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General Comment

Subject: Strong Opposition to Proposed Revision to CFR35.75 - Critical Impact on Radiopharmaceutical Therapy (RPT) Patients

To Whom It May Concern,

I am writing to comment on the upcoming revision to CFR35.75 as it relates to patient release criteria after radiopharmaceutical therapy (RPT). The proposed changes would lower patient release criteria to 8.6 mCi for I-131 and 110 mCi for Lu-177 (Table 1, page 11), and dramatically impact the care and management of our RPT patients. Under currently guidelines, I-131 and Lu-177 based therapies can be safely administered up to 200 mCi ranges. The prevailing trend of outpatient care for oncology patients, epitomized by chemotherapy and same-day outpatient surgical procedures, has seamlessly integrated RPT as an essential component, underscoring the negligible risk it poses to public safety under the current CFR35.75.

What becomes of our patients if revision 2 is adopted? I fear abandonment. Hospitalization of patients undergoing RPT for radiation protection of the public is not feasible. Hospital capacity in the United States continues to decline and post-pandemic shortages of skilled nursing and other staff have only exacerbated inpatient bed availability (3, 4). The added regulatory burdens of the proposed criteria will force many providers to stop offering RPT.

The proposed revision casts a shadow of uncertainty over the future of RPT patients. Conservative estimates project that up to 40,000 patients per year could benefit from Lu-177 based RPT in the United States alone, with further potential expansions of PSMA/DOTATATE therapies to diverse conditions and patient cohorts (5). This burgeoning landscape has also enticed pharmaceutical enterprises to initiate

numerous Phase I-III trials focused on imaging marker-guided treatments across various malignancies. These trials often adhere to treatment dosages consistent with our existing practices and certain instances even advocate personalized dosimetry to optimize therapeutic outcomes. A relevant example is the success of high specificity I-131 MIBG, wherein personalized doses of up to 500 mCi have engendered remarkable positive outcomes and subsequently secured approval as the first-line therapy for advanced paragangliomas and pheochromocytomas.

The past and future of RPT deserves a regulatory threshold that balances the public safety with the unmet needs of our patients. Revision 2 proposals on content of patient instructions, breastfeeding, and guidance on patient death after treatment are a welcome update to the current patient release guidelines. The remainder of the proposed revision, though well-intentioned, threatens to stifle innovation, impede patient access, and instigate the withdrawal of dedicated providers from offering RPT services. I urge the NRC to maintain the current release activity levels.

Sincerely,
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