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General Comment

On September 15th, the U.S. Nuclear Regulatory Commission (NRC) requested comments from the public on whether additional rulemaking is needed to require reporting of certain nuclear medicine injection extravasations as medical events. After reviewing relevant literature and regulatory guidelines from the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and NRC, I am submitting my personal comments.

I am a Board Certified Nuclear Pharmacist (BCNP) and Authorized Nuclear Pharmacist (ANP) with over 35 years of experience in the clinical development and routine use of radiopharmaceuticals for diagnosis and therapy. In my vast experience in two major academic hospital settings, radiopharmaceutical extravasations have been extremely rare. Additionally, all of the extravasations I have investigated with our safety teams over these 35 years were self-limiting and without significant harm to the patients. In my experience, radiopharmaceutical injections are an issue of quality control NOT patient safety. Based upon my experience, requiring the reporting of even "certain" radiopharmaceutical extravasation is not justified. These are and must be handled at the institutional level as quality control issues as they always have been.

Another concern is the economic impact of requiring the purchase and use of expensive monitoring devices and associated patient specific disposable supplies. It seems obvious to me that the company promoting this potentially new regulatory requirement is biased by the potential opportunity to benefit financially. It has been estimated that there are over 40 million radiopharmaceutical injections in the US annually. Assuming a cost of $5 per patient for the

monitoring disposable supplies, the cost to providing nuclear medicine services could be up to $200 million annually. Historically and currently, an existing standard gamma camera is utilized to investigate the significance of a potential extravasation for no cost. Simply stated, there is no justification for utilizing new regulations to promote or require the use of a costly function specific extravasation monitoring device when existing devices such as a gamma camera be easily utilized.

Additionally, the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the American College of Nuclear Medicine (ACNM), and the American Society of Nuclear Cardiology (ASNC), have provided comment on this issue. I am in complete agreement with these organizational perspectives which have been summarized as follows.

In summary, we believe that extravasations are best managed on an institutional level at the discretion of the authorized user and do not require additional NRC regulation. Furthermore, the SNNMI recognizes the effect that extravasation of diagnostic radiopharmaceuticals may have on the quality of diagnostic images, particularly on quantitative studies, and is actively addressing this as the quality-control issue that it is, rather than a patient-safety issue. Accordingly, the SNMMI Technologist Section (TS) has adopted reduction of extravasations as an essential initiative of the TS Quality Committee.

Sincerely submitted,

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