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General Comment

As a health physicist and nuclear medicine medical physicist, this revision to RG 8.39 poses several undesirable or unnecessary effects. While there are several minor issues, the two primary issues are summarized below:

1) I don't believe that is has been shown that previous versions of this regulatory guide allowed for unnecessary or increased exposure to members of the public. Many of the methods included in this guide require more detailed calculations or measurements, yet with little justification in reducing exposure. This increases the regulatory burden for both licensees (to comply) and the Commission (to inspect and confirm compliance) for little or no stated benefit.

2) The suggestion to use patient specific data rather than published data for "patient specific" release calculations is an unnecessary burden. For example, suggested uptake and effective half life values for I-131 provided in the previous version of this guide (Appendix B, Table B-1) have been shown to already be conservative when compared to measured patient specific values (e.g. Martin TM, Reinhart AJ. Dose-to-Public Calculations Using Standard Values Versus Patient-Specific Values in Differentiated Thyroid Carcinoma. 2022 IRPA North American Regional Conference: St. Louis, MO; 23 February). Additionally, several years of experience with Lutathera (Lu-177 dotatate) has shown measured dose rates at 1 m 4-6 hours following administration to be consistent with published uptake and effective half life data, as well as considerably less than stated using conservative assumptions in the NRC guidance (i.e. uncorrected exposure rate constants). See (Cappon DJ, Fang S, Berry K, Capone G, Carlton GL, Chrétien M, Gough J, Kamen J, Khoorshed A, Miller A, Nelli S, Petric MP, Tourneur F, Zic JJ. Clinical Best Practices for Radiation Safety During Lutetium-177 Therapy. Health Phys. 2023 Feb 1;124(2):139-146. doi: 10.1097/HP.0000000000001644. Epub 2022 Dec 10. PMID: 36508552; PMCID: PMC9803381., and Olmstead C, Cruz K, Stodilka R, Zabel P, Wolfson R. Quantifying public radiation exposure related to lutetium-177 octreotate therapy for the development of a safe outpatient treatment protocol. Nucl Med Commun. 2015 Feb;36(2):129-34. doi: 10.1097/MNM.0000000000000232. PMID: 25356620.)

This suggestion also would impact patient care, as patients would need to come back for several visits over 24-72 hours to effectively measure uptake/retention values. Not only does this place a significant burden on the patient, it also increases workload for a busy clinical area which may not be reimbursed by insurance. To summarize, this adds an unnecessary burden and increase in effort to an already conservative approach and unnecessarily complicates effective patient care.

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