Hartford HealthCare

St. Vincent's Medical Center

January 20, 2023

From: St. Vincent's Medical Center
2800 Main Street
Bridgeport, CT 06606
License No. 06-30162-01

To: U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406

Subject: Medical Event reporting, St. Vincent's Medical Center, Radioactive Materials License No. 06-30162-01

The prescribing physician Erika Strohmayer, MD, scheduled the patient to receive a radioactive Iodine (RAI) therapy procedure, with 150 mi of I-131, on September 29, 2022 for a thyroid ablation procedure. The TSH level must be high to maximize the amount of I-131 that enters the thyroid cells. Two ways to raise the TSH blood concentration are the injection of Thyrogen before the procedure or early discontinuation of the thyroid hormone pill for about 2-3 weeks before the RAI therapy.

The patient arrived for his appointment on September 29, 2022 and received a dose of 147.8mCi of I-131 NaI. It later became apparent that the patient neither received a Thyrogen injection nor discontinued the thyroid pill to maximize the amount of I-131 that enters the thyroid. The patient stopped the thyroid pill on the day of the treatment only; contrary to instruction provided by their physician. Concerns were raised about the risk of unintended radiation exposure to the patient by the patient's minimum thyroid uptake of the RAI. St. Vincent's Medical Center notified the NRC of a potential misadministration pending investigation.

At the time of this concern, the radiation risk to the patient was unknown, but was initially calculated assuming 0% uptake. The whole-body effective dose in that scenario would have been around 39 Rem, and the bladder wall 17 Rem. However, 7-day post treatment imaging of the patient's whole body revealed a significant RAI uptake by the patient's thyroid, contrary to the initial assumption of 0% uptake.

While exact figures are unable to be calculated, the patient's effective dose calculations with non-0 % thyroid uptake would likely cause the whole-body effective dose and organ dose to be at levels that any patient receiving this type of therapy would have received. Based on the significant uptake of the I-131, there are no immediate plans to re-treat the patient until clinical status is followed

for many months, and there was no measurable significant harm to the patient. Because of the initial heightened concern, the procedure workflow was still reviewed for improvement, and a root cause analysis is being performed.

After a thorough review, we have determined that the cause was a patient action and not a hospital misadministration and are requesting a withdrawal of the Medical Event Report that St. Vincent's Medical Center submitted on September 30. There was an assumption that the patient had an unintended radiation exposure but after further investigation, found the assumption to be inaccurate. Because of this concern, St. Vincent's Medical Center took this matter very seriously and made improvements where necessary. At St. Vincent's, we take ownership of our actions every day and pride ourselves on being open, honest, and transparent.

If you have any questions or need further information, please do not hesitate to contact me. Thank you for your attention to this request.

Sincerely,

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