

Chairman Resource

From: zanzonip@MSKCC.ORG
Sent: Monday, August 29, 2022 3:42 PM
To: Chairman Resource; CMRBARAN Resource; CMRCaputo Resource; CMRWright Resource
Subject: [External_Sender] Management of household radioactive waste of radiopharmaceutical therapy patients-9/29/22(o1)

Dear Chairman and Commissioners,

My name is Pat Zanzonico, I am a Member and Attending Physicist at Memorial Sloan Kettering Cancer Center in New York City and also Co-Head of the Radiopharmaceutical Therapy Dosimetry Task Force of the Society of Nuclear Medicine and Molecular Imaging (SNMMI). I also served as a Member and, later, Co-Chairman of the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) from 2010 to 2018 - It was one of the highlights of my professional career. I was enormously impressed with the expertise and dedication of the entire NRC staff.

I am writing to express my *personal* opinion on a long-standing regulatory issue which continues to adversely impact, at times, radiopharmaceutical therapy. As you may know, such therapy (in the form of iodine-131 sodium iodide) has long been used to safely and effectively treat thyroid disease, including hyperthyroidism and thyroid cancer. More recently, very promising radionuclide-based therapies for a variety of other cancers have been developed and, in some cases, approved. Most recently, in fact, lutetium-177 vipivotide tetraxetan (PLUVICTO, Novartis) has been approved for treatment of progressive, PSMA-positive metastatic castration-resistant prostate cancer - a seminal development, I think, in the search for more effective treatments of advanced cancer. While the NRC's regulatory guidance (such as the updated version of Regulatory Guide 8.39) provides generally sound information on release of patients administered radioactive material (including radiopharmaceutical therapy patients), **guidance on the disposal of household waste contaminated or potentially contaminated with radioactivity remains unclear and inconsistent, frankly, across regulatory jurisdictions.** In my personal opinion, the safest, most scientifically sound approach to disposing of radioactive/radioactively contaminated household waste is to dispose of it in the *regular* waste stream, that is, as one would dispose of household waste ordinarily. Holding (and thereby concentrating) such waste in one's home for "decay-in-storage" not only creates a source of exposure for family members, visitors etc of the patient but also an enhanced risk of spillage and contamination. Diluting such waste by disposal via the general waste stream minimizes any such exposure. It seems, however, that neither the NRC nor the Agreement-State regulators are willing or able to engage the waste haulers, municipalities, and other *local* regulators, so a hodge-podge of misguided rules/guidance has resulted, up to and including penalizing patients who "inappropriately" dispose of radioactive household waste. If and until this situation is resolved with cogent and consistent guidance - across jurisdictions - on management of household radioactive waste, the full utilization of new and very promising radiopharmaceutical therapies may be compromised and patients as well as practitioners unnecessarily burdened.

Thank you for your consideration. And I emphasize that these are my personal opinions only and not those of either Memorial Sloan Kettering or the SNMMI.

Sincerely,

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