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

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General Comment

See attached file(s)

Attachments

T. Bryant NRC Petition Comments

November 30, 2020

Annette L. Vietti-Cook
Secretary, U.S. Nuclear Regulatory Commission
Attn: Rulemakings and Adjudications Staff
Docket ID NRC-2020-0141

Dear Secretary Vietti-Cook,

I am writing to you regarding the proposed changes to the U.S. Nuclear Regulatory Commission regulations concerning the reporting of nuclear medicine injection extravasations as medical events. I have reviewed not only the docket and supporting documentation, but also the comments submitted by physicians, technologists, patients, concerned family members of patients, societies, and associations.

The North Carolina Healthcare Association (NCHA, comment ID NRC-2020-0141-0340) comment needs to be addressed for several reasons. I have captured the essence of the comments in the left column and added an analysis in the column on the right.

Preventing and treating extravasations of radiopharmaceuticals is a medical practice issue.	It appears the NCHA and Mr. Lawler have been misled regarding the nuclear medicine profession's use of the practice of medicine argument. The practice of medicine argument appears to be founded on the principle that the NRC will not intrude into a physician's judgement on the proper use of radioactive material to treat patients. If a physician believes that the use of radiation may benefit their patient, the NRC policy is not to intrude into this medical judgement. A radiopharmaceutical extravasation is the unintentional misadministration of a radioactivity to the wrong location. Since no physician would ever intentionally recommend that a patient experience an extravasation, therefore this is not a practice of medicine issue.
Extravasation events require no additional regulation by the U.S. NRC, an agency whose founding purpose is prevention of a major nuclear power reactor accident that would threaten public health and safety.	The NCHA and Mr. Lawler have mischaracterized the purpose of the NRC regarding the practice of medicine. According to the NRC medical Use Policy Statement, the NRC is responsible for regulation of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public. Additionally, on the bottom of page PS-MU-5 Issue 2 of the Federal Register https://www.nrc.gov/reading-rm/doc-collections/commission/policy/65fr47654.pdf the NRC specifically states they are responsible for the accurate administrations of radioactive material and it rejects the nuclear medicine profession opinion that the NRC should not protect patients from unintentional doses of radiation.
Professional medical organizations such as The Joint Commission, the	The organizations mentioned by the NCHA and Mr. Lawler do not have accreditation programs that monitor the quality of

Society of Nuclear Medicine and Molecular Imaging and the American College of Radiology have accrediting and reporting programs in place that adequately protect the health and safety of the public.	nuclear medicine extravasations. If members of NCHA that practice nuclear medicine were polled for their accreditation results for nuclear medicine administrations no facility would be able to share these results, since they are not evaluated.
Adding additional reporting to the U.S. NRC is duplicative, as the above-mentioned medical organizations regulate and monitor patient safety standards.	In fact, Subpart M of 10 CFR Part 35 specifically address extravasations already, but these misadministrations have been exempted from reporting by an internal NRC policy from 1980 that is incorrect. These regulations are not duplicative, since there are no other regulations that monitor this patient safety issue.
The NRC's exemption of extravasations of diagnostic radiopharmaceuticals from its medical event definition has been in place for four decades.	This is a true statement.
It has been reviewed periodically, most recently in March 2020, when the NRC's medical use advisory committee once again recommended that the exemption be maintained.	The NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI) recommended against reporting extravasations in 2008 and 2009. Transcripts from these meetings revealed that the ACMUI members are on the record stating that these events frequently happen, they can dramatically exceed the dose that the NRC and the ACMUI agreed is the right dose for medical event reporting, and can exceed the dose that the nuclear medicine societies say will lead to patient adverse tissue reactions. But the ACMUI members are on record saying that they want to keep the exemption, so they do not have to worry about the administrative burden of reporting.
The petitioner claims that diagnostic extravasations may be causing patient harm because there has been no rigorous "clinical trial" type of follow-up program for them.	This statement is incorrect. The petition describes that radiation injury is well-known to take several years to manifest in patient tissue. The petition suggests that the nuclear medicine profession's claim that patients are not harmed by radiation because the profession does not see harm immediately is not evidence. Without following patients for the appropriate time period, the profession is reaching a conclusion without evidence.
That allegation of harm from diagnostic infiltrations is not supported by decades of clinical experience nor recognized by patient safety organizations as a serious issue.	The medical literature is clear on this issue. Diagnostic infiltration patients have <u>NEVER</u> been studied sufficiently. However, the nuclear medicine profession has published a paper that states that a patient should expect adverse tissue reactions after irradiations that exceed a dose equivalent of 1.0 Sv. ~1,500 of patients every day in the United States are receiving dose to tissue that exceed 1.0 Sv.
Adoption of this petition would have significant negative impact on the nuclear medicine practitioners in our	There is no evidence that the petition will cause "significant negative impact" on nuclear medicine practitioners in North Carolina or any other state. Centers that do not infiltrate

