RI - DNMS Licensee Event Report Disposition

Licensee:	Virtua-West Jersey Hospitals				
Event Description:	Patient release prior to 10 CFR 35.75 evaluation; potential public dose > 500 mrem				
License No:	29-01862-02	Docket No:	03002443	MLER-RI:	2005-036
Event Date:	03/30/2005	Report Date:	06/01/2005	HQ Ops Event #:	

1. REPORTING REQUIREMENT

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

2. REGION I RESPONSE

	Immediate Site Inspection	Inspector/Date		
	Special Inspection	Inspector/Date		
X	Telephone Inquiry	Inspector/Date	S. Gabriel, 06/07/05	
	Preliminary Notification/Report		Daily Report	
	Information Entered in RI Log		X	Review at Next Inspection
	Report Referred To:			

3. REPORT EVALUATION

X	Description of Event	X	Corrective Actions
X	Levels of RAM Involved	X	Calculations Adequate
X	Cause of Event	X	Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

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

See attached documents from licensee and comments from inspector. There is no evidence that any individual received greater than 500 mrem from this patient.

■ Non-Public — Inspector Signature: /for/ S Gabriel — Date: 6/9/07

□ Public-SISP REVIEW COMPLETE — Branch Chief Initials: — Date: 6/9/07

Location of File: P:\virtual ler.wpd

Rev. 02/25/05

Virtua HEALTH

West Jersey Hospital - Marlton Division
Office of Radiation Physics
90 Brick Road
Marlton, NJ 08053

(856) 355-6282 fax (856) 355-6121

June 1, 2005

Medical Licensees
Nuclear Materials Safety Branch
U.S. NRC Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Reference: NRC License #29-01862-02, Virtua-West Jersey Hospitals
Subject: **REPORT OF RADIATION LEVEL EXCEEDING PUBLIC DOSE LIMIT (10CFR 20.2203)**

To Whom It May Concern:

Virtua Health-West Jersey Hospitals wishes to make notification that a patient was incorrectly released from confinement following an unsealed radiopharmaceutical therapy treatment as required by 10 CFR 35.75. This action could result in a member of the public being exposed to more than the 500 mrem dose limit.

Specifically, a patient undergoing radioiodine (^{131}I) thyroid ablation was screened for release suitability, received at our facility for outpatient treatment, and given verbal and written instructions by the Authorized User on methods to reduce dose to others. A dose of 157 mCi was then administered and the patient was released.

The error was detected when the nuclear medicine staff forwarded the patient information to the medical physicist for calculation of estimated exposure to the public. Upon reviewing the case it was learned that the patient had an abnormally high thyroid uptake value from a recent ^{123}I thyroid uptake study. When these values were utilized in the calculations it was found that potential exposure to family members or others could exceed 500 mrem even when precautions were taken.

An investigation as to the cause of the error was the unusually high uptake value and the unfamiliarity of the technical staff with the implication of a high uptake on the exposure release calculations. As a result, the patient data was transmitted to the physicist after the patient had been released.

Although the calculation indicates a potential exposure above the 500 mrem limit, the estimated value was less than 100 mrem in excess and does not imply any safety consequence to the public. Furthermore, the calculations assume worse-case scenario planning, and in practice a patient who closely follows the instructions provided would exposure family member to considerably less dose than predicted.

Several actions have been taken to reduce the probability of recurrence of this type of error. First, all staff have been re-instructed in proper release of patients treated with radioisotopes based on activity, measured dose rate and calculated dose estimates, and the factors that affect each. Second, additional questions and indicators have been added to both our Outpatient Screening and Written Directive forms to account for uptake values in thyroid disease patients and to alert the AU/RSO of any abnormal readings. Finally, any patient with an uptake value > 5% or a prescription > 200 mCi of ^{131}I must first be reviewed by the physicist/RSO for outpatient suitability before the patient can be treated.

We regret this unfortunate error but are satisfied that it does not present a health and safety issue to the family of this patient or the general public, and have instituted practical corrective actions which will prevent future recurrence.

Should you have any questions please contact out staff physicist Daniel Januseski at (856) 355-6282.

