

DCS No.: 99990001060525
Date: November 21, 2006

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE - PNO-I-06-015

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by the Region I staff on this date.

Facility

McLeod Regional Medical Center
Agreement State Licensee
Florence, SC
SC License: SC-139

Licensee Emergency Classification

Notification of Unusual Event
 Alert
 Site Area Emergency
 General Emergency
 Not Applicable

SUBJECT: EXPOSURE TO FETUS FROM THYROID ABLATION THERAPY

On October 18, 2006, the South Carolina Department of Health and Environmental Control (SC DHEC) was notified by letter, dated October 9, 2006, that a possible Medical Event involving a fetus occurred in May 2006. The letter from the State of South Carolina licensee, McLeod Regional Medical Center (McLeod), stated that a female patient was administered 14 microcuries of iodine-131 on May 24, 2006, and 15 millicuries of technetium-99m on May 25, 2006, for diagnostic imaging prior to thyroid ablation therapy. The patient denied that she was pregnant and signed an informed consent for the procedure that specifically addressed pregnancy and fetal exposure. On May 25, 2006, 14.8 millicuries of iodine-131 was administered to the patient for the thyroid ablation.

On October 3, 2006, the patient's OB/GYN physician notified McLeod that the patient was approximately 32 to 34 weeks pregnant. The baby was born in mid-November 2006. The baby was to be examined by an endocrinologist and placed on a treatment plan. McLeod and SC DHEC have reviewed the event and determined that the thyroid ablation treatment was performed contrary to licensee procedures, which require a mandatory pregnancy test prior to the treatment for all women of child-bearing age.

This event has also been reviewed by a qualified independent consultant hired by McLeod to assess the dose to the embryo. However, the consultant's dose assessment differs from the licensee's calculations by a factor of 4 to 5. A formal report from the first independent review is expected to be provided to SC DHEC in the near future. Meanwhile, McLeod is planning to hire a second consultant for an additional independent review. SC DHEC has not made a final determination regarding any enforcement action until the results of the second independent review of the event are completed and made available. An Abnormal Occurrence report will be prepared by SC DHEC after the results of the second review are made available.

The facts of this Preliminary Notification (PN) were verified with a representative from SC DHEC and are current as of November 21, 2006.

The Region I Public Affairs Office is prepared to respond to media inquiries.

Region I will continue to monitor the State's review of this event and this PN will be updated as new information is received.

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