

# PUBLIC SUBMISSION

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**Docket:** NRC-2020-0141

Reporting Nuclear Medicine Injection Extravasations as Medical Events

**Comment On:** NRC-2020-0141-0004

Reporting Nuclear Medicine Injection Extravasations as Medical Events; Notification of Docketing and Request for Comment

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Comment on FR Doc # 2020-19903

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## Submitter Information

**Name:** James Gannon

**Organization:** Society of Nuclear Medicine & Molecular Imaging

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## General Comment

As a nuclear medicine physician, practicing at the VA Medical Center in Fayetteville, NC I can tell you from 14 years of my experience, there has never been a detrimental side effect from extravasation of nuclear medicine radio tracers. Why should there be a complication, the fluid is mostly normal sailing with a trace amount of radiotracer.

Lucerne Dynamics has an unnecessary idea in search of a market place and is trying to manipulate the regulatory system to create that market. Just because you can measure some thing, does not mean it needs to be measured, legislated and marketed and sold. Once Lucerne Dynamics has corrupted the legitimacy of the NRC to create a politically mandated demand, they will make a stock offering and become wonderfully rich. In short, Lucerne is petitioning you because it has a product it wants you to force on patients and providers. Meanwhile, more onerous regulations and ridiculously expensive cost will be added to the healthcare system. Their product is not going to provide any patient safety, Lucerne dynamics is just trying to use patient safety hysteria to manipulate the narrative and destroy actual science. I recommend you do not allow this terrible corruption of NRC by the Lucerne dynamics to occur.

In summary, there is no clinical data that supports Lucerno Dynamics' claim that extravasation of diagnostic radiopharmaceuticals is a patient safety issue. In the absence of such data, I believe that extravasations are best managed on an institutional level at the discretion of the authorized user and do not require additional NRC regulation.

Sincerely,  
James Gannon  
VAMC Fayetteville, NC.