UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

July 14, 2006

Ed Ness, President, CEO
Munson Medical Center
1105 Sixth Street
Traverse City, MI 49684

SUBJECT: NRC INSPECTION REPORT 030-02074/06-001(DNMS) - MUNSON MEDICAL CENTER

Dear Mr. Ness:

This refers to the special inspection conducted on May 24 and 25, 2006, with continued in-office review through July 3, 2006, of an unintended dose to an embryo/fetus from an iodine-131 therapy that occurred on May 3, 2006, at Munson Medical Center. The purpose of the inspection was to review the circumstances, causes, and corrective actions related to this event. The in-office review included a review of your written report of the event dated June 1, 2006 and the NRC medical consultants report dated June 29, 2006. At the conclusion of the inspection, the preliminary findings were discussed with selected members of your staff on May 24, 2006, and the final results were discussed with your staff on July 11, 2006.

The enclosed copy of our inspection report identifies areas examined during the inspection. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations, and interviews with personnel. Based upon the inspection, no violations of NRC requirements were identified.

The NRC contracted with a medical consultant, Ronald Goans, Ph.D., M.D., to review the medical significance of this incident. Dr. Goans' report indicated that this case was discussed with two leaders in the field of internal and fetal dosimetry, and they concluded that the most likely outcome from this event is a normal fetus because the iodine-131 was given in the stem cell blastocyst stage of embryo fetus development. In addition, the fetal thyroid does not take up iodine until 10 to 11 weeks of gestation. However, Dr. Goans recommended, for medical completeness, that a complete thyroid evaluation after delivery should be performed. A copy of the results of Dr. Goans' evaluation is also enclosed.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

Docket No. 030-02074
License No. 21-08317-01

Enclosures:
1. Inspection Report No. 03002074/06-001(DNMS)
2. NRC Medical Consultant's Report

cc w/encls: B. Kiami, M.D., Referring Physician
D. Szmania, MS, Radiation Safety Officer

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-02074
License No.:	21-08317-01
Report No:	03002074/06-001(DNMS)
Licensee:	Munson Medical Center
Location:	1105 Sixth Street Traverse City, MI 49684
Date:	May 24 through 25, 2006, with continued in-office review through July 3, 2006
Inspector:	Darrel G. Wiedeman, Senior Health Physicist
Approved By:	John R. Madera, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure 1

EXECUTIVE SUMMARY

Munson Medical Center
Traverse City, Michigan

NRC Inspection Report 030-02074/06-001(DNMS)

This was a special, announced inspection to review the circumstances, root and contributing causes and corrective actions regarding a reported medical event that occurred at the Munson Medical Center on May 3, 2006, and reported to the NRC by the licensee on May 23, 2006. The reported medical event involved an administration of a 150.1 millicurie sodium iodine-131 (I-131) therapy dosage on May 3, 2006, to a female patient which resulted in an unintentional dose to an embryo/fetus. At the time of the therapy, the patient was unaware that she was pregnant. On May 22, 2006, the patient informed the hospital that she was approximately 10 to 14 days pregnant at the time of the I-131 therapy.

The event appeared to be an isolated occurrence. The root cause of the event was attributed to the patient's belief and affirmation in writing that she was not pregnant. Although the physician authorized user and the technologist asked the patient on several occasions, prior to the administration of the I-131 dosage, if she was pregnant or believed that she could possibly be pregnant, the patient denied the possibility of pregnancy and signed a form attesting to the fact that she was not pregnant.

The licensee estimated the dose to the embryo/fetus to be approximately 40 rem. The licensee indicated that there was a remote possibility of a spontaneous abortion of the fetus due to the insult from the I-131 and/or possible birth defects to the brain. The NRC medical consultant report indicated that this case was discussed with two leaders in the field of internal and fetal dosimetry, and they concluded that the most likely outcome from this event is a normal fetus because the I-131 was given in the stem cell blastocyst stage of embryo/ fetus development. In addition, the fetal thyroid does not take up iodine until 10 to 11 weeks of gestation. However, the medical consultant recommended, for medical completeness, that a complete thyroid evaluation be performed after delivery.

The licensee implemented immediate corrective actions that included the following: (1) a procedure was developed that requires a pregnancy test on all women of childbearing age 48 hours prior to the administration of any therapy dosage of radioactive material unless the patient has had a hysterectomy; (2) a technologist check-off sheet was developed that reminds the technologist to ensure that a pregnancy test was ordered prior to the administration of a therapy dosage; and (3) an in-service training session was held with all technologists to discuss the event and corrective actions.

