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CENTRO MEDICO DE MAYAGUEZ  
DEPARTAMENTO DE SALUD  
MAYAGUEZ, PUERTO RICO



August 24, 1992

U.S. Nuclear Regulatory Commission  
Region II Division of Radiation Safety  
101 Marietta Street, N.W.  
Atlanta, Georgia 30323

Re: Lic. #52-13598

Gentlemen:

This letter is in relation to an incident with abnormal occurrence of radiation dose to a fetus. The case summary is as follows:

Abnormal Occurrence (Unintended Dose to fetus)

This is a 46 year old, female ([REDACTED]) Hospital record ([REDACTED]) with medical history of Papillary Ca. of Thyroid, treated by surgery and I-131 therapy in 1985 with a dose of 129 millicuries. She has been followed up by Endocrinologist and Total Body Scans performed in 1987, 1990 and 1992. F44

On February 24, 1992 a Whole Body Scan with 10 mCi of I-131 was performed. Patient didn't know she was pregnant. Her last menstrual period was December 1991, but due to her medications for thyroid condition believed her menstrual period was irregular.

On May 28, 1992 the Nuclear Medicine Department is notified by an OB & Gyn doctor about this patient pregnancy condition. During the first week of June 1-5, 1992 the R.S.O. is notified about this situation by Dra. Araceli Rivera from Nuclear Medicine. The case is analyzed and meeting is scheduled for June 8, 1992 where all medical personnel involved in the case and the patient invited to be present.

The meeting is carried out on June 8, 1992 with the following staff and patient present.

1. Dra. Araceli Rivera - Nuclear Medicine Director
  2. Dr. José Gándara - Endocrinologist
  3. Dra. Vilma González - Director of Ob & Gyn
  4. Dr. Henry González - OB -Gyn
  5. Mr. Daniel Torres - Physicist
  6. ([REDACTED]) - Patient
- F44

The patient is oriented about the effect of radiation in the fetus and possible consequences. She is well informed about the high probability of congenital anomalies due to the radiation received by the fetus. Also

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in accordance with the Freedom of Information

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she receives orientation about the possibility of termination of the pregnancy. The dose to the fetus is considered to be relatively high, around 10-15 rads whole body and above 700 rads to the thyroid due to the fact that the mother has no thyroid and all the I-131 will be excreted.

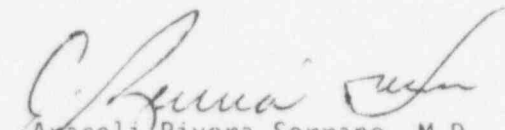
The patient informs that she is well aware of the consequences of her pregnancy. That because this is her first baby, and also because her religious believes she want to continue her pregnancy. She refuses studies for determination of amniotic levels. She will continue under follow up observation by OB-Gyn and her Endocrinologist.

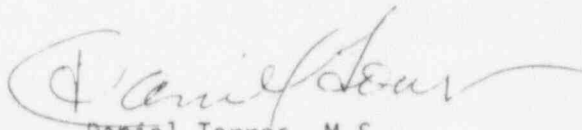
This case was considered by the R.S.C. in detail and the final agreement was that it was not a misadministration. Late consultations recommends to report the incident as an abnormal occurrence with an unintended dose to a fetus.

To prevent the occurrence of similar cases the Hospital Administration is considering the need for pregnancy test to every woman capable of being pregnant, even if she denies or if not sure of her status.

Please consider this case and advise us based on your experience.

Sincerely,

  
Araceli Rivera Serrano, M.D.  
Nuclear Medicine Director

  
Daniel Torres, M.S.  
R.S.O.