PATIENTS
FOR SAFER NUCLEAR MEDICINE

October 23, 2023
U.S. Nuclear Regulatory Commission
Office of Inspector General

To whom it may concern,

We are writing to ask you to investigate the failure of NRC management to appropriately address a patient safety matter.

Background

In January 2022, on behalf of the Patients for Safer Nuclear Medicine (PSNM) coalition, we wrote to the NRC about our patient safety concern that the NRC medical staff had been captured by the industry that the staff regulates. We were concerned about the continued reluctance of NRC medical staff to address the incorrect policy that exempted all extravasations from medical event reporting.

Since our initial meeting in the Spring of 2022 with NRC OIG, we have provided the OIG with additional documentation and introductions to others who could shed light on how NRC was being negatively influenced by the industry they regulate. In October 2022, January 2023, and February 2023, we provided further information and requested updates on OIG progress. As of today, we have not heard back from your department. We have, however, continued to see evidence that indicate NRC management has failed to appropriately address the patient safety matter of large extravasations.

Allegation

Based on our research and review of public documents, we have found five examples that show a pattern of how NRC management has failed to appropriately protect patient safety.

1. ACMUI/NRC meeting minutes from 2008 and 2009 reveal that NRC medical staff learned that the 1980 extravasations reporting exemption was incorrect. NRC management failed to remove the exemption. Since then, thousands of patients have experienced large extravasations every year.
2. From 2018-2023, NRC management has failed to address obvious conflicts of interest within the Advisory Committee on the Medical Uses of Isotopes (ACMUI). As a result, NRC medical staff continued to receive advice that does not appropriately protect patient safety.
3. In 2021, when faced with evidence that an existing reporting exemption was not appropriate, NRC medical staff adopted the industry recommendations to create a unique, harm-based reporting criterion, rather than addressing these accidental exposures like any other medical event.
4. In 2022, medical staff provided a misleading report to the Commission on the extravasation issue. NRC management failed to ensure that the quality of information used to make a regulatory decision met internal NRC information quality standards. As a result, NRC management failed to appropriately protect patient safety.
5. Based on improper information, the Commissioners proposed rulemaking to use patient harm as the proposed reporting criterion. Using this proposed criterion, by definition, rather than existing dose-based reporting criterion for all other medical events, is a failure of NRC management to

appropriately protect patient safety. As a result, thousands of patients continue to be irradiated with radiation doses that should be reported to the NRC.

We officially request that the OIG investigate this matter with the utmost urgency.

Supporting Evidence

Here is our supporting evidence for the five examples of how NRC management has failed to appropriately protect patient safety.

1. Since 2008, NRC management has been aware that the exemption policy, based on the premise that radiopharmaceutical extravasations are virtually impossible to avoid, is not true. A reading of the meeting minutes of the December 2008 and May 2009 ACMUI/NRC meetings, rather than the summaries of these meetings, reveals clear evidence that NRC staff learned extravasations:
    a. Could almost be eliminated if technologists were provided proper training, tools, and experience.
    b. Could result in radiation doses to patient tissue that easily exceeded NRC reporting dose-based thresholds.

    Staff also learned that the nuclear medicine community simply did not want to go through the process of informing patients or their referring physicians of an extravasation and did not want to remove the exemption because then they would then have to do all the “blah, blah, blah” work associated with reporting.

    Rather than remove the 1980 reporting exemption once they were aware it was incorrect, NRC management continued to retain the exemption. And for the past 15 years, patients continued to be extravasated with large radiation doses. NRC management has failed to act to protect patient safety even after being provided with evidence.

2. NRC management has failed to critically assess recommendations from the ACMUI for alignment with the NRC mission to protect patient safety and has failed to address the inherent conflicts of interest of ACMUI members. A review of the historical and current arguments made by ACMUI members regarding the reporting of extravasations show these arguments are not supported by science or are simply nonsensical (passive patient intervention causes extravasations not actions by clinicians). Often, ACMUI positions don’t support their previous positions. Most recently, the ACMUI radiation safety officer accomplished this feat simultaneously when he publicly commented that extravasations should not be medical events but only large extravasations that exceed the 50 rem dose threshold should be reported as medical events. Most of these arguments are the result of the fact that almost all members are inherently conflicted. In 2019, the ACMUI patient advocate, Ms. Weil, had no conflict of interest and she officially dissented in writing with the opinion of the ACMUI subcommittee on extravasations. Ms. Weil stated that extravasations should be treated like any other medical event. Her position was ignored. When her term ended, Ms. Weil was eventually replaced with a new ACMUI patient advocate who is a member of the Society of Nuclear Medicine and Molecular Imaging (SNMMI), a society that has aggressively and publicly opposed the reporting of any extravasations, no matter the dose to patients. This current ACMUI patient advocate receives

funding from the SNMMI for their own patient advocacy organization. Furthermore, the current ACMUI patient advocate reached out to SNMMI members on the *SNMMI Community* public forum to encourage them to attend the May 24, 2023 NRC rulemaking public meeting. The patient advocate DID NOT reach out to either of us or any other patient advocacy organizations we are aware of—ignoring the groups the advocate is supposed to represent as a member of the ACMUI.

3. In May 2020, NRC received a petition to remove the reporting exemption and to treat these extravasations like any other medical event. Over several years, NRC medical staff received clear evidence that extravasations were not virtually impossible to avoid. Additionally, they learned that:
    a. Extravasations are frequent in many centers.
    b. Extravasations have and can result in large absorbed doses in tissue.
    c. Extravasations have caused harm.
    d. Nuclear medicine is not using best vascular access practices and extravasations can almost be completely eliminated by improving technologists' training and providing better tools.
    e. Free, simple software exists for technologists to quickly perform patient-specific dosimetry to characterize an extravasation.
    f. New and existing equipment can monitor for extravasations and therefore provide clinicians an opportunity to minimize radiation dose to extravasated patients.

