1/29/97 Events RIDS Dist. SP01

EVENT REPORT COVER PAGE

AGREEMENT STATE

EVENT REPORT NO. SC- 97- 001

DATE: January 14, 1997 1/27/97

TO: Paul ~~Lohaus~~
Deputy Director
Office of State Programs

SUBJECT: Medical Misadministration at Tuomey Regional Medical Center, December 11, 1996, involving I-131

STATE: South Carolina
Bureau of Radiological Health

Signature and Title: Melinda Bradshaw
Section Manager, Medical Div.
Bureau of Radiological Health
S.C. DHEC
Columbia, SC 29201

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NRC FORM 566 (4-94)

U. S. NUCLEAR REGULATORY COMMISSION

MEDICAL MISADMINISTRATION

APPROVED BY OMB: NO. 3150-0178
EXPIRES: 04/30/97

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH TH INFORMATION COLLECTION REQUEST: 1 HOUR. THIS INFORMATION REQUESTED TO ASSESS MISADMINISTRATIONS AND EVALUA ACTIONS NECESSARY TO PREVENT THEIR RECURRENCE. FORWA COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATI AND RECORDS MANAGEMENT BRANCH (T-6 F33), U.S. NUCLE REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND T THE PAPERWORK REDUCTION PROJECT (3150-0178), OFFICE O MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

LICENSEE	CITY AND STATE	ORIGINAL ITEM NUMBER
Tuomey Regional Medical Ctr	Sumter, SC	
TYPE OF LICENSE *(e.g., Broad Scope, Private Practice Medical, etc.)*	**LICENSE NUMBER**	**THIS ITEM NUMBER**
Medical Institution	010	
ABNORMAL OCCURRENCE	**FOLLOW-UP REPORT**	**THE PATIENT WAS NOTIFIED**	**DATE OF EVENT**
✓ YES / NO	✓ YES / NO	✓ YES / NO	12-11-96
			DATE OF THIS REPORT
			1-14-97

SODIUM IODINE, I-125 OR I-131, > 30 MICROCURIES

- [ ] WRONG PATIENT
- [ ] WRONG RADIOPHARMACEUTICAL
- [✓] ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY > 20% AND DIFFERENCE EXCEEDS 30 MICROCURIES

THERAPEUTIC RADIOPHARMACEUTICAL DOSE, OTHER THAN I-125 OR I-131

- [ ] WRONG PATIENT
- [ ] WRONG RADIOPHARMACEUTICAL
- [ ] WRONG ROUTE OF ADMINISTRATION
- [ ] ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY > 20%

STEREOTACTIC RADIOSURGERY (GAMMAKNIFE)

- [ ] WRONG PATIENT
- [ ] WRONG TREATMENT SITE
- [ ] ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY MORE THAN 10%

TELETHERAPY

- [ ] WRONG PATIENT
- [ ] WRONG MODE OF TREATMENT
- [ ] WRONG TREATMENT SITE
- [ ] ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY MOR[illegible]N 10% IF THERE ARE 3 OR FEWER FRACTIONS PRESCRIBED; OR WHEN WEEKLY CALCULATED ADMINISTERED DOSE EXCEEDS PRESCRIBED DOSE BY > 30%; OR WHEN CALCULATED TOTAL ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY > 20%

BRACHYTHERAPY

- [ ] WRONG PATIENT
- [ ] WRONG RADIOISOTOPE
- [ ] WRONG TREATMENT SITE
- [ ] LEAKING SOURCE
- [ ] ONE OR MORE SOURCES NOT REMOVED AT END OF TREATMENT
- [ ] CALCULATED ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSE BY > 20%

DIAGNOSTIC RADIOPHARMACEUTICAL DOSE, OTHER THAN QUANTITIES THAT EXCEED 30 MICROCURIES OF I-125 OR I-131, OR BOTH, WHEN THE PATIENT DOSE EXCEEDS 5 REM EFFECTIVE DOSE EQUIVALENT OR 50 REM ORGAN DOSE AND INVOLVES:

- [ ] WRONG PATIENT
- [ ] WRONG RADIOPHARMACEUTICAL
- [ ] WRONG ROUTE OF ADMINISTRATION
- [ ] ADMINISTERED DOSE DIFFERS FROM PRESCRIBED DOSAGE

ABSTRACT *(Include the cause of the misadministration, contributing factors, and licensee corrective action. May be continued on the reverse side.)*

See attached sheets

NRC FORM 473
(6-87)
10 CFR § 35.33

3150-0140
Expires 5-31-88

DIAGNOSTIC MISADMINISTRATION REPORT

(N1) LICENSEE NAME: THOMEY REGIONAL MEDICAL CENTER

(N2) LICENSE NUMBER: 1-1-0-1-0

(N3) CITY: SUMTER

(N4) STATE: SC

(N5) EVENT DATE: MONTH 12 DAY 11 YEAR 96

(N6) REPORT DATE: MONTH 12 DAY 12 YEAR 96

(N7) TYPE OF MISADMINISTRATION
- [ ] (01) WRONG RADIOPHARMACEUTICAL
- [X] (02) DOSAGE DIFFERING FROM PRESCRIBED BY 50%
- [ ] (03) WRONG PATIENT
- [ ] (04) WRONG ROUTE

(N8) DID THE MISADMINISTRATION INVOLVE AN ISOTOPE OF IODINE
- [X] (999) YES
- [ ] (111) NO

(N9) NUMBER OF PATIENTS WHO RECEIVED A MISADMINISTRATION UNDER THIS REPORT: 1

(N10) INTENDED
- [ ] (05) NO CLINICAL PROCEDURE
- [X] (06) NUCLEAR MEDICINE STUDY (Complete (N10A) INTENDED and (N11) GIVEN)
- [ ] (07) X-RAY STUDY
- [ ] (08) ULTRASOUND STUDY
- [ ] (09) CT STUDY
- [ ] (10) NMR STUDY
- [ ] (11) OTHER

