



AMERICAN ASSOCIATION
of PHYSICISTS IN MEDICINE



American College of Nuclear Medicine



AMERICAN COLLEGE OF
RADIOLOGY



SOCIETY OF
NUCLEAR MEDICINE &
MOLECULAR IMAGING

Position Statement

Society of Nuclear Medicine and Molecular Imaging Radiopharmaceutical Therapy Dosimetry Task Force Working Group on Disposal of Household Waste of Radiopharmaceutical Therapy Patients

Endorsed by

American Association of Physicists in Medicine
American College of Nuclear Medicine
American College of Radiology

Problem statement: There is currently a lack of regulatory guidance regarding appropriate disposal of contaminated solid waste by patients receiving radiopharmaceutical therapy (RPT), and as a result, some patients are being instructed to retain contaminated waste within their homes to avoid being fined by local waste management facilities and regulators.

Position summary: To minimize radiation exposure to members of the public, national and local regulations should clearly state that patients may dispose of contaminated waste in their normal household waste stream. Additionally, local regulators should engage with waste facilities to ensure that patient waste is not refused due to detection of medical radioisotopes.

Overview

Radiopharmaceutical therapy (RPT) in the form of iodine-131 (^{131}I)-sodium iodide has long been used to safely and effectively treat thyroid disease, including hyperthyroidism and thyroid cancer. Recently, promising RPTs for a variety of other cancers have been developed or are under development, and a number of these have already been approved by the US Food and Drug Administration. The latter include XOFIGOTM (radium Ra-223 dichloride; Bayer Cross) and LUTATHERATM (lutetium-Lu 177-DOTATATE; Novartis) for treatment of skeletal metastases in castrate-resistant prostate cancer (CRPC) and for somatostatin receptor-positive neuroendocrine tumors, respectively. Most recently, PLUVICTOTM (lutetium Lu 177 vipivotide tetraxetan, Novartis) has been approved for treatment of progressive, prostate-specific membrane antigen (PSMA)-positive metastatic CRPC – a seminal development in the search for more effective treatments of advanced cancer. These highly effective RPTs typically exhibit biodistribution profiles that include elimination of radioactivity from the patient's body via both the urinary and hepatobiliary pathways over a time frame comparable to the physical half-life of the radiopharmaceutical.

While it is established practice that excreta from RPT patients are exempt from regulatory oversight for disposal into the sanitary sewer system (1) , there are instances (e.g., patients with urinary incontinence who routinely wear diapers), where radioactively contaminated items may enter a household's solid-waste stream.

Although the Nuclear Regulatory Commission (NRC) provides generally sound guidance (e.g., in the updated version of Regulatory Guide 8.39 (2)) on release of patients who have received RPT and related precautions, guidance on the disposal of household waste contaminated or potentially contaminated with radioactivity includes "Holding trash to allow for radioactive decay may be important if the landfill may detect the radiation and send the trash back to the patient." Some RPT patients have consequently been directed to hold contaminated household waste for decay in storage or to return it to the treating facility and there have even been anecdotal reports of RPT patients being confronted at home by regulators for disposing of radioactively contaminated household waste in the general waste stream (i.e., with regular trash). Understandably, this has created considerable anxiety among patients and consternation among facilities administering RPTs, with reports of some treating facilities considering not offering RPT to their patients. Importantly, the foregoing guidance, it appears, is based not on safety considerations but simply on possible *detectability* of radioactively contaminated household trash at landfills. Denying patients with life-threatening diseases access to safe and effective therapies is unacceptable under any circumstances, but doing so is especially egregious when it is ultimately driven by baseless regulatory considerations.