    Once again, the NRC medical staff deferred to the industry they regulate, just as they did in 2008 and 2009 after being confronted with evidence that extravasations were not virtually impossible to avoid and causing high patient doses. Rather than recommend that the exemption be removed, NRC medical staff failed to appropriately protect patient safety when they adopted the exact written and oral comments provided by the ACMUI and the SNMMI for the September 1, 2021 extravasation meeting. Based on the industry position, rather than evidence, NRC medical staff produced a recommendation that has continued to ensure that patients are routinely extravasated.

4. In 2022, NRC medical staff drafted SECY-22-0043. We have thoroughly reviewed the information that was provided to the Commissioner and are extremely disappointed. It is clear that NRC medical staff did not critically assess the evidence as they considered the extravasation topic, as the report they prepared was misleading. From a review of an Information Correction Request that was submitted to the NRC in February 2023, we see that the SECY-22-0043 document that the Commissioners used to reach their extravasation petition decision repeats common industry misinformation and contained at least 35 significant errors. This is an egregious example of how NRC management failed to ensure the quality of the information that was used by the Commissioners to make a regulatory decision.

    Furthermore, in SECY-22-0043, NRC medical staff suggests that a patient injury reporting criterion, rather than the existing dose-based threshold, would reduce the number of potential medical event reports of large extravasations from 28,000 to 80. This is a clear management failure. Rather than proposing regulations to encourage licensees to *minimize the frequency of extravasations*, the staff chose an option clearly designed to *minimize reporting*.

    This systemic failures evident in SECY-22-0043 have direct patient safety implications. It resulted in a flawed Commissioner decision that inherently fails to appropriately address a patient safety matter.

5. The rulemaking proposed and approved by NRC management places responsibility for identifying a radiation safety-significant extravasation on the patient. This proposal is not only completely inconsistent with NRC's long-standing radiation protection schema of objective dose-based reporting threshold, it also does not appropriately address the extravasation patient safety issue for the following reasons:

    a. Patients are not told they have been extravasated and are obviously not qualified to detect symptoms of radiation injury, and many would not self-report.
    b. A subjective patient harm reporting criterion will lead to inconsistent and incomplete reporting. As the Commission noted in the May 14, 1980 Federal Register when establishing an objective dose-based threshold, patient harm is not an adequate criterion to ensure patient safety when it is difficult to agree on radiation symptoms. 43 years later, nothing has changed about the lack of reporting clarity with a subjective harm-based criterion. A review of the public comments from the May 24, 2023 NRC public meeting reveals that physicians still cannot agree on radiation injury symptoms. Patients and physicians are not alone in agreeing that patient harm is an inadequate reporting criterion. The National Institutes of Health Radiation Safety Officer, Catherine Ribaudo, has stated that:
        i. "It would be preferable for the NRC to adopt the medical event reporting criteria already established in 10 CFR 35.3045(a) and (b) [in order] to define extravasation risk."
        ii. "…clear guidance as to the applicability of a medical event reporting requirement should cover extravasations no differently that other events covered in 10 CFR 35.3045(a) and (b)."
    c. In their 9/1/2023 public comment, the SNMMI has attempted to address the subjective nature of radiation injury in a manner that will only serve to further bury the issue. SNMMI recommends that that NRC adopt the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE). Consistent with their longstanding efforts to continue to hide this issue and discourage reporting, they suggest that only patients with CTCAE grades 3 or 4 injuries should be reported. This criterion only applies to visible skin damage and therefore is inadequate (see next point).
    d. The vast majority of patient harm from an extravasation's ionizing radiation occurs beneath the surface of the skin. Based on the distance travelled by the energy emissions of an extravasated isotope, there may be no visible symptoms of harm. The combination of no visible symptoms with patients not being informed they were extravasated ensures that few patients will be alerted and consider reporting. Of course, that does not mean that patients have not been harmed.
    e. The Commission's decision to use patient harm as the reporting criterion fails to appropriately address a patient safety matter by its very nature. Rather than relying on existing dose-based thresholds to identify licensees that may be having potential issues in the handling of isotopes **before** patients are harmed, the Commission's proposed rulemaking requires for reporting **after** patients are harmed. NRC management's patient harm decisions means that patients must wait for symptoms to present; as a result,

mitigation steps will come too late. Rather than implementing existing reporting criteria used for all other medical event reporting, which would encourage licensees to take appropriate steps to protect patients and reduce extravasations, NRC is asking patients to monitor themselves for months or years while waiting for an injury to present itself.

Conclusion

NRC management ignored evidence in 2008 and 2009 that extravasations should be reported. NRC management has continued to accept ACMUI recommendations, even though members are conflicted. In 2021, they ignored scientific evidence and adopted the recommendation of the industry they regulated—a recommendation designed to allow patients to continue to be harmed by extravasations. In 2022, they provided the Commissioners with misleading information that does not meet NRC's internal information quality guidelines. And to sum it all up, NRC management completely failed patients by proposing rulemaking that requires patients actually be injured by an extravasation before reporting could take place. The nature and magnitude of all of these issues undeniably indicates that NRC management has failed to appropriately address a patient safety matter.

We respectfully request that the OIG open an investigation into the NRC mismanagement of the extravasation topic. While we understand from previous communications with Agents Johnson and Spicher that OIG is responsible for several investigations, we find it hard to believe that many investigations would affect more members of the public than the extravasation issue. We look forward to hearing your acceptance of this allegation and are standing by to help the investigation in any manner that we can.

Sincerely,

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