PRM-35-22
85 FR 57148

PUBLIC SUBMISSION

As of: 11/23/20 10:19 AM
Received: November 16, 2020
Status: Pending_Post
Tracking No. 1k4-9k4g-aweg
Comments Due: November 30, 2020
Submission Type: API

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-0364
Comment on FR Doc # 2020-19903

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General Comment

SEE ATTACHED

Attachments

Lucerno Dynamics

My name is Don Kiepert and I would like to comment on Docket ID NRC-2020-0141.

First allow me to tell you a little about my background. I have a BS and MS in clinical pharmacy from Purdue University. Initially I served as Director of Pharmacy at a 400-bed hospital. After five years in that role, I began my career in industry joining Baxter Travenol as head of their home infusion business. I then began an entrepreneurial career and started twelve successful health care companies, including a public biotechnology company that was developing the first orally active immunotherapy agent. In 2008, I became CEO of Lantheus Medical Imaging, one of the leading global radio pharmaceutical companies in the industry. I served in that role for six years and learned a great deal about the nuclear medicine industry and the use of various isotopes to diagnose and treat disease. After Lantheus Medical Imaging, I began advising and serving on boards of private equity portfolio companies. Today I serve on three boards and advise five other radio pharmaceutical companies. I am on the board of Curium Pharma, a company headquartered in Paris that is a leading global radio pharmaceutical company with 30 PET radio pharmacies in Europe and a large US presence in St. Louis, MO. Throughout my career I have been fortunate to be involved in patient-centric companies that provided unique products and services that improved patient care. I have always been committed to the thinking of "patient first". Because of this strong commitment, I joined the board of Lucerno Dynamics.

Because of my role at Lucerno, I deliberated over whether I should send my comments to you, but for a variety of reasons I felt compelled to write. First, I have learned a lot about infiltrations in the past couple of years. I have learned that approximately 15% of all radio pharmaceutical injections are infiltrated. Based on my extensive experience in the field of radio pharmaceuticals, I fully understand the side effects that isotopes create to the tissue of patients that have infiltrations. Just as importantly, I am concerned about suboptimal dosing leading to inaccurate diagnosis and inappropriate treatments. And many of these cases go completely undetected due to the nature of radiopharmaceutical infiltrations – non-vesicant, small volumes, and injection sites out of the imaging field of view. Inaccurate diagnosis and treatment makes me think about all those cancer patients receiving PET/CT scans with FDG who may have infiltrations. Consequently, the oncologists may be mis-treating patients because of the compromised imaging process. And these concerns are completely supported by the references that have been provided to the NRC. These patients deserve better care! Especially when you consider their health status, the strong and expensive drugs they are receiving, and the evolution of a cancer diagnosis that is not being managed in an optimal way.

I'm also writing because I've read the ACMUI meeting transcripts. I have seen their report. I have seen the public statements and the public comments. The nuclear medicine community is, unfortunately, "looking the other way" on this issue. Infiltrations are caused by tools, technique, and training of technologists and the nuclear medicine departments do not want to accept accountability for this problem. These infiltrations are**absolutely preventable**. The evidence that has been provided to the NRC is abundant. The NRC has even heard themselves that infiltrations are avoidable directly from the ACMUI members is 2008 and 2009. In these meetings, ACMUI members admitted that if they took as much care with diagnostic administrations as they do with therapeutic administrations, then infiltrations would be a rare event. The current position of the nuclear medicine community is definitely not a "patient first" approach and should not be acceptable to the NRC.

I have reviewed the public comments as they are posted, and I have reached the conclusion that there is a very disturbing **lack of knowledge being represented by hundreds of members of the nuclear**

medicine community and by the societies themselves. These individuals are clinicians who should be educated on the properties of the radiopharmaceuticals that they are supposed to be safely administering. Yet, their comments suggest the following:

- The community does not understand medical event reporting. They believe that patient harm is a medical event criterion. It is not. Tissue doses greater than 0.5 Sv represent 500 times the dose that the patient's tissue would receive from an ideal injection. A 0.5 Sv dose to tissue represents material that was not handled properly. Many nuclear medicine centers and technologist rarely infiltrate. That is great, and patients should know about these centers. But if a center or technologist routinely infiltrates patients and many of these are significantly infiltrated, that indicates one thing – there is an issue in handling medical isotopes. And patients need to know. This is what proper reporting does. It provides transparency, and that is good for healthcare.
- But speaking of harm, the community comments show that they do not understand the energy spectrum of diagnostic isotopes and the danger/harm that can come to the patient if these drugs are not administered properly. I know as well as anyone in the industry that if the dose is delivered as intended, the risk to the patient from a diagnostic radiopharmaceutical is incredibly minimal. The benefit of the procedure will FAR outweigh the risk. But it is incomprehensible to me that the community is suggesting that dumping these same diagnostic radiopharmaceuticals into the tissue is not causing harm. **THIS IS A PATIENT SAFETY ISSUE**. It is not a practice of medicine issue. No clinician could ever argue that there is any benefit at all for infiltrating a patient. No clinician would ever volunteer to have 15 mCi of FDG or 25 mCi of Tc99m dumped into their tissue. A dose of FDG or Tc99m that is infiltrated into the tissue is irradiating the tissue with energy. Either positron emitting energy or conversion electron energy is being deposited into the tissue. This is basic physics. I read the petition and saw the dosimetry cases. I read the manuscript that was accepted by the Health Physics Journal on this more accurate dosimetry method. The NRC and community have been presented with over 20 cases of patients receiving high tissue doses from diagnostic radiopharmaceuticals. It is clear that infiltrations of diagnostics are not good for patients.
- The community does not understand that symptoms from radiation injury to tissue will not be immediately evident.

These concerns represent significant educational gaps in the group of clinicians who are responsible for the safe administration of radiopharmaceuticals. NRC should take note and require that these licensees receive additional training from radiopharmacy companies or from the top radiopharmacy schools (I am partial to Purdue) to close the gap. Ironically, this is the same group that argued the importance of patient safety in their recent NRC public comments regarding modifications to Training and Experience requirements.

Furthermore, it is obvious that no one in the industry is performing dosimetry on severely infiltrated patients (or any infiltrated patients). No one is following these patients. No one is telling these patients what happened. And again…these compromised images are often being used to guide care. Public comments from physicians suggest that significant infiltrations are "trivial". How do these physicians know the infiltration is not an issue? They are not characterizing infiltrations. These same physicians state that patients should not be told. In the year 2020, nuclear medicine physicians are publicly stating that patients should not be told when they have been unintentionally irradiated with a dose that far exceeds reporting limits, and even limits that the community has publicly stated leads to adverse tissue reactions (1.0 Sv). This is unacceptable.

As a pharmacist and former CEO of a major radio pharmaceutical company and current board member of a leading global radio pharmaceutical company, I am fully aware of the quality commitment that goes into the manufacturing and preparation of radio pharmaceutical doses. Our goal is always ensuring that the right dose gets to the right patient at the right time. All of the value from this commitment to quality manufacturing and distribution is lost when a patient receives the incorrect dose of the agent because of an infiltration.

In summary, I strongly endorse the petition to make the reporting of significant infiltrations a standard in the industry. By implementing this requirement our patients will dramatically benefit.

Sincerely,

Don Kiepert