PUBLIC SUBMISSION

As of: 1/14/21 3:15 PM
Received: November 30, 2020
Status: Pending_Post
Tracking No. 1k4-9ke4-qftq
Comments Due: November 30, 2020
Submission Type: Web

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

Document: NRC-2020-0141-DRAFT-0483
Comment on FR Doc # 2020-19903

Submitter Information

Name: Tracy King
Address:
214 E Huron Street
Ann Arbor, MI, 48104
Email: tking@mpcphysics.com

General Comment

Three words accurately describe this petition: Unwarranted, Burdensome, Ineffective,

I am a Radiation Safety Officer, a consulting medical physicist at Medical Physics Consultants, Inc, an Authorized Medical Physicist, and a formerly certified Nuclear Medicine Technologist with 34 years of experience in the field of Nuclear Medicine and Radiation Oncology.

I say this petition is unwarranted because I have consulted over a hundred Nuclear Medicine Departments of all sizes and worked with hundreds of Nuclear Medicine Technologists(NMTs) over the past 34 years. The petition implies a cavalier approach by NMTs to IV injections which I believe is rare. In fact, NMTs focus a great deal of effort to achieve optimal injections. NMTs are often the "experts" when it comes to starting IVs in the outpatient departments. I often see NMTs called upon by other departments to assist with difficult IV starts. It is inaccurate to imply that extravasations are preventable if NMTs were just better trained.

None of my client Nuclear Medicine Departments have experienced a patient injury from a poor quality radiopharmaceutical injection. This leads me to conclude that this petition does not have a clinical basis.

This petition is burdensome because there is no accurate method (even including the product which the petitioner advocates) of determining how much of the injection volume is extravasated. Given the physical nature of an intravenous injection, there will always be some volume that escapes from the vein/artery. No threshold has been established that defines when an "extravasation" has occurred. Is it 1% of the injected volume, 10%, 50%? Use of an absorbed dose threshold to determine if an extravasation qualifies as a medical event will require advanced radiopharmaceutical dosimetry. The dosimetry models

that a licensee will need are not readily available. Therefore, a cautious licensee will over-report to avoid being cited for not reporting. In 1992, new reporting regulations were established for radiopharmaceutical administration errors. The dosimetry models for use in determining when a medical event had occurred were available from multiple sources(ICRP, FDA package inserts, etc). The definition and, therefore, reporting requirements were clearly established and easily determined. This is definitely not the case in this situation.

This petition will be ineffective because the rulemaking requested will not improve patient care by implementing more reporting requirements. There are many causes of extravasations and most are patient factors such as rapid blood pressure or temperature changes causing venous spasms, patient movement, poor vasculature health, etc. Technologist skill level is low in frequency as a contributing factor.

The petitioner advocates use of a device for quantifying extravasations. The time requirements(data is acquired for over 30 minutes according to the petitioner's studies) are unreasonable for most clinical settings especially the smaller community based hospitals. Additionally, the expense of using this equipment(purchase and ongoing user fees) is significant especially for these community hospitals who are already struggling to provide a much needed service to their patients.

It is my concern that patients will suffer if this petition is approved. Nuclear Medicine Technologists may not attempt the "difficult" injections for fear of a resulting "medical event". In smaller nuclear medicine departments with limited resources, the patient would then be sent elsewhere for their Nuclear Medicine exam. This could harm the patient due to a delay in diagnosis/treatment.

Hospitals which are struggling financially may discontinue providing Nuclear Medicine imaging if the petition is approved and they are forced to purchase the equipment advocated by the petitioner in order to prove they have not had extravasation "medical events". Many of these smaller struggling hospitals are in rural settings with the nearest alternative many miles away. The change proposed by the petition is not a method of improving patient overall care.

It is surprising that this petition has been taken seriously despite the repeated evaluations and resulting decisions on this very issue by clinical experts in Nuclear Medicine. The continued and consistent opinions of the Nuclear Medicine clinical experts are evidence of the validity of the existing policy not the opposite which the petitioner and affiliates have implied.