RI - DNMS Licensee Event Report Disposition

Licensee: Lewis Gale Medical Center

Event Description: Report of I-131 Therapy Medical Event

License No: 45-09267-01 Docket No: 030 03333 MLER-RI: 2005-078

Event Date: 12-9-05 Report Date: 12-13-05 HQ Ops Event #:

1. REPORTING REQUIREMENT

- [ ] 10 CFR 20.1906 Package Contamination
- [ ] 10 CFR 20.2201 Theft or Loss
- [ ] 10 CFR 20.2203 30 Day Report
- [ ] Other
- [X] 10 CFR 30.50 Report
- [X] 10 CFR 35.3045 Medical Event
- [ ] License Condition

2. REGION I RESPONSE

- [ ] Immediate Site Inspection
- [X] Special Inspection
- [ ] Telephone Inquiry
- [ ] Preliminary Notification/Report
- [X] Information Entered in RI Log
- [ ] Report Referred To:

Inspector/Date: Weidner 12/20/05

Inspector/Date: Beardsley 12/20/05

Inspector/Date:

- [ ] Daily Report
- [ ] Review at Next Inspection

3. REPORT EVALUATION

- [✓] Description of Event
- [✓] Levels of RAM Involved
- [✓] Cause of Event
- [✓] Corrective Actions
- [ ] Calculations Adequate
- [ ] Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

- [ ] Release w/Exposure > Limits
- [ ] Repeated Inadequate Control
- [ ] Exposure 5x Limits
- [ ] Potential Fatality
- [ ] Deliberate Misuse w/Exposure > Limits
- [ ] Pkging Failure>10 rads/hr or Contamination>1000x Limits
- [ ] Large# Indivs w/Exp>Limits or Medical Deterministic Effects
- [ ] Unique Circumstances or Safeguards Concerns

If any of the above are involved:

- [ ] Considered Need for IIT
- [ ] Considered Need for AIT

Decision/Made By/Date:

5. MANAGEMENT DIRECTIVE 8.10 EVALUATION (additional evaluation for medical events only)

- [ ] Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
- [ ] Medical Consultant Used-Name of Consultant/Date of Report:
- [ ] Medical Consultant Determined Event Directly Contributed to Fatality
- [ ] Device Failure with Possible Adverse Generic Implications
- [ ] HQ or Contractor Support Required to Evaluate Consequences

6. SPECIAL INSTRUCTIONS OR COMMENTS

[ ] Non-Public

[ ] Public-SISP REVIEW COMPLETE

Inspector Signature: Date: 1-18-06

Branch Chief Initials: Date: 1-18-06

Location of File: G:\Reference\Blank Forms\LER FORM.wpd

Rev. 02/25/05

Lewis-Gale
Medical Center
Your Hospital of Choice

1900 Electric Road
Salem, Virginia 24153
Telephone 540.776.4000/ FAX 540.776.4196
www.lewis-gale.com

Lewis-Gale Medical Center
Department of Radiology
Division of Nuclear Medicine

December 23, 2005

Pamela J. Henderson, Medical Branch
United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

REPORT OF AN I-131 THERAPY MEDICAL EVENT

I. Licensee: Lewis-Gale Medical Center LLC

II. Prescribing Physician: James Matthews, M.D.

III. Description of the Event:

On Tuesday, December 13, 2005 at approximately 1300 I found an I-131 therapy capsule (in a lead pig in our lead storage area in our hot lab) measuring 44.4 mCi belonging to a patient who had been dosed for a total thyroid ablation on Friday, December 9, 2005. Upon investigating further, it was discovered that the patient only swallowed two of her three I-131 capsules on the day of her therapy.

The patient had been prescribed 215 mCi of I-131 for a thyroid ablation. This therapy dose was sent from Cardinal Health Nuclear Pharmacy (Roanoke, VA) on 12/09/05 in three capsules which came in two small thin plastic bottles; one capsule in one container and two capsules in the other container. Each of the bottles also contained a desiccant packet. Just prior to administration the two containers (including all three capsules) were assayed together at 217.4 mCi. The three capsules were not assayed separately. The technologist did not note the total number of capsules and believed there were only two capsules; one in each container.

