Full Report

Item Number: TX080032 Last Updated: 09/15/2009

Narrative:

I-8568, Overexposure to a Patient's Thyroid Gland, South Texas Radiology Imaging Centers, L00325, September 2, 2008.

On September 2, 2008 a patient was referred to an out patient imaging center and was mistakenly dosed with 3.8mCi of I-131 instead of 30mCi of Tc-99m for a routine bone scan. In placing the order for a nuclear medicine study, the referring physician's receptionist had first checked "Bone Scan - Total Body" but then drew a line through that entry and marked "I-131 Whole Body Scan". Apparently the appropriateness of this study for the patient was not verified by the referring physician, nuclear medicine technologist or authorized physician user (APU). The error was discovered 48 hours after the dose was administered on September 4, 2008 when the patient returned to the center for imaging. Because the dose was given in accordance with a signed Written Directive, there was some confusion as to whether this misadministration strictly met the provisions of a Medical Event. Therefore, it was not until today, October 2, 2008, at 1200hrs. when the Medical Event was declared within 24 hours of an on-site inquiry conducted by Agency staff. In the APU's Final Report it was determined "that a total body scan with Technetium was intended to be ordered". A licensed Medical Physicist report estimates the dose to the thyroid as 4940 rem which is identical to the value on the manufacturer's package insert both having been derived from MIRD Dose Estimate Report No. 5, Summary of Current Radiation Dose Estimates to Humans from Sodium Iodide, Journal of Nuclear Medicine 16:857-860, 1975. This Medical Event exceeds Reporting Material Events - SA-300, Abnormal Occurrence (AO) Criteria, Section IV, For Medical Licensees where it states that A Medical Event that: (a) Results in a dose...greater than 10Gy (1,000 rad) to any organ; and (b)Represents...(2) a prescribed dose or dosage that is the wrong radiopharmaceutical... A more detailed report is being assembled as the investigation continues.

12/29/08 RSO calls about question of NOV. Response already accepted for corrective action. File closed

Licensee/Reporting Party Information:

Name: SOUTH TEXAS RADIOLOGY IMAGING CENTERS License Number: L00325

City: SAN ANTONIO State: TX Zip Code: 78229

Site of Event:

Site Name: Village Square Med. Bldg. State: TX

Additional Involved Party:

Name: South Texas Radiology Imaging Centers License Number: L00325

City: San Antonio State: TX Zip Code: 78229

Other Information:

Reportable Event: Y Reciprocity: NONE
Atomic Energy Act Material: Y Abnormal Occurrence: P
Investigation: Y Include in Transfer File: Y
Consultant Hired: N Event Closed: Y

Corrective Actions Information:

Action Number: Corrective Action:

MD2

1 PERSONNEL REPRIMANDED

- 2 PROCEDURE MODIFIED
- 3 PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 09/04/2008

Given:

Diagnostic Study: WHOLE BODY I-131/THYROID

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Activity: 3.8 mCi 140.6 MBq

Intended:

Diagnostic Study: BONE

Radiopharmaceutical: METHYLENE DIPHOSPHONATE

Radionuclide: TC-99M Activity: 25 mCi 925 MBq

% Dose Exceeds Prescribed: NA % Dose is Less Than Prescribed: NA

Effect on Patient: UNKNOWN

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131

Manufacturer: Activity: 0.025 Ci 0.925 GBq

Model Number: Serial Number:

Reporting Requirements:

MD2

Reporting Requirement: 35.3045 - notifications and reports of medical involving administration and use of byproduct marterial, with the

exception of patient intervention events

Keywords:

MD2

RADIOPHARMACEUTICAL OVEREXPOSURE

References:

Reference Number: Entry Date: Retraction Date: Coder Initials: Reference Type:

TX I-8568 10/02/2008 DRJ AGREEMENT STATE EVENT REPORT