Report Details

1.0 Program Summary and Inspection History

NRC Byproduct Material License No. 21-08317-01 authorizes the Munson Medical Center (licensee) to use a variety of byproduct materials for medical purposes, including diagnostic and therapeutic nuclear medicine. The licensee routinely performed an average of 35 patient treatments for thyroid cancer per year using iodine 131 (I-131). The licensee is authorized to conduct licensed activities at two authorized locations in Traverse City, Michigan.

The NRC last inspected the licensee's activities on September 6, 2004, with no violations noted. The previous NRC inspection occurred on September 28, 1998, and no violations of NRC requirements were identified during that inspection.

2.0 Sequence of Events

a. Inspection Scope

The inspection included a review of the sequence of events that resulted in an unintentional dose to an embryo/fetus. The review included interviews of selected licensee staff, reviews of selected records, and observations of equipment and facilities.

b. Observations and Findings

A 26 year-old female patient was referred to the nuclear medicine department for a consultation and treatment for thyroid carcinoma. The patient received a pregnancy test in March 2006 by her private physician and its results were negative. The patient informed the authorized user physician that her last menstrual period was normal. The physician authorized user prepared a written directive dated April 20, 2006, and the patient was scheduled to be treated on May 3, 2006, prescribing a patient treatment for thyroid carcinoma with a dosage of 150 millicuries of I-131. Prior to the administration of the I-131 dosage, the nuclear medicine technologist and the physician authorized user interviewed the patient and provided instructions on radiation safety precautions. During these discussions, both the physician authorized user and the technologist asked the patient if she was pregnant or believed that she could be pregnant at that time. The patient informed the staff that she believed she was not pregnant and was not breast feeding and indicated such on a form affirming that she was not pregnant nor breast feeding.

The nuclear medicine staff provided the patient with a list of written radiation safety instructions. The licensee proceeded with the administration of 150.1 millicuries of I-131 in accordance with the written directive. The patient was unaware at the time of the administration, that she was approximately 10-14 days pregnant.

On May 22, 2006, the patient contacted the radiology department and informed them that she believed that she was 10-14 days pregnant on the day she was treated with I-131. The patient also inquired about possible radiation effects on the unborn child.

c. Conclusion

The inspector determined that on May 3, 2006, the licensee administered a 150.1 millicurie of I-131 treatment to a female patient which resulted in an unintended dose to an embryo/fetus. Based on the patient's understanding, the patient informed the nuclear medicine staff, the physician authorize user, and affirmed in writing that she was not pregnant at the time of administration; however, the patient was approximately 10-14 days into her pregnancy at the time of the I-131 therapy treatment. The root cause of the event was attributed to the patient's belief and assertion that she was not pregnant.

3.0 Licensee Investigation

a. Inspection Scope

The inspector evaluated the licensee's investigation of the event which included a root cause assessment. The inspector also interviewed the authorized physician user, the Radiation Safety Officer (RSO), the nuclear medicine technologist, the consulting physicist, and other selected licensee staff.

b. Observations and Findings

Upon identification of the incident, the licensee's staff immediately initiated an investigation of the event and determined that the root cause of the event was human error by the patient. The RSO and the licensee's outside consultant reviewed the nuclear medicine departmental policies and procedures and interviewed personnel who participated in the treatment. The RSO and the consultant determined that the staff who participated in the I-131 administration appropriately followed the departmental policies and procedures. They determined that the staff made reasonable attempts to ascertain the medical status of the patient, specifically her pregnancy status, prior to the administration of the I-131 dosage. The physician authorized user and the nuclear medicine technologist asked the patient on several occasions, prior to the administration of the I-131 dosage, if she was pregnant or believed that she could possibly be pregnant. In each case, the patient denied the possibility of pregnancy.

c. Conclusions

The inspector concluded that the licensee had conducted a thorough investigation of the event, which included identification of the root cause. The root cause of the event was attributed to human error by the patient, in that the patient believed and affirmed in writing that she was not pregnant. The inspector agreed with the licensee's identification of the root cause.

4.0 Notifications and Reports

a. Inspection Scope

The inspector interviewed the RSO, authorized user, and Administrative Director of Radiology Services in order to determine what notifications and reports had been made. The inspector also reviewed the licensee's 15-day written report dated June 1, 2006.

b. Observations and Findings

The licensee determined that the incident was a medical event on May 22, 2006. The licensee notified the NRC Operations Center of the event on May 23, 2006, at 10:23 a.m. (EDT). The referring physician was notified on May 23, 2006. The licensee's 15 day report dated June 1, 2006, contained the required information and was timely.