After proper interviewing and counseling about I-131 therapy treatments the patient was invited into the hot lab to receive her capsules. She was handed a small medicine cup and

instructed to take each of the small bottles, which contained the capsules, and dump the therapy capsule into the medicine cup and then swallow the capsule without touching it. She successfully did this twice, swallowing one pill from each of the plastic bottles. At this point neither the technologist nor the patient realized there was still a third pill left in one of the original plastic bottles. This third pill was not noticed visually because there was a sticker wrapped around the bottle, and was not noticed by the feel of the container not being empty because of the desiccant packet. At this time the patient was given the appropriate paper work and was sent home.

On Monday morning, December 12, 2005 I opened the hot lab and noticed behind the L-block shield, the supposedly empty plastic bottles and lead pigs from the I-131 therapy from 12/09/05. I placed the plastic bottles back in the pigs and placed the pigs in the lead storage cabinet.

On Tuesday (12/12/05) at approximately 1300 I decided to look further into why the plastic bottles and pigs had not been put in storage on Friday, the day of administration. When I took out the bottles I noticed that there was an I-131 capsule in one of the bottles which measured 44.4 mCi. Using a 3 day I-131 pre-calibration factor of 1.410 it was determined that at the time of the therapy on Friday, December 9, 2005 this pill would have measured 62.6 mCi. Upon discovering this error I immediately conferred with Dr. James Matthews; the radiologist responsible for this I-131 therapy treatment.

IV. Why the Event Occurred:

This medical event occurred because it was not noted how many capsules the therapy dose was distributed among. Secondly, it was not in our procedure protocol to perform a post administration assay of the empty containers.

V. The Effect of this Event on the Patient:

None

VI. Plan to Prevent Recurrence:

Upon analysis of this event, several changes have been implemented to help preclude another therapeutic medical event in the future. The changes have been made in our Procedure Manual and on the Physician Written Directive. The revised versions of both of these are attached to this report with the changes highlighted in bold red. A summary of the changes are:

1. Post- administration assay of the containers the capsules were shipped in
2. Observation and documentation of the total number of capsules received and administered
3. Authorized user will administer the therapy dose
4. Authorized user signature post administration

All nuclear medicine technologists have been properly educated about these changes.

VII. Notification of the Individual

The patient was notified on 12/15/05 at 0700 that she had not taken her third pill. On Friday, December 16 at 1600 she spoke in person in the Nuclear Medicine Department with Dr. Matthews. At this time she refused to take her third therapy capsule.

Derek Blaakman, B.S., C.N.M.T.
Lead Nuclear Medicine Technologist

Lee S. Anthony, Ph.D.
Radiation Safety Officer

Robert Lindsey
Diagnostic Services Director

James Matthews, M.D.
Radiologist, Authorized User

Attached: I-131 Therapy For Thyroid Cancer – procedure guidelines
Physician Written Directive – for I-131 > 30μCi

Cc: Dr. Myron Levey – annotated with patient name and medical record number
Charlotte Tyson, C.O.O.
Radiation Safety Committee

1-131 THERAPY FOR THYROID CANCER
(I-131 as Sodium Iodide)

Overview

- I-131 therapy for Thyroid Cancer, of the papillo-follicualr type, is intended to ablate residual functioning thyroid tissue, either remaining normal thyroid tissue in the thyroid bed or functioning thyroid cancer anywhere in the body. The maximum effect is achieved when the residual functioning tissue is maximally stimulated by a high thyroid stimulating hormone (TSH) level and when the circulating non radioactive iodine level is relatively low. Thyroid cancer that has become undifferentiated will take up relatively little radioiodine.

Indications

- Ablation of residual normal thyroid tissue post subtotal thyroidectomy in certain groups of patients (1-5).
- Treatment of residual functioning thyroid cancer (1-10).
- Treatment for a rising serum thyroglobulin antibody level in the absence of abnormal uptake in the whole body I-131 study (1).

