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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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Submitter Information

Name: Meryl Gorge Address: 12594 Tennyson Ln 205 Carmel, IN, 46032 Email: mwgorge@gmail.com

General Comment

I have been an Allied Health Professional for almost 30 years and have often counselled people in nutritional support while undergoing cancer treatments. From the perspective of my experience and as a potential patient, it is stunning to consider that the NCR stayed with their 40-year old policy of accepting extravasation because back then they were "virtually impossible to avoid." Now in 2020, there is a better way and there is no doubt that among many medical journal reviews on the topic, the best treatment for extravasation is prevention.

In the past extravasations were rarely measured, but recent testing shows that tissue can often be irradiated with extremely high doses that are above the NRC reporting limit and above the limit that the Nuclear Medicine Community considers safe. All patients and their doctors have the right to know when this occurs and for this reason the NRC has strict reporting

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requirements when patients receive unintentionally high dose of radiation....except if it occurs as extravasation.

Extravasation of a therapy is potentially very damaging to the patient beyond the fact that they receive extraordinarily little if any benefit from the expensive cancer procedure since the much of the medicine did not get to the tumor.

Extravasations can unintentionally irradiate patient tissue with high doses that increases risk of cancer at the injection site and leads to adverse tissue reaction months to years later. Unfortunately, this is not a rare occurrence, but extravasation may be occurring in the US at a rate of 1,500 times per day.

Tracking these injection errors offers the health care professionals a way to improve their process. Further, patients and their doctors must be informed of the misadministration to consider the immediate and long-term effect on the patient. The oncologist must know of the extravasation to evaluate the information from the diagnostic test. For a treatment, an injection that does not reach the tumor or in inadequate quantities can not be evaluated as a treatment. The NRC policy from 1980 that makes extravasations of radioactive pharmaceuticals non-reportable is no longer acceptable medicine and should be changed.

Improvements in medical methods, technology and efficacy should be considered requirements. Simple monitoring and tracking to correct and/or avoid extravasations will ultimately improve patient care and efficacy as well as cause less harm.