The licensee's report indicated that the estimated dose to the embryo/fetus is 40 rads. The licensee also indicated that large radiation doses to the embryo/fetus during the more sensitive stages of development can cause birth defects, especially to the brain.

c. Conclusions

The inspector determined that the licensee made the required notifications to the patient, referring physician, and the NRC. Additionally, the licensee complied with the written reporting requirements in 10 CFR 35.3047(d). The notification and the written report included all the required information and were timely.

5.0 NRC Medical Consultant's Review

The NRC staff contracted with a medical consultant, Ronald Goans, Ph.D., M.D., to review the possible health effects associated with the dose to the embryo/fetus as a result of the event. Dr. Goans' report indicated that the total effective dose equivalent (whole body) to the embryo/fetus was approximately 40 rads. Dr. Goans further stated that this case was discussed with two leaders in the field of internal and fetal dosimetry, and they concluded that the most likely outcome from this event is a normal fetus because the iodine-131 was given in the stem cell blastocyst stage of embryo/fetus development . In addition, the fetal thyroid does not take up iodine until 10 to 11 weeks of gestation. However, Dr. Goans recommended, for medical completeness, that a complete thyroid evaluation be performed after delivery.

6.0 Corrective Actions

On the day of the inspection the licensee presented its long-term corrective actions, These corrective actions included the following: (1) development of a procedure that requires a pregnancy test on all women of childbearing age 48 hours prior to the administration of any therapy dosage of radioactive material unless the patient has had a hysterectomy; (2) development of a technologist check-off sheet that reminds the technologist to ensure that a pregnancy test was ordered prior to the administration of a therapy dosage; and (3) the conduct of an in-service training session with all technologists to discuss the event and corrective actions.

7.0 Exit Meeting Summary

The inspector discussed the conclusions described in this report with licensee management during a preliminary exit meeting conducted at the licensee's facility on May 24, 2006 and during the final exit conference call with selective licensee staff on July 11, 2006. The licensee did not identify any information reviewed during this inspection as proprietary in nature.

PARTIAL LIST OF PERSONS CONTACTED

Charles Dziedzic, Administrative Director of Radiology
Dennis Szmania, MS, Radiation Safety Officer
Kevin Shoskey, CNMT, Nuclear Medicine Technologist
Clark Phelps, M.D., Authorized Physician User

Medical Physics Consultants

James Botti, Consultant, Medical Physics Consultants (MPC)

Medical Consultant Report

(To be completed by medical consultant)

Medical Consultant Name: Ronald E. Goans, PhD, MD, MPH
Report Date: 7/07/2006

Signature Ronald E Goans MD

Licensee Name Munson Medical Center
1105 Sixth Street
Traverse City, MI 49684

License No. 21-08317-01
Event No. 42600
Docket No. 030-02074

Facility Name: Biederman Cancer Treatment Center
Munson Medical Center
1105 Sixth Street
8Traverse City, MI 49684

Patient ID Number [redacted] Grand Traverse Radiologists, P.C.

Incident Date: May 3, 2006.

Date of Notification May 23, 2006. Notification by Mr. Szmania, RSO.

Individuals' / Patient Physician Name and Address:

Dennis R. Szmania, M.S., RSO
(231) 935-7100

Steven Hodges, M.D., Radiologist
Clark Phelps, M.D., Radiologist
(231) 931-7100

Bashar Kiami, M.D., Referring Physician (Endocrine)
1250 E. Michigan Ave.
Graying, MI 49738

Enclosure 2

Individuals Contacted During Investigation:

Dennis R. Szmania, M.S., RSO
(231) 935-7100

Clark Phelps, M.D., Radiologist
(231) 931-7100

Records Reviewed: (General Description)

1. NRC Enclosure - Description of the Medical Event
3. NRC Preliminary Notification of Event (Event # 42600)
4. NRC Medical Event Reporting and supporting literature
5. NRC Conversation Record
6. Detailed review of Munson Hospital I-131 calibration sheet
7. Hospital summary on oncology procedures for I-131 administration
8. Hospital Report and Notification of a Dose to an Embryo/Fetus
9. Minutes, Radiation Safety Committee

Estimated Dose to Unintended Anatomic Region:

Administration of 150.1mCi I-131 NaCl for thyroid ablation in a 26 year old patient. Unintentional dose of 40.5 rad to 10-14 day embryo via MIRD method calculation of dose to early embryo. These results are consistent with the dose estimate supplied by the hospital.

Probable Error Associated with Estimation: <25 %. MIRD technique for early pregnancy.

Prescribed Dose (Medical Misadministration Only):

150 mCi I-131 NaCl.
Calibrated dose 150.1 mCi.

Method Used to Calculate Dose: MIRD technique and results of Russell and Stabin.