state, and on the hospitals where their practices are based.	patients will experience NO impact whatsoever. Centers that routinely infiltrate patients will have to address their poor administration skills. However, the four leading societies for nuclear medicine have stated that centers should do this anyway. The petition suggests a grace period for reporting of infiltrations. Therefore, centers that address this issue as encouraged by the medical societies should have nothing to report once the petition passes. If a center does not address the issue, they will be required to report significant extravasations which exceed NRC reporting limits.
Approximately 75 million radiopharmaceutical administrations are performed annually in the United States, many of them in North Carolina.	Approximately 18M nuclear medicine procedures require radiopharmaceutical administrations in the United States annually. Of these procedures, approximately 12M require two administrations. As a result, market data suggest that there are approximately 30M administrations annually in the US.
The petitioner maintains that virtually all nuclear medicine infiltrations can be prevented.	This statement is supported by evidence. For example, in the Journal of Nuclear Medicine Technology 2019; 47:1-6 a quality improvement initiative to assess and improve PET/CT injection infiltration rates at multiple nuclear medicine centers demonstrated that through injection monitoring, determining associative factors, and implementing interventions improves injection quality and prevents infiltrations.
However, if even a tiny fraction of the millions of injections of diagnostic radiopharmaceuticals were to be classified as medical events, the time and resources that would have to devoted to reporting them under the burdensome requirements of 10 CFR 35.3045(d) – (g) would be enormous and would contribute little to the health and safety of North Carolina residents.	As noted previously, the petition would have **NO REPORTING BURDEN** at all for NC facilities that do not infiltrate patients. For centers that do infiltrate, the petition is suggesting a 12-month reporting grace period so that these centers also experience **NO REPORTING BURDEN** at all for a period of time which is more than adequate to reduce these misadministrations. It is disturbing that the NCHA, which represents healthcare providers in the state of North Carolina, suggests that fixing these misadministration issues would "contribute little to the health and safety" of the state's residents. The four leading nuclear medicine societies have publicly stated that these infiltrations negatively affect the quality and quantification of the images that drive patient care. In addition, there is recent evidence that these infiltrations result in doses that exceed the societies' limits for when patients will experience adverse tissue reactions. The fundamental principles that guide the delivery of radiation is anchored on the ALARA (as low as reasonably achievable) effort. Eliminating extravasations is in complete alignment with this effort to improve patient safety and health.
The very rare infiltrations of therapeutic radiopharmaceuticals	This statement is incorrect. The Joint Commission sentinel event program SHOULD be including radiopharmaceutical

that result in actual harm would be included in The Joint Commission's program for reporting "sentinel events."	extravasations but does not. The current radiotherapy guidance the NCHA and Mr. Lawler highlights is for external beam radiotherapy delivered by radiation oncologists. There are NO reports of extravasations in the Joint Commission Sentinel Event database. Interestingly, in the Comprehensive Accreditation Manual for Hospitals released January 1, 2020, the Joint Commission Sentinel Event guidelines suggest that hospitals should at least be monitoring extravasations as patient safety events. However, there is no evidence that this is happening.
Furthermore, determining whether an infiltration exceeds the tissue radiation dose reporting threshold (0.5 sievert) requires practitioners to calculate the radiation dose to the skin. The technical issues of measuring the infiltrated radioactivity and the volume of infiltrated tissue aside, there is no widely accepted way to calculate radiation doses to the skin from extravasations. Radiation dosimetry is beyond the scope of practice for many nuclear medicine practitioners and would require them to engage the services of medical physics consultants.	The NCHA and Mr. Lawler have been misled. Dosimetry is already required to be performed for other reportable medical events. There is a published method for performing dosimetry of infiltrations. The petition also cites a recently submitted method that will take centers less than 10 minutes to calculate dose.
The petitioner overstates the problems associated with diagnostic infiltrations.	If anything, the harm caused by diagnostic extravasations are understated in the petition.
Mr. Lattanze purports that errors in calculation of PET imaging parameters such as SUV and clinical misinterpretation of infiltrated activity as "false positives" are serious patient care issues that require NRC intervention.	This is correct. The NRC has stated that diagnostic errors can lead to improper treatment and that is this also an NRC concern. Furthermore, as noted previously, the four leading nuclear medicine societies admit that infiltrations negatively affect the quality and quantification of images. Dr. Daniel Sullivan (comment ID NRC-2020-0141-0206) who has been a diagnostic radiologist for 40 years with a specialty certification in Nuclear Radiology and practices at Duke University Medical Center provides a narrative regarding the negative effect of infiltrations with supporting points.
For example, he cites a few isolated case reports of extravasations, some decades old, leading to false-positive lymph node uptake. Qualified practitioners are aware of this and	The petition does cite references that are decades old; however, these references are still valid. It is impossible for any qualified practitioner to accurately interpret an image that has been extravasated without first characterizing the extravasation. A process required to also perform dosimetry of the tissue.

take this into consideration when interpreting images.	
He makes a number of similar arguments that he asserts would be remedied by requiring practitioners to report extravasations to the NRC.	This is true. Reporting of extravasations will lead to members of the NCHA to improve their nuclear medicine administration quality. This will lead to significantly fewer extravasations and thus, improved patient safety and care.
Virtually all issues raised by the petitioner would be more effectively addressed by quality control programs, not by reporting to the U.S. NRC.	The nuclear medicine profession has been aware of infiltrations since the beginning of nuclear medicine. However, while the nuclear medicine community knows that infiltrations are frequent and negatively affect patients, they will not address the issue unless mandated to address the issue. This attitude is plainly evident in the public comments submitted to the NRC. It would be naïve to believe that facilities across the state of North Carolina and in the rest of the US, that have lobbied so hard against the petition and the significance of the issue, would in fact dedicate the time and training required to improve nuclear medicine administrations without a mandate to do so.

I understand that the nuclear medicine community does not want additional and unnecessary regulation that is burdensome. However, nuclear medicine extravasations do meet regulatory reporting requirements, and these regulations would provide incentives for nuclear medicine institutions to implement quality improvement programs that minimize patient harm and increase patient safety.

Respectfully,

Tonia E. Bryant