

RI - DNMS Licensee Event Report Disposition

Licensee:	Williamsport Hospital				
Event Description:	Unplanned Dose to Fetus				
License No:	37-0418501	Docket No:	03002037	MLER-RI:	2008-009
Event Date:	03/28/08	Report Date:	03/28/08	HQ Ops Event #:	4405

1. REPORTING REQUIREMENT

<input type="checkbox"/>	10 CFR 20.1906 Package Contamination	<input type="checkbox"/>	10 CFR 30.50 Report
<input type="checkbox"/>	10 CFR 20.2201 Theft or Loss	<input checked="" type="checkbox"/>	10 CFR 35.3045 Medical Event
<input type="checkbox"/>	10 CFR 20.2203 30 Day Report	<input type="checkbox"/>	License Condition
<input checked="" type="checkbox"/>	Other <u>not reportable</u>		

2. REGION I RESPONSE

<input type="checkbox"/>	Immediate Site Inspection	Inspector/Date	
<input checked="" type="checkbox"/>	Special Inspection	Inspector/Date	4/2/08 SXH
<input type="checkbox"/>	Telephone Inquiry	Inspector/Date	
<input type="checkbox"/>	Preliminary Notification/Report	<input type="checkbox"/>	Daily Report
<input checked="" type="checkbox"/>	Information Entered in RI Log	<input type="checkbox"/>	Review at Next Inspection
<input type="checkbox"/>	Report Referred To: _____		

3. REPORT EVALUATION

<input checked="" type="checkbox"/>	Description of Event	<input checked="" type="checkbox"/>	Corrective Actions
<input checked="" type="checkbox"/>	Levels of RAM Involved	<input checked="" type="checkbox"/>	Calculations Adequate <u>Submitted, Medical Consultant reviewing.</u>
<input checked="" type="checkbox"/>	Cause of Event	<input type="checkbox"/>	Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

<input type="checkbox"/>	Release w/Exposure > Limits	<input type="checkbox"/>	Deliberate Misuse w/Exposure > Limits
<input type="checkbox"/>	Repeated Inadequate Control	<input type="checkbox"/>	Pkging Failure > 10 rads/hr or Contamination > 1000x Limits
<input type="checkbox"/>	Exposure 5x Limits	<input type="checkbox"/>	Large # Indivs w/Exp > Limits or Medical Deterministic Effects
<input type="checkbox"/>	Potential Fatality	<input type="checkbox"/>	Unique Circumstances or Safeguards Concerns
If any of the above are involved:			
<input type="checkbox"/>	Considered Need for IIT	<input type="checkbox"/>	Considered Need for AIT
Decision/Made By/Date: _____			

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

<input checked="" type="checkbox"/>	Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)		
<input checked="" type="checkbox"/>	Medical Consultant Used-Name of Consultant/Date of Report:	5/2/08	Ronald E. Grans N.D.
<input type="checkbox"/>	Medical Consultant Determined Event Directly Contributed to Fatality		
<input type="checkbox"/>	Device Failure with Possible Adverse Generic Implications		
<input type="checkbox"/>	HQ or Contractor Support Required to Evaluate Consequences		

6. SPECIAL INSTRUCTIONS OR COMMENTS

None

<input type="checkbox"/> Non-Public	Inspector Signature: _____	Date: 5/7/08
<input checked="" type="checkbox"/> Public-SUNSI REVIEW COMPLETE	Branch Chief Initials: _____	Date: 5/7/08



**Susquehanna
Health**

The art of caring. The science of healing.

April 3, 2008

United States Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406
Attention: Shirley Xu

RECEIVED
REGION 1
2008 APR 10 PM 11:15

Report on administration of I-131 to a pregnant patient.