(N10A) INTENDED				(N11) GIVEN			
MILLICURIES	ISOTOPE	CHEMICAL FORM	STUDY	MILLICURIES	ISOTOPE	CHEMICAL FORM	STUDY
2.0	I131	CAPSULE PILL	TX	10.5	I131	CAPSULE PILL	TX

(N12) PRECIPITATOR
- [ ] (71) REFERRING PHYSICIAN
- [ ] (72) WARD NURSE
- [ ] (73) WARD CLERK
- [ ] (74) NUCLEAR PHARMACY
  - NAME OF NUCLEAR PHARMACY | CITY | STATE
- [ ] (76) HOT LAB TECHNOLOGIST
- [X] (77) IMAGING TECHNOLOGIST
- [ ] (78) CLINIC RECEPTIONIST
- [ ] (79) SCHEDULING TECHNOLOGIST
- [ ] (80) PATIENT
- [ ] (81) OTHER

(N13) ERROR

HOT LAB
- [ ] (11) MISLABELED A SYRINGE
- [ ] (12) MISLABELED A VIAL OR VIAL SHIELD
- [ ] (13) RECONSTITUTED WRONG REAGENT KIT
- [ ] (14) PLACED RECONSTITUTED VIAL IN WRONG SHIELD
- [ ] (15) SELECTED WRONG VIAL WHEN DRAWING DOSAGE
- [ ] (16) SET DOSE CALIBRATOR IMPROPERLY
- [ ] (17) MISREAD DOSE CALIBRATOR
- [X] (18) MISUNDERSTOOD RADIOPHARMACEUTICAL OR DOSAGE ORDER

REFERRAL
- [ ] (20) MISUNDERSTOOD REFERRING PHYSICIAN'S REQUEST
- [ ] (21) REQUESTED WRONG STUDY
- [ ] (22) REQUESTED STUDY FOR WRONG PATIENT

ADMINISTRATION
- [ ] (30) SELECTED WRONG PATIENT
- [ ] (31) ANSWERED WAITING ROOM PAGE INTENDED FOR OTHER PATIENT
- [ ] (32) BROUGHT WRONG PATIENT TO CLINIC
- [ ] (33) SELECTED WRONG SYRINGE FROM DOSAGE CART

OTHER
- [ ] (40) Specify

(N14) CONTRIBUTING FACTORS
- [ ] (80) STUDENT TECHNOLOGIST
- [ ] (81) NEW EMPLOYEE
- [ ] (82) FOREIGN LANGUAGE
- [ ] (83) PATIENT INCOHERENT OR UNCONSCIOUS
- [ ] (84) ID BRACELET NOT CHECKED
- [X] (85) REQUISITION NOT CHECKED
- [ ] (86) PATIENT CHART NOT CHECKED
- [ ] (87) NEW PROCEDURE
- [X] (88) HEAVY WORKLOAD
- [ ] (89) OTHER

(N15) ACTION TAKEN TO PREVENT RECURRENCE
- IMPLEMENT NEW PROCEDURES FOR
  - [X] (C1) VERIFICATION OF REQUEST
  - [ ] (C2) RADIOPHARMACEUTICAL LABELING AND HANDLING
  - [ ] (C3) VERIFICATION OF PATIENT IDENTIFICATION
- [ ] (C4) REINSTRUCT PERSONNEL
- [ ] (C5) REPRIMAND PERSONNEL
- [ ] (C6) IMPROVE SUPERVISION OF PERSONNEL
- [ ] (C7) NO ACTION
- [ ] (C8) OTHER

(N16) EFFECT ON PATIENTS
- [ ] NONE APPARENT
- [ ] SEE ABSTRACT

(N17) ABSTRACT (If more space is required, attach additional sheets.)

PHONE ORDER FOR I-131 TREATMENT WAS TAKEN AS 10.0 MCi FOR THIS PT. WITH GRAVES DX. RADIOPHARMACY WAS NOTIFIED AND WE RECEIVED 10.5 MCi I131 WHICH WAS GIVEN TO PT. FAXED ORDER FOR TREATMENT WAS MISREAD BY ADMINISTERING TECH. ORDER WAS FOR ONLY 2.0 MCi I131. REFERRING PHYSICIAN AND RADIOLOGIST NOTIFIED. RADIOLOGIST STATED HE WILL PERSONNALLY SPEAK TO PT.

NUCLEAR REGULATORY COMMISSION USE

(N18)	(N19) AS	(N20) REGIONAL LOG NUMBER	(N21) ACCESSION NUMBER	(N22) INITIALS	
[ ] (999) YES [ ] (111) NO					

To Melinda Bradshaw

Re: Linda Morris
I-131 Treatment

Referring physician was Dr. Lilawvat.

Effect on pt. per physicist, Bob Dixon, is five times the organ dose of ordered patient dose, not to have residual effect on patient and not fatal dose: Major organs:

Thyroid received 1.9 Rads
Stomach 17.0 Rads
Bladder 15.0 Rads

To prevent further occurrence, advising technologist importance of reading prescribed order. We are going to try to have written order on hand before even ordering dose, much less administering. Also recommend have second person to verify before administering.

Dr. Lilawvat (referring physician) told me that he spoke to patient and reassured her that the therapy dose she received would not have any major effect and she would be alright. That he sometimes orders that dosage everyday. She received twice that amount

(cont'd)

one year prior). The radiologist has not spoken to patient, since referring physician has -

Thank you.

Peggy Susan Starker CNMT/RT(R)

20 Dec 96