Sincerely,
VIRTUA - WEST JERSEY HEALTH SYSTEM

Daniel J. Januseski, MS
Radiation Safety Officer

U.S. NUCLEAR REGULATORY COMMISSION **TELEPHONE CONVERSATION RECORD**	Conversation Date: 06/07/05 Time: various	
Mail Control No.: N/A	License No.: 29-01862-02	Docket No.: 03002443
Licensee/Applicant Participant(s): Dan Januseski, RSO	Organization: Virtua-West Jersey Hospital	Telephone No.: 856-355-6282
Person(s) Calling: SGabriel, RI		
Subject: Licensee Event Report		

Summary:

I called Dan to discuss the LER stating that a thyroid carcinoma patient was released prior to performing the evaluation required by 10 CFR 35.75. The treatment of 157 millicuries was administered on March 30, 2005, however the release evaluation was not done until May 13, 2005. At that time it was noted that the patient's post-thyroidectomy, pre-treatment I-123 uptake was16.8% (the assumed maximum value in NRC guidance is 5%). Calculations showed that the maximum possible exposure to a member of the public was 595 mrem. I asked Dan to fax the calculations and we spoke again. I asked if licensee was familiar with the patient's living situation and if it might be possible to justify use of an occupancy factor of 0.125 at 1 meter instead of occupancy factor of 0.25. Dan faxed a copy of the outpatient assessment form, which documents that the patient met the criteria for use of 0.25 occupancy factor, however does not ask questions that could justify use of the lower occupancy factor.

Dan reiterated that this was a conservative, worst-case calculation and it is unlikely any member of the public actually received greater than 500 mrem.

We reviewed the corrective actions described in the LER. Based on Dan's description, these appear to be comprehensive and effective.

Action Required/Taken:	Complete LER form; recommend review at next inspection; apparent violation of 10 CFR 35.75(a)
Prepared By: SGabriel	Date: 06/08/05

Document Name:P:\telecon_060705_nomailctrl.wpd
Blank Form: G:\Reference\Blank Forms\telcon1.wpd

Virtua HEALTH

West Jersey Health System - Voorhees Division
Department of Nuclear Medicine

I-131 Release Calculations

based on Public Dose Limit of 500 mrem†

Assessment Date: 13-May-05 Type of Therapy: Thyroid Ablation

Patient Name: [redacted] ID: [redacted]

Date of Administration: March 30, 2005 Attending Physician: Snyder, MD

Administered Activity	E1	E2	[redacted]	F_1	F_2	T_{1eff} (Extrathyroidal)	T_{2eff} (Thyroidal)
157	0.75	0.25		0.832	0.168	0.32	7.3

Estimated maximum dose to a member of the public for total time of treatment: 595 mrem

$$D(\infty) = \frac{34.6(\Gamma_{in})(Q_o)}{(100\ cm)^2}\left\{E_1 T_{1/2eff}(0.8)\left(1 - e^{\frac{-0.693(8)}{T_{1/2eff}}}\right) + e^{\frac{-0.693(8)}{T_{1/2eff}}} E_2 F_1 T_{1eff} + e^{\frac{-0.693(8)}{T_{1/2eff}}} E_2 F_2 T_{2eff}\right\}$$

where:

E_1 = Occupancy factor for first 8 hours
E_2 = Occupancy factor from 8 hours to total decay
F_1 = Extrathyroidal uptake fraction
F_2 = Thyroidal uptake fraction

[redacted]		
T_{1eff}	0.32	0.32
T_{2eff}	5.2	7.3

Calculated by: *D. Januseski, MS, Medical Physicist* DJ

† calculations and assumed factors based on model procedures found in Appendix B of U.S.N.R.C. Regulatory Guide 8.39 (rev. April 1997) for I-131 Thyroid Cancer ablation studies and hyperthyroid treatment.
Additional references can be found in that guide.

Virtua HEALTH

West Jersey Hospitals
Department of Nuclear Medicine

Outpatient Assessment for ^{131}I Therapy > 33 mCi

Postthyroidectomy for Thyroid Cancer

Patient Name: _____ Date: 3/22/05

	YES	NO
• Patient is able to care for themselves	X	
• Patient exhibits/is aware of good hygiene	X	
• Patient is continent	X	
• Patient has ability to follow directions	X	
• Patient has separate bedroom	X	
• Patient has separate bathroom	X	
• Patient does not travel by public transportation to and from hospital	X	
• Patient is not living with pregnant relatives or is not the sole caretaker of young (under age 12) children	X	
• Patient is able to maintain distances of 3 feet or more from family members for 2 to 5 days (based on activity)	X	

Patient does / does not meet criteria for being treated as an outpatient: D. Carson

Authorized User's Signature

Patient prescribed activity: 150 mCi on 3/25/05

Confirmation of Pregnancy / Breastfeeding

N/A (male patient)

	YES	NO
• Patient confirms or is unsure if she is pregnant		
• Patient is currently breastfeeding		
Last Menses		
• Pregnancy Test Ordered?		

Instructions to Patient

	YES	NO
• Patient given verbal & written instructions on minimizing dose to others	✓	

The instructions have been explained to me and I understand and agree to follow these instructions:

X _____
Patient Signature

Daniel R. Carson
Nuclear Medicine Signature

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