Procedure Time

- Initially: 20 minutes for obtaining informed consent and administering the dose.

Preparation

- When a patient is scheduled for I-131 ablation treatment, the following must be performed 3-5 business days prior to date of treatment:
  - Provide the radiologist with the following:
    - H & P - recent
    - Recent blood lab values
    - Reports of previous thyroid uptake and/or imaging
    - Completed "*Questionnaire for patients to receive I-131 therapy, being considered for outpatient therapy with doses greater than 33 mCi I-131*" (this determines the occupancy factor).
    - Discharge planning sheet (based on interview determined occupancy factor)
    - Cardinal Health Radiopharmaceutical Therapy Fax Form
  - Radiologist will fill out and sign the therapy fax form for the appropriate dosage of I-131
  - I-131 must be ordered no later than 1:00 pm the business day before it is needed. The therapy dose must be ordered by faxing the physician signed Radiopharmaceutical Therapy fax form to Cardinal Health.
- The patient must discontinue iodide containing preparations, thyroid hormones, and other medications that could potentially affect the ability of thyroid tissue to accumulate iodide (6,7).

Medication	Time of withdrawal
Antithyroid medication (propylthiouracil, methimazole, carbimazole)	3 dy
Multivitamins	7 wk

Thyroid hormones	2 wk for triiodothyronine
	4 wk for thyroxine
Expectorants, kelp, agar, carageen, topical iodide	3 wk
Radiographic contrast agents	3 wk
Amiodarone	3 mo

- Obtain a list of all medications patient is on and compare to the list of medications affecting thyroid uptake and scan.

Treatment Procedure – on day of therapy

- Complete a Physician Written Directive (PWD) form for I-131 > 30 μCi.
- Verify the patient ID by at least 2 methods (Name & DOB).
- Verify patient is off appropriate meds, and has not eaten for at least 6 hours.
- **Record the total number of pills received from the nuclear pharmacy on the PWD.**
- Assay the capsule(s) **in its original plastic container. Note this on the PWD.**
- Have patient sign the form, "Instructions for patients receiving radioiodine therapy". Give copy of this form to patient.
- Have patient sign the form, "Questionnaire for outpatient I-131 therapy > 33 mCi". Give copy of this form to patient.
- Technologist reviews instructions with patients.
- Radiologist reviews instructions with patients and explains the expected benefits and possible complications (6).
- Patient is dosed by **an Authorized User** in the hot lab. Put capsule in small cup and have patient put capsule in their mouth without touching.
- **Note the total number of pills administered to the patient on the PWD**
- **Assay the empty container in which the I-131 capsule came in, and the small cup it was placed in. Note this on the PWD.**
- Ask patient not to eat anything for 2 additional hours.
- **Have the Authorized User sign the PWD post administation.**
- File together in Nuc Med: patient signed instruction form, physician written directive, prescription order for therapy, radiopharmaceutical order sheet, discharge planning sheet for thyroid cancer patients, questionnaire for outpatient I-131 therapy > 33 mCi

Post Treatment Restrictions

- Hospitalization (for those patients who cannot meet the requirements for outpatient treatment) (12):
  1. Contact James Nunn or Dr. Anthony to facilitate hospitalization.
  2. Room location: A-6
  3. Room preparation:
     a) tape absorbent paper to:
        i surface patient will eat on.
        ii floor around toilet.
        iii likely walkways on floor.
     b) place plastic sheets:
        i under bed sheet and pillow case.
     c) wrap plastic or absorbent paper around:
        i telephone base and hand set.

ii television and bed controls; nurse call button.
iii faucet and toilet handles; toilet seat.

d) place plastic bags in room for disposal of waste, i.e. paper plates, tissues, soiled linens.

e) put cart by door with disposable gloves, shoe covers, and gowns for nurses to wear.

f) place tape on floor to indicate line visitors should stay behind.

g) remove patient's personal belongings so they will not become contaminated.

