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March 7, 2016

Chairman Stephen G. Burns
U.S. Nuclear Regulatory Commission
Mail Stop 0-16G4
Washington, DC 20555-0001

Dear Chairman Burns:

On behalf of the American College of Radiology (ACR)—a professional organization representing more than 35,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—we are writing to recommend that the U.S. Nuclear Regulatory Commission (NRC) advance its final rule to update the agency's medical use regulations without reducing the training and experience (T&E) requirements for authorized users (AUs) of alpha- and beta-emitters. We understand that the Commission is being urged by certain radiopharmaceutical manufacturers and affiliated groups to delay the rulemaking in an effort to increase utilization of products such as Xofigo® and Zevalin ®. We appreciate the need for NRC to comprehensively examine any issues and concerns brought forth by the stakeholder community. However, we believe there is a lack of sufficient evidence at this time to support the underlying arguments. We understand that a subcommittee of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), NRC's expert committee on medical issues, questioned whether a reduction in the T&E requirements would lead to an increase in appropriate utilization. Moreover, the patient safety and public health considerations of the proposed 80 hours of training for alpha- and beta-emitter use under the alternate pathway have yet to be fully considered.

For years, the ACMUI and NRC staff publicly vetted and discussed the medical community's concerns that would be addressed in some manner by this current Part 35 rulemaking. Conversely, the relatively new request by product manufacturers has not benefitted from in-depth analyses by advisors, staff, and the medical community. Key issues still need to be studied before a basis for rulemaking can be established:

- Evidence supporting alleged shortage of 35.390 AUs and any regulatory causes.
- Possible clinical underutilization of alpha- and beta-emitters and any potential cause(s) of such underutilization.
- The advisability from a radiation safety perspective of lessening training requirements for those seeking AU status via the alternate pathway.

An ACMUI subcommittee determined in October 2015 that the perceived underutilization of Zevalin® was likely caused by multiple factors, including cost/reimbursement shortfalls, rise of alternative therapies, and a general lack of familiarity of radiopharmaceuticals within the referring physician (hematology/oncology) community. They found insufficient evidence that there was a shortage of AUs,

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or that the alleged shortage caused underutilization of Zevalin®. The subcommittee pointed to large medical centers where an abundance of referring physicians and AUs work in close proximity with ready access to these agents, and yet patients are still infrequently referred for these treatments. The ACMUI subcommittee also indicated that Xofigo® has been on the market for too short of a time to discern or analyze any utilization trends.

The more pertinent concern in terms of NRC's regulatory authority is public safety. Before the requested modifications to 35.390 are considered for inclusion in a future rulemaking, ACR recommends that NRC perform a comprehensive safety assessment of providing AU status to clinicians who do not have extensive radiation safety and radioactive materials training. As the responsibility of an AU is to oversee the radioactive materials safety components of the medical procedure, the various alternate pathway T&E requirements in 35.390 go far beyond learning the basic mechanics of administration—a physician needs to know about radiation protection, radiation physics and instrumentation, radiation biology, etc; and have work experience in ordering/handling radioactive materials, dose calculation, safe containment of spilled byproduct material using proper decontamination procedures, etc. The alternate pathway is prescriptive and comprehensive to ensure that physicians without the appropriate board certifications are able to demonstrate an ability to be responsible for the radiation safety aspects of the procedures in question.

Therefore, the ACR supports ACMUI's recommendation that NRC—or, perhaps, other federal agencies like the Centers for Medicare and Medicaid Services—investigate regulatory reasons for purported underutilization of the therapies in question. However, we strongly oppose delaying the current Part 35 rulemaking or revising 35.390 at this time, especially without a better understanding and anticipation of the possible public and patient safety outcomes. As mentioned, it is unclear that the requested decrease in training requirements would increase appropriate and safe utilization of these materials.

The NRC's Petition for Rulemaking (PRM) process exists for stakeholders to request new regulatory revisions. Submitting a PRM for further exploration would be the more appropriate pathway for the requested modification in this case, as the change urged by industry is relatively new territory. Meanwhile, the other fixes and updates that would be made by the current rulemaking—nearly a decade in the making—have already been fully vetted and should move forward without further delay.

Thank you in advance for your consideration of these recommendations. Please contact Gloria Romanelli or Michael Peters in ACR's Government Relations Office at (202) 223-1670 with any questions or to request more information.

Sincerely,

Bibb Allen, MD, FACR
Chair, Board of Chancellors
American College of Radiology