The patient is a 30-year-old female who was diagnosed with hyperthyroidism and recommended for I-131 therapy by her family practitioner. She was seen by the Nuclear Medicine physician who concurred with his recommendation and discussed with the patient her options for therapy. The risk of pregnancy with I-131 therapy was discussed both verbally and in a written consent form which the patient signed. The patient was given a laboratory slip to have a pregnancy test performed prior to the therapy which was scheduled for 3/28/08. On the day of the scheduled therapy the Nuclear Medicine physician checked the computer for the pregnancy test results. The most recent available pregnancy test was printed out and was negative. Unfortunately the date of that test was 1/23/08 and this was not recognized by the ordering physician. The patient stopped in the laboratory for her pre-therapy pregnancy test immediately before coming to the department so that the results were not yet available at the time the therapy was scheduled to be given.

Prior to the therapy the patient signed the standard pregnancy questionnaire for women and consent form indicating that she was definitely not pregnant. This was confirmed verbally by the technologist who prepared the dose for therapy.

On 3/28/08 at 1:00 p.m. the patient received 17.7 mCi I-131 orally. After the patient left the department the laboratory called to indicate that the patient was in the early stages of pregnancy with a quantitative HCG of 159.4 uIU/ml.

On receiving this information the ordering physician immediately contacted the patient to advise her of her pregnancy status and to urge her to drink extra fluid and void frequently to avoid radiation exposure to the embryo. The patient's obstetrician was notified that same day.

The patient's last menstrual period was on 3/2/08 so that as of 3/28/08 she had not missed any menstrual periods. The presumption is that she was within the first 2 weeks of her pregnancy. A subsequent HCG level on 4/3/08 is 2250 uIU/ml.

In evaluating the root cause of this inappropriate administration there were two significant factors:

1. The patient did not come for the pregnancy test in a timely fashion but rather obtained it immediately before coming for the therapy, at which point the test results were not available.
2. The ordering physician did not double check the date of the pregnancy test result indicating it was in fact not the test she had ordered but one from two months prior.

On the afternoon of the therapy the Williamsport Hospital Health Physicist was advised of the problem and proceeded to calculate the potential exposure of the embryo to radiation. His results suggest that at most the embryo received at most 4.7 rems of exposure. Following our institutional policy for incident reporting we notified the patient safety officer. The Nuclear Regulatory Commission was also notified on the afternoon of the event and on 4/2/08 representatives of the Nuclear Regulatory Commission and Pennsylvania Department of Environmental Protection met with the Nuclear Medicine Department leaders as well as hospital administration (patient safety officer) to discuss what transpired and how to prevent it in the future.

To prevent this in the future the following recommendations have been put in place:

1. The protocols for administration of therapeutic isotopes have been modified. Female patients of childbearing age will have pregnancy tests performed unless they have had a hysterectomy, tubal ligation, or are clearly post-menopausal. It is recommended that that test be performed within a week of therapy and optimally at 72 hours before therapy so that the results are available.
2. The QMP/written directive will now include a space for the authorized user to record the date of the pregnancy test. This change will require the authorized user to view the date of the test. The changes to the I-131 procedure and the I-131 QMP written directive are enclosed for your review.


Judith A. Gouldin, M.D.
Radiation Safety Officer
The Williamsport Hospital
and Medical Center
License # 37-04185-01

JAG/cd

Hospital	Event Number: 44105
Rep Org: WILLIAMSPORT HOSPITAL Licensee: WILLIAMSPORT HOSPITAL Region: 1 City: WILLIAMSPORT State: PA County: License #: 37-04185-01 Agreement: N Docket: 03003037 NRC Notified By: JUDITH GOULDIN HQ OPS Officer: PETE SNYDER	Notification Date: 03/28/2008 Notification Time: 15:35 [ET] Event Date: 03/28/2008 Event Time: 13:00 [EDT] Last Update Date: 03/28/2008
Emergency Class: NON EMERGENCY 10 CFR Section: INFORMATION ONLY	Person (Organization): RONALD BELLAMY (R1) DUNCAN WHITE (FSME)

