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Chair, ACR Workgroup on NRC Training and Experience Regulations
Verbal Testimony to the Nuclear Regulatory Commission (NRC),
Committee on the Medical Uses of Isotopes (MUIO)
RE: 10 CFR 35.390 *Training for Use of Unsealed Byproduct Material for Which Written Directive is Required*

Hello, my name is Dr. Paul Wallner. I am a radiation oncologist who is separately board certified in radiation oncology and diagnostic radiology and nuclear medicine. I previously served as chief of the Clinical Radiation Oncology Branch of the NCI, where my research interest was in targeted radiopharmaceuticals. I am speaking today on behalf of the American College of Radiology (ACR). The ACR represents over 35,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists.

The ACR understands the tight deadline and external pressure prompting the staff's draft paper. However, we strongly urge more extensive, public engagement of the medical stakeholder community before NRC takes any significant action on the issues covered by the draft paper.

Forward movement on this topic seems to be predicated on the presumption that the 700-hour training and experience requirement in 35.390 is no longer appropriate, particularly for individuals without NRC-recognized board certification. But, the underlying concerns have yet to be substantiated in a quantitative, impartial, and apolitical fashion. Before there is any serious movement toward modifying T&E content or hours, there should be a fact-driven assessment of the external criticisms regarding 35.390. After all, 35.390 has a track record of success in providing NRC with reasonable assurance of the adequate protection of public health and safety.

To help substantiate or disprove AU population concerns, it is most important for NRC to gather trustworthy data on the active AU population providing various therapies under 35.390. The collected data should enable exploration of AU numbers and coverage over a multi-year period of time. This suggestion has been made previously, and we understand such an activity would be labor intensive and require collaboration with Agreement States and broad-scope licensees. However, without confirmation by NRC of a problem, there is a questionable technical basis for any rulemaking to modify 35.390, or the other subparts of Part 35.

Moreover, any presumption of a future AU shortage informed solely by ABNM trends neglects the radiation oncology and new nuclear radiology pathways, which we understand to be stable or, in the case of nuclear radiology, expanding in size and distribution.

While prescriptive, the 700-hour training and experience prerequisite in 35.390 was fundamentally intended to ensure prospective AUs without certification from an NRC-recognized Board have an adequate base of knowledge in radiation safety to supervise the proper use of these therapeutic medical nuclear materials—including medical event prevention, identification, and mitigation. If NRC determines, based on data, that a rulemaking to overhaul 35.390 T&E requirements are ultimately necessary, any future regulatory modifications must reasonably ensure that clinicians who do not possess the expertise obtained via their residency programs and fellowships can appropriately fulfill AU responsibilities and protect their patients, staff, and other members of the public.

In conclusion, the ACR supports more extensive engagement of medical stakeholders on the issues discussed in the draft paper. We look forward to seeing the final product at the end of summer and hope it reflects both the need for more public engagement as well as the need for an NRC assessment of AU numbers to justify any further action. The ACR also hopes to provide input to the ACMUI on its own efforts related to these issues. Thank you for your time.