February 28, 2020

Attn: The Honorable Kristine L. Svinicki
U.S. Nuclear Regulatory Commission
Mail Stop O-16 B33
Washington, DC 20555-0001

Subject: SECY-20-0005, Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35); Perspectives from the American College of Radiology

Dear NRC Chairman Kristine Svinicki:

The American College of Radiology (ACR)—a professional association representing nearly 40,000 diagnostic/interventional radiologists, nuclear medicine physicians, radiation oncologists, and medical physicists—appreciates the opportunity to provide feedback on SECY-20-0005, *Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35)*.

SECY-20-0005 recommends a rulemaking to remove "alternate pathway" Authorized User (AU) training and experience (T&E) requirements in 10 CFR Part 35, Subpart D ("unsealed byproduct material-written directive not required") and Subpart E ("unsealed byproduct material-written directive required"), and to replace these with new board recognition criteria for specialty certifications that would imbue their holders with AU-eligibility. While the recommendation—if well-implemented—may be the least problematic of the pro-rulemaking options described in the Rulemaking Plan and Enclosure 5, the ambiguity of the board recognition criteria, as well as many other concerns discussed in this letter, renders the NRC staff recommendation impossible for ACR to support at this time.

Therefore, the ACR continues to recommend that NRC maintain the current AU T&E in 10 CFR Part 35 that have protected the health and safety of patients, the public, and healthcare personnel for nearly two decades and through numerous care innovations. We urge the Commissioners to align with the prior recommendations of the NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) and the general consensus of NRC's diverse physician and physicist stakeholder communities.

A multispecialty and multidisciplinary ACR task force of experts representing diagnostic radiology, nuclear medicine, radiation oncology, medical physics, healthcare facility accreditation, practice standard development, specialty board certification, and regulatory affairs reviewed the NRC staff recommendation and enclosure documents within SECY-20-0005. We would like to share the following concerns for the Commissioners' consideration:

1. Unsupported assumption of patient access issue caused by AU T&E

SECY-20-0005 describes a theoretical, undemonstrated patient access concern related to certain therapeutic radiopharmaceuticals under 10 CFR Part 35, Subpart E, and recommends a rulemaking to

correct it. The SECY paper does not provide an evidence-based rationale for NRC's speculation—merely that two drug manufacturers and those mobilized in a lobbying campaign have voiced concerns about an AU shortage. In contradiction to this speculation, the ACMUI evaluated the number of trainees in the existing board certification and alternate pathway pipelines to AU eligibility for §35.390 and reported stability and growth in the future AU population. More germane to the manufacturers' complaints of access problems, causality has not been established between §35.390 requirements and the perceived access issue the rulemaking would attempt to solve. SECY-20-0005 appears to assume without evidence that more AU-eligible physicians would equate to increased numbers of rurally located licensees able to provide Subpart E therapies.

SECY-20-0005 also included Subpart D in the rulemaking recommendation alongside Subpart E, despite the NRC not benefitting from public discourse on this idea. Diagnostic nuclear medicine and molecular imaging studies are the most common of all medical uses under NRC oversight, and licensed facilities able to provide imaging services are ubiquitous. The tenuous industry claims of patient access problems to Subpart E therapies are demonstrably inapplicable to Subpart D uses.

2. Changing AU T&E would not address perceived patient access issue

As with most specialized cancer care modalities, patients that could benefit from Subpart E modalities are referred to institutions equipped with appropriate resources, facilities, and experienced/trained personnel to provide the procedures in question. The advanced radiopharmaceutical therapies of particular interest to NRC staff during this evaluation (i.e., those that require AUs to meet the T&E requirements under §35.390) are typically provided in academic medical centers, large community-based healthcare facilities, and other major cancer care institutions that have numerous affiliated AU-eligible physicians. These agents are uncommonly ordered, expensive to acquire, resource-intensive to provide, suffer from prohibitive payer coverage/reimbursement uncertainties, and often involve complex patient cases with significant preparation and care team coordination. These are not treatments that would routinely be provided in physician offices and small/rural hospitals.

