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22 August 2023

Adelaide Giantelli, Chief [via e-mail: [Adeliade.Giantelli@nrc.gov](mailto:Adeliade.Giantelli@nrc.gov)]  
State Agreement and Liaison Programs Branch  
Division of Materials Safety, Security, State, and Tribal Programs  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

RE: Notification of Issuance of Federal Register Notice Requesting Information Regarding a Rulemaking on The Reporting of Nuclear Medicine Injection Extravasations as Medical Events (STC-23-033).  
Notice of Extension of Comment Period for Information Request Regarding Rulemaking on The Reporting of Nuclear Medicine Injection Extravasations as Medical Events (STC-23-052)

Dear Ms. Giantelli:

The Rhode Island Agreement State Program has received and reviewed the Commission's Federal Register Notice Requesting Information Regarding a *Rulemaking on The Reporting of Nuclear Medicine Injection Extravasations as Medical Events* (STC-23-033), Notice of *Extension of Comment Period for Information Request Regarding Rulemaking on The Reporting of Nuclear Medicine Injection Extravasations as Medical Events* (Stc-23-052). the Commission's preliminary proposed rule language for reporting nuclear medicine extravasations as medical events [NRC-2022-0218; RIN 3150-AK91], and relevant supporting documents on the Commission's rulemaking website. We appreciate the opportunity to comment on these documents.

Our first concern is the PRM itself. We consider the original petition to the NRC to be an unethical, alarmist attempt to make money off unavoidable medical exposure to radiation and feel that the petition process was abused by a profit-seeking entity and in so doing, cost the American public millions of dollars in NMP staff productivity debating their unreasonable requirement to detect the extent of extravasations.

Our second concern is the lack of specificity as to when a nuclear medicine extravasation must be reported as a medical event. The proposed criterion for reporting a medical event appears to be a *suspected radiation injury* which is further defined as *a potential or observable deterministic health effect for to the area around an injection site that can be attributed to radiation*. This is subjective at best and there will probably be as many definitions as there are nuclear medicine licensees. The majority of the criteria in the current regulations which deal with reporting a medical event are definitive and linked to a specific exposure in one way or another. The original SECY brief on this topic included an exposure level which was the threshold for *suspected radiation injury*. However, this value was not included in the proposed regulatory text. We ask that NRC revisit this issue and come out with some definitive exposure that meets the *suspected radiation injury* criteria. Otherwise, we are likely to have a situation where an identical situation occurs at two facilities and reporting is inconsistent because each facility has used a different basis for determining what constitutes a *suspected radiation injury*.

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A quick review of the comments already submitted to the rulemaking docket would appear to indicate that there is no consensus as to the frequency of extravasation events or at what point does an exposure from an extravasation event rise to the rigorous standard set for currently reporting medical events. Until these two basic issues are resolved, we strongly recommend that NRC withdraw this proposed rule from any future consideration.

We have no further specific comments to offer at this time.

If you have any questions regarding this letter, please contact the undersigned at (401) 222-4249 or via e-mail ([alexander.hamm@health.ri.gov](mailto:alexander.hamm@health.ri.gov)).

Sincerely,



Alexander Hamm  
Supervising Radiological Health Specialist  
Radiation Control Program  
Center for Health Facilities Regulation

cc: Irene Wu [via e-mail: [Irene.Wu@nrc.gov](mailto:Irene.Wu@nrc.gov)]  
Phillip Peterson, OAS Director of Rulemaking [via e-mail: [phillip.peterson@state.co.us](mailto:phillip.peterson@state.co.us)]