The safest, most scientifically sound approach to disposing of radioactively contaminated household waste is to dispose of it in the *regular* waste stream, that is, as one would dispose of household waste ordinarily. This is consistent with the established practice of disposal of patient excreta via the sanitary sewer system. Holding solid household waste for decay in storage and thereby accumulating it in one's home creates not only a source of exposure for family members, visitors to the patient, and other members of the public, but also an enhanced risk of spillage and contamination. Diluting such waste by disposal via the general waste stream minimizes any such exposure. Importantly, with respect to possible radiation exposure of sanitation workers, calculations utilizing conservative (i.e. dose-maximizing) assumptions yield trivially low dose estimates – of approximately 0.02 mSv (2 mrem) – for a worker handling and transporting contaminated trash from the home of a patient receiving the standard 7400-MBq (200-mCi) therapeutic activity of PLUVICTO® (calculations by Zanzonico P and Graves S; manuscript under review).

An important practical consideration impacting disposal of household radioactive waste in the general waste stream is radiation monitoring by waste haulers (3), as noted above. Landfills as well as many

transfer stations and solid waste-processing facilities are now routinely equipped with radiation detection systems, typically high-sensitivity, solid-state detectors. Operators of such facilities have thus become sensitized to the presence of even low-level radioactivity in the waste arriving at their facilities. In

2000, the Pennsylvania Department of Environmental Protection (DEP) was the first in the nation to adopt new regulations requiring landfills to monitor all incoming waste, including residential trash, for radioactivity (4). However, the Pennsylvania DEP suggested that trash contaminated with short-lived radionuclides (i.e., radionuclides with physical half-lives shorter than 2 months) - such as those used in RPT - can be immediately disposed of in landfills (4). Two additional considerations, neither of which represents a public health hazard, are the following. While it is recognized that in some instances, trace amounts of radioactive impurities having a physical half-life greater than 2 months (e.g., Lu-177m in Lutathera®) may result in persisting detectable radioactivity, these do not represent a public health hazard. Likewise, transportation of household radioactive solid waste from patients which are subject to US Department of Transportation regulations does not constitute any such hazard. Although prescription of relevant policies and procedures is beyond the scope of this Position Statement and lies, appropriately, in regulatory/guidance space, there are practical approaches to dealing with household waste of patients who have received RPT (3). Radioactively contaminated waste detected at landfills, transfer stations, solid waste-processing facilities can be distinguished on the basis of where such waste originated, residential versus commercial/institutional, with the former processed in the general waste stream and the latter interdicted for further investigation. Additionally, many radionuclides used in RPT can be identified in the field using inexpensive gamma spectrometry systems and routed to immediate disposal in landfills. Importantly, therefore, monitoring of radioactive trash at landfills can be realistically managed in a way as to avoid detecting short-lived contaminated household trash of RPT patients while still appropriately interdicting high-level, long-lived radioactive waste not suitable for disposal in municipal landfills.

Excreta from RPT and other nuclear medicine patients are exempt from NRC regulations for disposal into the sanitary sewer system. Radioactive waste discarded into the patients' household trash and ultimately landfills should be similarly exempt from regulatory oversight. Thus far, however, federal and state regulators have been unable to constructively engage and educate waste haulers and municipalities on the safety of disposal of radioactively contaminated household waste in the general waste stream. A collection of unnecessary regulatory practices has thus resulted, up to and including penalizing patients who "inappropriately" dispose of radioactive household waste. **Cogent and consistent guidance on management of patients' household radioactive waste as well as guidance applicable across jurisdictions and emphasizing the safety of disposal of such waste in the regular waste stream are**

therefore urgently needed. If and until such authoritative guidance is promulgated, the full utilization of and accessibility to promising RPTs may be compromised and patients unnecessarily burdened. Such

guidance is critical in maintaining the current practice of generally administering RPT in an outpatient setting and making it widely available as well as cost-effective.

References

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4. Pennsylvania Department of Environmental Protection. Final guidance document on radioactivity monitoring at solid waste processing and disposal facilities. Document number 250-3100-001; 2000.
5. Conference of Radiation Control Program Directors. Dealing with stray radioactive material. Frankfort, KY: Conference of Radiation Control Program Directors, CRCPD Publication 98-4; 1998.