There is no clear cause-and-effect relationship between the size of the AU-eligible physician population and the number/geographic distribution of licensed facilities willing and able to provide the advanced radiopharmaceutical therapies of interest. A rulemaking that revises AU T&E, but is ultimately intended to increase the number of licensed institutions where patients can access these therapies, would be akin to revising requirements for senior reactor operators under 10 CFR Part 55 in order to establish new nuclear power plants.

3. Tenuous, late suggestion of a conflict with 20-year-old NRC Medical Use Policy Statement

SECY-20-0005 suggests that AU T&E criteria in §35.390 may conflict with the August 2000 NRC Medical Use Policy Statement. The 10 CFR Part 35 reforms of the early-to-mid 2000s were promulgated under the auspices of the policy statement in question, so the recent suggestion of a conflict between regulatory approaches and policies that have been operating in symbiosis for nearly 20 years is puzzling. It is inaccurate to insinuate that AU T&E requirements intrude into medical judgements, as the independent practice of medicine occurs only after completion of training. Other requirements unaddressed by the evaluation, such as NRC regulations and guidance related to written directives, medical event reporting, and patient release instructions are more pertinent NRC influences on medical decision-making.

The AU T&E requirements are meant to ensure that physicians supervising medical uses of byproduct material have the base radiation safety and nuclear materials knowledge and skills needed to adequately provide safe treatments. SECY-20-0005 describes the unfortunately real scenario that some referring clinicians may not wish to refer their patients to other physicians for subspecialized care; however, this should not be inferred as evidence of a conflict with the Medical Use Policy Statement. To be clear, any clinician's decision to arbitrarily limit their patient's treatment options to only those treatments that can be provided and billed by that clinician is ethically dubious and not a "medical judgement" issue. This type of financially-driven decision-making is deeply frowned upon in medicine, and there are extensive federal healthcare laws and regulations meant to deter inappropriate self-referral.

4. Multiple Part 35 paradigms: Subpart D included, while Subparts F, G, and H excluded

SECY-20-0005 unexpectedly expanded the staff evaluation beyond Subpart E to include Subpart D (diagnostic uses), but did not include the other therapeutic modalities in Subparts F or H. While unsealed therapeutic radiopharmaceuticals clearly share certain physical characteristics with unsealed byproduct material used in imaging and localization studies, the types of institutions that can provide the more advanced radiopharmaceutical therapies often provide Subpart F and/or Subpart H modalities as well. Thus, revising the AU authorization, documentation, and site inspection paradigms for Subpart E therapies, but not also for Subparts F and H therapies, would create discordant compliance methodologies for these institutions, thereby introducing confusion and undue administrative burden for licensees that provide multiple therapeutic modalities.

It is important to note that the current Subparts F and H are specialty-constrained to radiation oncology, and that only two board certifications—both for radiation oncologists—are appropriately recognized by NRC for those modalities. It would be a more straightforward process for NRC to eliminate alternate pathways and come to a community consensus on minimum "board recognition criteria" for §35.490 and §35.690 than it would be for §35.390 and §35.290, given that more than one subspecialty works with diagnostic and/or therapeutic unsealed materials.

Additionally, the assumption in SECY-20-0005 of a patient access concern related to certain Subpart E therapies—as tenuous as that assumption may be—is demonstrably irrelevant to Subpart D, which contains the most common of all uses under 10 CFR Part 35. By contrast, modalities under Subparts F and H are offered by many of the same institutions that provide Subpart E modalities, and certain radiation therapy technologies are significantly rarer (in terms of the geographical locations of licensees) than Subpart E radiopharmaceutical therapies. Thus, the different modalities across the three therapeutic subparts of 10 CFR Part 35 (i.e., Subparts E, F, and H) share similar patient accessibility characteristics.

5. State-to-state uniformity and reciprocity concerns

SECY-20-0005 refers to the concept of "Agreement State-recognized" boards, which is extremely concerning given the mercurial nature of state politics. We foresee problems with states being compelled to recognize inadequate specialty boards for Subpart D or Subpart E uses merely because a manufacturer or group has a strong in-state lobby. There could also be issues with Agreement States neglecting to recognize the same specialty boards as NRC for Subpart E uses, which would create uniformity and continuity problems for all involved. Inconsistency would also undermine the reciprocity process.

