From: Laura Weil
To: RulemakingComments Resource
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The NRC's stated mission is to regulate the use of radiopharmaceuticals in order to promote their safe use. As the Patients' Rights Advocate on the ACMU from 2011-2019, I was a member of the subcommittee asked to review the 1980 exemption that excluded extravasation from required medical event reporting. I disagreed with the majority findings of the ACMUI subcommittee, submitting a dissenting statement in subcommittee report arguing that the 1980 exemption was no longer appropriate. The 1980 exemption stated that extravasation, even if it resulted in unintended tissue exposure, or compromised the delivery of the radiopharmaceutical to the intended organ, was "impossible to avoid" and therefore should not be held to the same standard as other misadministrations. Even if this were true in 1980, improvements in technology have certainly made it a less relevant consideration today.

If the "impossible to avoid" assertion were real, one would expect the incidence of extravasation across American treating facilities to present a predictable and uniform rate. This is not the case. Some institutions committing to improvement of extravasation rates have been successful in accomplishing significant reductions. Extravasation is clearly something that can be minimized with appropriate care, training, and oversight. The argument that such institutional initiatives belong in the realm of quality improvement - and therefore do not represent a regulatory opportunity - is not compelling. There is no bright line dividing quality improvement from areas of regulatory oversight. Examples abound of NRC rules and guidance governing safety requirements and procedures for the use of byproduct material. These regulations provide effective incentives for institutions to implement appropriate procedures that minimize harms. The ongoing exemption of extravasations on the basis of "impossible to avoid" does not contribute to the of goal of safety in the use of radiopharmaceuticals.

Respectfully,

Laura Weil