Event Text

<p>UNPLANNED DOSE TO FETUS</p> <p>"A written directive was completed on 3/18/08 prescribing 18 mCi of I-131 (capsule) for the treatment of hyperthyroidism on 3/28/08. The [prescribing physician] indicated on the form that pregnancy test was negative and she was not breastfeeding. The pregnancy test result was attached to the directive.</p> <p>"Upon arrival the patient completed an assessment form and consent form and she indicated in writing that she was not pregnant or breastfeeding. Staff and authorized user verified patient identity (name and birth date), dose, dose calibrator setting, and route of administration. The patient received the dose as prescribed.</p> <p>"Nuclear Medicine was contacted by the lab shortly after the administration with a positive pregnancy result that was done on the day of the therapy. The patient's physician was notified. The patient was notified to increase fluids and void frequently and advised to make an appointment with her OBGYN physician. [A] Health Physicist Consultant was also notified and [the hospital] is awaiting the dose calculation to the embryo."</p> <p>At the time of the report, the hospital had not calculated a dose to the unborn child. The hospital will provide the calculated dose when it is available but the Radiation Safety Officer believes that the result will be less than 50 milliSieverts (< 5 rem).</p>

301-8165151

777 Rural Avenue
Williamsport, PA 17701
Fax: (570) 321-2496
Phone: (570) 321-2400



Fax

To: NRC From: The Williamsport Hosp
 Fax: 570-321-2496 Pages: 2
 Phone: 570-321-2400 Date:
 Re: 1-131 Rx / pregnant pt CC:

- Urgent For Review Please Comment Please Reply Please Recycle

• Comments:

Follow-up from 1-131 Rx given to pregnant pt
 on 3/28/08. Health physicist has calculated
 Estimated dose to fetus = 4.715 rads
 Please let us know if you require further reports

Judith Gouldin MD

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THANK YOU

Gouldin, Dr. Judith

From: Kemmler, Jeff
Sent: Monday, March 31, 2008 8:38 AM
To: Gouldin, Dr. Judith; Essel, Dr. Adwoa
Cc: Dewar, Candy
Subject: FW: I-131 Dose
Importance: High

Based on Sam's calculations (see below) the dose to embryo is below 5 rad and is not reportable to the NRC. I discussed this issue with Sam and we agree that since contact with NRC was made on Friday we should follow-up with them indicating the dose not meeting reportable criteria and that we will continue to monitor patient and fetus

Jeff

-----Original Message-----

From: Sam Payne [mailto:sampayne@epix.net]
Sent: Friday, March 28, 2008 8:27 PM
To: Kemmler, Jeff
Subject: I-131 Dose

3/28/08

Jeff,

We did the dose calculations based on Absorbed Dose Estimate tables published by Russell et al, (1997), which I have attached (see arrow for 131-I Sodium Iodide). These data are also found in the publication by Michael G. Stabin, Ph.D., in his article: "Health Concerns Related to Radiation Exposure of the Female Nuclear Medicine Patient". This is the guy from Oak Ridge who put together the MIRD tables for nuclear medicine doses.

The patient received 17.7 mCi's of 131-I Sodium Iodide or 655 MBq. As this was considered Early pregnancy the 7.2E-02 values was utilized in the calculation.

Thus: $7.2E-02 \text{ mGy/MBq} * 655\text{MBq} = 47.15 \text{ mGy}$ or 4.715 rad.

As a rem = rad * Q (quality factor) which for X-rays, gamma or beta radiation has a Q of 1 per 10 CFR 20.1004 "Units of Radiation Dose", the absorbed dose in rads is the same number in rems or 4.715 rems (47.15 mSv).

Please also note that this dose is probably lower than we've calculated because of her increased thyroid uptake.

Based on these calculations, you would not be required to issue a report to the NRC based on § 35.3047 "Report and notification of a dose to an embryo/fetus or a nursing child".

Let me know how you'd like to proceed.

Sam

3/31/2008