The contradictory feedback provided to NRC staff by the Organization of Agreement States (OAS) Executive Board—with the most recent ideas summarized in the "Discussion" subsection of the Rulemaking Plan—suggests a fundamental misunderstanding of the responsibilities of AU-physicians in the planning and supervision of advanced radiopharmaceutical therapies, as well as those of AU-supervised allied health professionals. The notion discussed on pages 4 and 5 that NRC could specify T&E for supervised personnel (e.g., nuclear medicine technologists) instead of AU-physicians is misaligned with reporting structures, care coordination/authority within clinical environments, and accountability/medico-liability considerations. Moreover, there is significant state-to-state variability related to licensure and scope regulations for allied health professionals—indeed, some states unfortunately have no such requirements for technologist personnel. NRC's current approach of authorizing the AU-physicians ultimately responsible for supervising patient care is the most appropriate and practical means of ensuring radiation safety during medical uses.

The ACR agrees that the rulemaking described in SECY-20-0005 would require a minimum of Compatibility Category B; however, this categorization should also apply to the list of NRC-recognized boards. Agreement States should not have any ability to independently recognize physician specialties authorized for medical uses of byproduct material.

6. Employability issues in the gap between physician training and board certification

The recommended rulemaking in SECY-20-0005 would eliminate alternate pathways in favor of more inclusive board recognition criteria. Physicians without NRC-recognized board certification, who previously would have obtained AU-eligibility via the alternate pathway, would instead need to practice under AU supervision. While this concept is not necessarily problematic for the therapeutic modalities—especially if NRC works with the boards on their own alternate pathways for internationally-boarded specialists—this may be a potential issue for Subpart D uses, and specifically §35.290 AU T&E for imaging and localization studies.

Young diagnostic radiologists have a mandatory 15-month gap between completion of residency and the American Board of Radiology's Certifying Exam. The gap before final certification is meant to facilitate a subspecialty fellowship or permanent employment. In the current AU T&E paradigm, these young physicians would be AU-eligible for imaging and localization studies through compliance with the alternate pathway in §35.290. If the alternate pathway in §35.290 is eliminated by NRC, single-boarded diagnostic radiologists would oddly need to wait longer than physicians from other specialties after completion of training to obtain AU-eligibility for imaging studies.

7. Ambiguity surrounding board recognition criteria

The effectiveness of the rulemaking described in SECY-20-0005 to adequately protect public health and safety would rely on the strength of the "board recognition criteria" and the implementation of the board recognition process. Currently, NRC-recognized specialty boards must essentially demonstrate that their exam candidates meet the T&E prerequisites prescribed for the alternate pathways. Thus, alternate pathway T&E hours and curricula are currently serving as de facto "board recognition criteria."

If NRC were to move forward—against the opposition of the medical use stakeholder community—with an AU authorization process relying solely on new board recognition criteria, it would be imperative for radiation safety that those criteria are as comprehensive and stringent as the current alternate pathway

T&E requirements. SECY-20-0005 does not describe the envisioned criteria in detail, only that the goal is to be more inclusive of specialty boards that do not intrinsically have nuclear medicine or radiation oncology sub-specialization. We imagine it difficult for the Commission to decide in favor of the NRC staff recommendation without a much clearer understanding in advance of how the criteria might differ (if at all) from the current alternate pathway T&E requirements.

The ACR appreciates the consideration of the Commissioners and NRC staff. As NRC's largest and most comprehensive professional association actively representing the majority of subspecialties under NRC oversight, the ACR stands ready to serve as a resource to the agency. Please contact Gloria Romanelli, JD, Senior Director of Government Relations, and Michael Peters, ACR Director of Legislative and Regulatory Affairs, at (202) 223-1670 / mpeters@acr.org with questions.

Sincerely,

Geraldine B. McGinty, MD, MBA, FACR
Chair, Board of Chancellors
American College of Radiology