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Reporting Nuclear Medicine Injection Extravasations as Medical Events

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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

As a nuclear medicine technologist, practicing at Nuclear Diagnostic Products in Mount Laurel, NJ, I believe no additional rulemaking is needed to require reporting of certain nuclear medicine injection extravasations as medical events. This issue of extravasations has been addressed by the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) several times in recent years. Most recently, in 2019 ACMUI Subcommittee on Extravasation reviewed the 1980 NRC decision to exclude extravasations from being considered a misadministration (medical event). They concluded that extravasations are a practice-of-medicine issue and thus beyond the scope, appropriately, of NRC regulatory oversight.

The Subcommittee reconfirmed that the exclusion of extravasation from medical-event reporting was appropriate for both diagnostic and therapeutic procedures. However, one of its recommendations was for extravasations to be considered a type of passive "patient intervention" and that extravasations that lead to "unintended permanent functional damage" be reportable as a Medical Event under 10 CFR 35.3045(b). This is not inconsistent with the NRC's policy from 1980 and therefore such policy is still current. The scientific literature also

confirms this. A systematic review performed by van der Pol, et al. concluded that, although extravasation of diagnostic radiopharmaceuticals is not uncommon, of more than 3,000 reported cases of extravasation of diagnostic radiopharmaceuticals, only 3 cases (<0.1%) resulted in patient symptoms that required follow-up. More specifically, none of the reported cases of extravasation of Tc-99m, I-123, F-18, or Ga-68-labeled tracers required intervention; the only cases where patient symptoms were reported were for the less-often-used tracers Tl-201 and I-131 Iodocholesterol. In summary, there is no clinical data that supports Lucerno Dynamics' claim that extravasation of diagnostic radiopharmaceuticals is a patient safety issue.

This systematic review also mentioned that extravasation of therapeutic radiopharmaceuticals is a more significant event that can potentially induce severe soft-tissue reactions. In this context, it is important to point out that extravasation of chemotherapeutic agents is an on-going concern in medical oncology and that there are well-established procedures for management of extravasated radiotherapeutic agents, similar to those in place for extravasated chemotherapeutic agents.

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,
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