

10/31/11

To: U.S. Nuclear Regulatory Commission  
Region I Office  
475 Allendale Road  
King of Prussia, PA 19406-1415

From: Hospital Metropolitano Dr. Pila  
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Ponce, PR 00733

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REGION I  
2011 NOV 21 AM 11:25

RE: Recordable Event

Greetings,

In conformance with CFR 10 part 35.3047, I wish to inform of a recordable event. On 8/17/2011, An oral dose of 100.2 mCi of NaI-131 sodium iodide was administered to a female patient of childbearing age for radioablation of papillary thyroid carcinoma post thyroidectomy. The patient became pregnant approximately a week after dose administration, despite proper pre-therapy orientation and against medical advice. This was brought to my attention by the patient's OB/GYN physician on 9/28/2011. On that same date, the patient was contacted via telephone and was alerted and oriented as to the possibility of harmful effects of radiation to the embryo. On 10/4/2011, that same orientation was performed more thoroughly in person. Full dosimetric analysis was performed by our medical physicist, Mr. Daniel Torres on 10/5/2011, and a complete medical report, including possible effects and complications was given to the patient and referring OB/GYN physician was given on 10/19/11. The list of possible complications included: Miscarriage, neurologic system damage, intrauterine growth retardation, mental retardation, increased risk of development of cancer.

To prevent recurrence of this incident, we have created a barrier system, where the department secretary and then the nuclear technologist verifies the patient's paperwork before the physician. We have also revised our patient instructions for childbearing age patients.

Please do not hesitate to contact me for any questions you may have about this matter.

Sincerely,



Adrian Alvarez de la Campa, MD  
Nuclear Medicine Director and Radiation Safety Officer