



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**
Division of Health Service Regulation

ROY COOPER • Governor
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November 30, 2020

Sara Lopas and Pamela Noto
Secretary, U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Ms. Lopas and Ms. Noto:

Thank you for the opportunity to comment on the Nuclear Regulatory Commission's (NRC) Notice of Request for Comment: "Petition for Rulemaking That Would Require Reporting of Certain Nuclear Medicine Injection Extravasations as Medical Events" (STC-20-066).

In short, the North Carolina (NC) Agreement State Program fully supports the position and evidence submitted by the Organization of Agreement States (OAS). NC does not recognize the NRC's 1980 exemption for extravasations; this aligns with many other agreement states. If there are extravasation events that surpass the current medical event criteria, we expect that the licensee will report those events like any other. The current regulatory framework presents some ambiguity on how to classify diagnostic extravasations, but therapeutic ones requiring a written directive are fairly easy to address. The NRC could choose to immediately abandon the 1980 exemption without rulemaking; however, the rulemaking process will engage all stakeholders so that National Materials Program (NMP) can clarify expectations for when an extravasation occurs.

NC strongly encourages the NRC to address this policy decision, one that has the potential to greatly improve the health, safety and clinical outcomes for hundreds of thousands of patients each year. Through accepting this petition for rulemaking we can create a framework that upholds the ideals of the NMP, provides for enhanced patient safety and allows for more consistent evaluations of extravasations.

Sincerely,

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