3. The patient should wear either a disposable gown or surgical scrub suit rather than personal night clothes.

Radiopharmaceutical, Dose, & Technique of Administration

- Radiopharmaceutical: I-131 as sodium iodide (6).
- Dose (weight adjust): **Determined by Radiologist**. Approximate doses are:
  - > Ablation of residual normal thyroid tissue: 70-150 mCi (7,13-15).
  - > Treatment of functioning thyroid cancer: 100- 300 mCi (1-8,16).
- Technique of administration: Oral.

Follow-up

- Obtain a whole body imaging study 7-10 days following the ablation or treatment dose of I-131 (6,7).
- The patient usually returns to the care of the referring physician.
- A follow-up whole body I-131 study is usually performed approximately 6-12 months following cancer/ablation treatment (6).

Complications

- In general, the risk of complications from I-131 therapy increases as the cumulative dose from I-131 increases and as the amount of residual post-operative thyroid tissue increases (6,17).

Complication	Time of onset	Frequency (%)	Reference
Acute radiation sickness, e.g. nausea	< 24 hr	30	6
Prolonged I-131 retention	< 24 hr	rare	17
Thyroid tissue pain & swelling	< 48 hr	20	17
Salivary and lacrimal gland dysfunction	< 1 wk	20-30	19,20
Taste dysfunction	< 1 wk	20	21
Hyperthyroidism	< 1 wk	rare	22
Radiation pneumonitis	< 1 wk	rare*	6
Impaired spermatogenesis	<2 wk	common	23
Facial nerve palsy	< 2 wk	rare	24
Marrow suppression	years	1	6
Colon cancer	years	1	25
Miscarriages, birth defects	years	rare	26,27

* Only in patients with diffuse lung metastases.

Principle Radiation Emission Data - I-131 (38)

- Physical half-life = 8.04 days.

Radiation	Mean % per disintegration	Mean energy (keV)
Beta-4	89.4	191.5
Gamma-14	81.2	364.5

Dosimetry - I-131 as Sodium Iodide (39-41)

Organ	rads/150 mCi	mGy/5,550 MBq
Thyroid	39,000.0	390,000.0
Stomach wall	255.0	2,550.0
Salivary glands	105.0	1,050.0
Total body	36.0	360.0
Upper spine	30.0	300.0
Red marrow	21.0	210.0
Ovaries	21.0	210.0
Testes	12.6	126.0

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PHYSICIAN WRITTEN DIRECTIVE

I-131 > 30 uCi

1. PATIENT NAME: _____

2. ISOTOPE: _____

3. PRESCRIBED DOSE: _____ MD SIGNATURE: _____ DATE: _____
(to be completed **PRIOR** to administration)

MD PRINT NAME: _____

4. ADMINISTERED DOSE (ASSAYED DOSE): _____ TOTAL NO. OF PILLS RECEIVED_____
(to be completed **PRIOR** to administration)

POST ADMINISTRATION ASSAY OF CONTAINERS: _____ TOTAL NO. OF PILLS ADMINISTERED_____

MD SIGNATURE: _____
(to be completed POST administration)

MD PRINT NAME: _____

**** ADMINISTERED DOSE MUST BE WITHIN PLUS OR MINUS 10% OF THE PRESCRIBED DOSE OR THE RADIOLOGIST MUST INITIAL AND DATE THE CHANGE ON LINE 4.**

5. TECHNOLOGIST: _____

6. ROUTE OF ADMINISTRATION: _____

7. RADIOLOGY NUMBER: _____ DATE: _____

8. PATIENT VERIFICATION BY AT LEAST TWO METHODS (write in information)

NAME: _____

ADDRESS: _____

DOB: _____

SS NUMBER: _____

9. BREASTFEEDING: _____

10. LMP: _____

11. CALCULATED EXPOSURE TO MAXIMUM EXPOSED PERSON FOR I-131 PATIENT RELEASED FROM MEDICAL CENTER BASED ON OCCUPANCY FACTOR OF _____ = _____ mrem.
0.125, 0.25, 0.50, 1.0

TEDE shall not exceed 500 mrem.
Written instructions needed if TEDE exceeds 100 mrem (> 7 mCi).