

Specific to Licensing Codes:

02110 Medical Institution Broad

02120 Medical Institution Other

02200 Medical Private Practice-Group, Quality Management Plan Required

The Maryland Department of the Environment's (MDE) Radiological Health Program (RHP) is issuing this Information and Regulatory Interpretation Notice (IRI) **05-03** to inform medical licensees who administer iodine-131 patient therapies of a recent incident. Additionally, the RHP is using this opportunity to emphasize the need for licensees to be familiar with Maryland regulations specific to the release of individuals containing radiopharmaceuticals.

The incident involved the residential collection of an iodine-131 adult diaper by a municipal trash service. The radioiodine subsequently set off alarms at a local landfill and was collected, evaluated and disposed of by a radiation-consultant firm. The activity of the radiation source was estimated to be 10 millicuries. The dose rate was approximately 800 millirem per hour at contact and approximately 10 millirem per hour at one meter. Neither the patient nor the medical facility that administered the therapy was identified.

COMAR 26.12.01.01, Regulations for the Control of Ionizing Radiation states in Section G.25 that a licensee may authorize release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (500 millirem). The licensee shall provide the released individual with written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there was no interruption of breast-feeding, the instructions shall also include guidance on the interruption or discontinuation of breast-feeding; and information on the consequences of failure to follow the guidance.

RHP recommends adherence to the United States Nuclear Regulatory Commission's Regulatory Guide 8.39 titled, "Release of Patients Administered Radioactive Materials," as guidance for maintaining compliance with the above regulation. This Regulatory Guide describes acceptable methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 millisieverts (500 millirem).

After careful analysis of the above-described incident, the RHP concluded that the total effective dose equivalent (TEDE) to any other individual from exposure to the released individual was not maintained as low as reasonably achievable and was likely to exceed 5 millisieverts (500 millirem).

. All Maryland licensees that administer radiopharmaceuticals where, upon release, the TEDE to any other individual is likely to exceed 1 millisievert (100 millirem), should closely examine procedures, written instructions to patients, and patient interview techniques to assure compliance with G.25.

Compliance with Section G.25 will be closely examined during all future RHP inspections of medical facilities that release patients containing radiopharmaceuticals. Should you have any questions regarding this information notice, please contact Ray Manley at (410) 537-3300. You may also reach our office toll-free by dialing 1-800-633-6101 and requesting extension 3300. Also, you may contact this office via facsimile at (410) 537-3198.