigm in 10 CFR 35.390 allows the ACGME, boards, and programs to evolve appropriately to address new agents and evolving subtopics of additional interest.[9]

ii. Work experience—What should the work experience requirement involve? How many hours of work experience should be required and what is the minimum number of patient or human research subject administrations that an individual must perform? Provide the basis for the number of hours and administrations. What should be the qualifications of the supervising individual?

The NRC's current minimum regulatory requirements provide reasonable assurance of adequate protection of public health and safety. Relevant ACGME-approved residency programs in nuclear me6(t)-3iU m re. radiation onU mlogy, and nuclear radiology invlve additional tra4(re)-ing and experienre3(h)13.1na wev

having the appropriate board certification in a relevant specialty, there must be a formal method for AU preceptors to document trainees' completion of NRC's regulatory prerequisites.

By contrast, specialists who obtain AU eligibility through the NRC-recognized board certification pathway have inherently demonstrated completion of NRC AU eligibility requirements. For these specialists, AU preceptor attestations would be redundant with their board certifications as well as with other sections of NRC/Agreement State forms documenting completion of T&E prerequisites, and thus the Part 35 updates in the 2018 final rule were warranted.

c. Should the radiopharmaceutical manufacturer be able to provide the preceptor attestation? Provide a rational for your answer.

The NRC should not allow radiopharmaceutical manufacturer attestation for uses under 10 CFR 35.300.
Physician

nuclear endocrinology are only recognized for 35.190 and 35.392 uses, respectively. **No other specialty boards intensively train in, or assess the necessary knowledge and skills, to provide AU-eligibility to their diplomates, as indicated by the previously referenced study guides/assessment-preparation materials.**

With utilization of radioactive substances, competency is determined by years of training and ongoing clinical experience, including management of adverse circumstances such as spills, extravasations, and disposal of unused material. This competency is developed only by 4-year residency-based training program followed by initial certification, and then career-long maintenance of certification oversight or continuing education activities.illsct e(n)2.3(,)9.9()10.6( )-11.uv nu,tn(e)-3(r(e)1-3(r)]TJ0.3(s)-1.(s)-1.n)2.2((s)-1.(-1((a)0.9

The current AU T&E prerequisites appropriately emphasize the dominion of NRC-recognized specialty boards and provide training programs with adequate flexibility under the auspices of the 700-hour regulatory minimum. Thus, the regulations should not be revised at this time.

We are aware that non-physician professionals, including nuclear pharmacists and nuclear medicine advanced associates, have leveraged NRC's current interest in less comprehensive physician T&E requirements to advocate for even more radical scenarios in which non-physician health professionals assuming AU responsibilities would circumvent the use of subspecialized physician AUs. Due to the complicated nature of cancer care beyond the expertise of nuclear pharmacists and extender professionals, these controversial ideas are fundamentally problematic from a clinical perspective, and rife with glaring legal issues beyond NRC's jurisdiction.

Authorized nuclear pharmacists (ANPs) should not directly provide or oversee patient care in substitution of appropriately subspecialized physician AUs. Such a scenario would be out of nuclear pharmacy's scope of practice, and ANPs would be unable to address patient-related problems. According to the Board of Pharmacy Specialties (BPS), there are only approximately 400 BPS board certified nuclear pharmacists,[13] the majority of whom work in commercial settings or in large medical centers and serve primarily as suppliers to healthcare facilities—not to patients. The typical nuclear pharmacist workflow, as described by the American Pharmacist Association (APhA), is characterized by atypical, early morning hours preparing and dispensing radiopharmaceuticals,[14] and thus is not conducive to supervision of non-expert physicians providing radiopharmaceutical therapy in disparate facilities. The overwhelming majority of commercial nuclear pharmacies are located in metropolitan areas and other population centers,[15, 16] and thus controversially expanding ANPs' scope of practice to include patient care services of any kind would not increase access in remote geographical areas beyond the coverage already provided by current licensees.

By definition, a Nuclear Medicine Advanced Associate (NMAA) is an advanced-level nuclear medicine technologist working *under the supervision* of a licensed physician, who is an authorized user of radioactive materials.[17] Being AUs on NRC or Agreement State licenses would be outside the recognized roles and responsibilities for these extenders and could be legally and professionally problematic. More importantly for the issues under NRC's purview, NMAA AU-eligibility would also be redundant with the inherent AU-eligibility of their supervising nuclear medicine/nuclear radiology physicians. The Nuclear

2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

We are currently unaware of AU T&E-specific requirements that are outside of NRC's regulatory authority.

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects?

No regulatory changes are necessary as the current regimen is not burdensome to the NRC, Agreement States, or medical community. The NRC's medical stakeholder community has not requested a tailored, limited-scope AU pathway for 10 CFR 35.390 uses or identified the AU T&E prerequisites as problematic. Less comprehensive AU prerequisites for those without NRC-recognized board certification would be misaligned with NRC's mission and radiopharmaceutical therapy practice standards, and would be fundamentally unhelpful for patien 6.12h7768-3(r.4(e)-3(e)7.9kv)-2.5i[u)2Tw 10.891 0 Td( )Tj-0.l9(at)-3(4l)-0.8(u).2(io)-2e