RI - DNMS Licensee Event Report
Disposition

Licensee:	Metro Ponce, Inc., d/b/a Hospital Metropolitano Dr. Pila
Event Description:	Non-Emergency 10 CFR 35.3047(a) Embryo/Fetus Dose>50 mSv

License No:	52-25255-01	Docket No:	03033207	MLER-RI:	2011-020
Event Date:	08/17/2011	Report Date:	10/31/2011	HQ Ops Event #:	

NMED # 110572

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
	10 CFR 20.2203 30 Day Report		License Condition
X	Other (10 CFR 35.3047 dose to embryo/fetus)		

2. REGION I RESPONSE

	Immediate Site Inspection	Inspector/Date	Lester Tripp/12/13/2011
X	Special Inspection	Inspector/Date	
	Telephone Inquiry	Inspector/Date	
X	Preliminary Notification/Report		Daily Report
	Information Entered in RI Log		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)
X	Medical Consultant Used-Name of Consultant/Date of Report: Edward Silberstein, M.D. Report received 4/3/2012
	Medical Consultant Determined Event Directly Contributed to Fatality
	Device Failure with Possible Adverse Generic Implications
	HQ or Contractor Support Required to Evaluate Consequences

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Cincinnati, OH 45219

To: Letter TMPP, NR
610 337 5269

Why Site Visit Is Not Required:

The event occurred 8/17, documented by a written directive which could be improved. The 2 pregnancy tests are documented, one 20 days before therapy, one 36 days after, with data which could be extrapolated back 2-5 weeks.

Assessment of probable deterministic effects of the radiation exposure on the individual:

Impossible to know since data of pregnancy could have been as much as 22 days after therapy, when the dose left in the mother would be $(1/2)^{44}$ of that given! Doubt any effects at all.

Factual Description of Incident:

26 year-old female received 102.2 mCi of ^{131}I for post-thyroidectomy ablation of papillary cancer 8/17/11. hCG pregnancy test administered 7/28/11, reported 7/30/11 as negative. This test came from a specimen obtained 20 days before therapy! On 9/22/11 a hCG test was obtained with a value of 1835.48 uIU/mL a value which this lab writes in the report could be seen at 2-5 weeks gestational age, a span of 21 days. Thus there is tremendous uncertainty as to whether the patient was pregnant and, if so, fetal gestational age when ^{131}I was given.

Assessment of probable deterministic effects of the radiation exposure on the individual:

I have enclosed the Health Physics Society analysis of radiation effects at this gestational age. CNS effects do not occur till 8-15 weeks so the patient was misinformed here.

The issues are: 1) pregnancy test not done within 24-48 hours of therapy but almost 3 weeks before. 2) the beta-hCG level does not permit a confident extrapolation back to embryonic gestational age-she might not have been pregnant! 3) a young woman has an effective t1/2 of I-131 post thyroidectomy of 12-16 hrs! Without knowing the date when pregnancy began, the radiation dose becomes impossible to calculate – e.g. an error of 72 hours in estimate would decrease radiation dose by $(1/2)^6$ or about 1.5% of initial dose.

Briefly describe the current medical condition of the exposed individual:

I do not know if the patient has delivered-probably fetus is 6 months in-utero.

In areas where you do not agree with the licensee's evaluation (report submitted under 10 CFR 20.2205 or 10 CFR 35.3045), provide the basis for our opinion:

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1. Pregnancy test should be done within 24-48 hours before I-131 therapy, not almost 3 weeks before.
2. Doubt effect on fetus (see Health Physics attachment) even if conception occurred 5 days after therapy as dose to the fetus would be $(1/2)^{12}$ or 0.02% (0.0002) of administered dose or a 20 uCi source!

3. 7 days passed before dosimetry-which I have not seen.

4. What is a "barrier system"?

Estimated Dose to Individual or Target Organ: 0-10 rem??
Probable Error Associated with Estimation: 100%
Prescribed Dose (Medical Misadministration Only): 102.2 mCi
Method Used to Calculate Dose: Unknown – I have too few data but there are potential large errors in the suggested dose. If she was given 100 mCi of ^{131}I and became pregnant 6 days later (really an impossible assumption based on the beta-hCG level), with a 12 hour patient effective t ½ (young woman's average in our lab, that's $(1/2)^{12}$ = (1/4096) 100 mCi or (0.00024) (100) mCi =0.02 mCi=20 uCi! That can't harm a fetus.

Edward B. Silberstein, M.D.
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