From:	Nam, Andrew (Tillis)
To:	RulemakingComments Resource
Cc:	Bode, Bill (Tillis)
Subject:	[External_Sender] Reporting Nuclear Medicine Injection Extravasations As Medical Events - Comment Submission
Date:	Friday, September 25, 2020 3:59:09 PM
Attachments:	image001.png NRC Infiltrations Letter.pdf

Good Afternoon—

Hope you are doing well! Senator Tillis would like to submit the attached letter for public comment on the petition for rulemaking, "Reporting Nuclear Medicine Injection Extravasations as Medical Events." Please let me know if you have any questions.

Best,
Andrew
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November 6, 2019

The Honorable Kristine L. Svinicki
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Chairman Svinicki:

I am writing to draw your personal attention to a policy issue pending before the U.S. Nuclear Regulatory Commission of concern to me, to my constituents, and to patients who undergo diagnostic and therapeutic nuclear medicine procedures.

As you know, the safety and effectiveness of nuclear medicine procedures depend greatly on the accuracy of the injected dose of a radiopharmaceutical. An 'infiltration' – in which an injection partially misses a vein and the dose is injected into the soft tissue – can compromise a patient's care and can also expose them to unintended radiation.

In 1980, the NRC instituted misadministration reporting requirements to protect current and future patients from potentially dangerous exposure to radiation. However, since 1980, NRC policy has exempted infiltrations[1] from reporting requirements on the assumptions that they occur frequently and are "virtually impossible to avoid." In 2002, medical event reporting replaced misadministration reporting and established radiation dose thresholds to focus reporting on only the more serious exposures. However, the NRC maintained the 1980 policy, which exempted infiltrations from reporting, even if they exceed serious exposure thresholds.

I understand that new evidence has come to light indicating that infiltrations are not "virtually impossible to avoid." In fact, with sustained monitoring, analytics, and a dedicated quality improvement plan, the occurrence of infiltrations can be drastically reduced.[2]

On April 3, 2019, the Advisory Committee on Medical Use of Isotopes (ACMUI) created a subcommittee to review NRC's 39 year-old policy that exempts infiltrations from reporting requirements. I was concerned to learn that on September 10, ACMUI recommended that infiltrations were not an item that should be regulated by the NRC, and further recommended engaging in formal rulemaking to classify infiltrations as a "patient intervention." In my judgment, the use of higher dose diagnostic radiopharmaceuticals in the past 20 years and the

[1] 45 FR 31703 https://www.govinfo.gov/content/pkg/FR-1980-05-14/pdf/FR-1980-05-14.pdf
[2] Terence Wong et al. Findings from Quality Improvement Initiatives to Assess and Improve PET/CT FDG Injection Infiltration Rates in Multiple Centers. Journal of Nuclear Medicine Technology. June 10, 2019. http://tech.snmjournals.org/content/early/2019/06/06/jnmt.119.228098.abstract

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recent and rapidly growing use of high energy radiotherapeutics calls for efforts to protect patients from unintended radiation exposure.

I therefore ask NRC to reject the recommendations of the ACMUI and to negate the infiltrations exemption set forth in the Supplementary Information to 10 CFR Part 35, published in the Federal Register on May 14, 1980.

You may also be interested to know that the Fiscal Year 2020 Senate Energy & Water Development Appropriations Act includes a provision that I requested expressing support for NRC's re-evaluation of this exemption and requiring the agency to report back to Congress on its progress. A similar provision has already passed the U.S. House of Representatives, and I will continue working for its enactment into federal law.

Thank you for your attention to this matter. I look forward to following closely the actions of NRC. If I can be of assistance, please do not hesitate to contact my staff, Bill Bode, at Bill_Bode@tillis.senate.gov.

Sincerely,

Thom Tillis

Thom Tillis
United States Senator