Description of Incident:

A 26 year old female patient was scheduled to receive 150 mCi I-131NaCl for thyroid ablation of papillary thyroid carcinoma (follicular variant). A fine needle aspiration (FNA) of a thyroid nodule had shown hyperplastic disease and a surgical thyroidectomy performed 4 weeks prior to the I-131 administration had shown a 0.6 cm nodule of papillary carcinoma. Her past medical history is notable for insulin-dependent diabetes and a history of multi-nodular goiter. A quantitative HCG was 15,663.6, and an ultrasound on 6/19/2006 showed 6 weeks 5 days ± 5 days by crown-rump (CR) length, all

consistent with a fetal age of approximately 10-14 days at the time of iodine administration.

Her obstetrical history is remarkable for a 4 cm uterine fibroid and a 9 month old daughter. The patient was asked multiple times if she could be pregnant and she denied this on each occasion and denied breastfeeding. She also signed written materials to this effect. On 5/22/06, the patient contact Munson Medical Center and stated that she was 5 weeks pregnant at that time and approximately 10-14 days pregnant at the time of the I-131 administration. Dr. Phelps and Mr. Szmania were contacted immediately and Dr. Phelps contacted the patient and the pregnancy was confirmed. The pregnancy dating is consistent with the patient history and with the subsequent ultrasound

Clinical Details

As noted above.

Assessment of Probable Deterministic Effects of the Radiation Exposure on the Individual:

The traditional health physics data regarding pre-implantation irradiation is an all or none effect. However, generally the obstetric literature indicates a transit time of 5-8 days through the fallopian tubes and then implantation in the endometrium. In this case, the embryo was slightly older and likely either in the blastocyst phase and in the process of implantation in the endometrium or in the early post-implantation phase.

Wake and Little (2003) have reviewed the estimates of the risk of childhood cancer per unit dose of radiation received in utero. Data from the Oxford Survey of Childhood Cancers (OSCC) case-control study of fetal exposure to diagnostic X-rays and from the cohort studies of the Japanese survivors of the atomic bombings of Hiroshima and Nagasaki were used, together with associated dose estimates. Excess relative risk and excess absolute risk coefficients were compared, fully taking into consideration the various sources of uncertainty.

The excess relative risk coefficient for childhood (< 15 years of age) cancer obtained from the OSCC yielded an excess absolute risk coefficient for incident cases of about 8% per Gy of exposure to the fetus. Using these conclusions and an embryo dose of 0.4 Gy, we might expect a maximum risk of childhood of approximately 3%. However, this is likely a very elevated estimate.

This case was discussed with two leaders in the field of internal and fetal dosimetry (J.Bushberg; R. Toohey, 2006; private communication) and we conclude that the most likely situation is a normal fetus because the I-131 was given in the stem cell blastocyst stage. In addition, the fetal thyroid does not take up iodine until 10-11 weeks gestation. However, in order to be medically complete, a thorough thyroid evaluation would be appropriate after delivery.

Briefly describe the current medical condition of the exposed individual:

The patient is doing well and the pregnancy is currently intact as of June 25, 2006.

References

LF Fajardo L-G, M Berthrong, and RE Anderson. *Radiation Pathology*. Oxford Press. 2001.

GH Fletcher. Textbook of Radiotherapy. 3rd edition. Lippincott, Williams & Wilkins. 1980.

RE Goans. Clinical Care of the Radiation Accident Patient: Patient Presentation, Assessment, and Initial Diagnosis. In The *Medical Basis for Radiation-Accident Preparedness. The Clinical Care of Victims.* Eds. Robert C. Ricks, Mary Ellen Berger, and Frederick M. O'Hara, Jr. Proceedings of the Fourth International REAC/TS Conference on the Medical Basis for Radiation-Accident Preparedness, March 2001, Orlando, FL. The Parthenon Publishing Group, 2002.

JR Russell, MG Stabin, RB Sparks, and LF Miller. Radiation Absorbed Dose to the Embryo/Fetus From Nuclear Medicine Procedures. University of Tennessee, Knoxville, Tennessee, and the Oak Ridge Institute for Science and Education, Oak Ridge, TN (RIDIC), 1997.

JR Russell, MG, Stabin, RB Sparks, and E Watson. Radiation Absorbed Dose to the Embryo/Fetus from Radiopharmaceuticals. Health Phys. 73(5): 756-69, 1997.

R Wakeford, MP Little. Risk Coefficients for Childhood Cancer after Intrauterine Irradiation: A Review. Int. J. Radiat. Biol. 79(5): 293-309, 2003.

Was individual or individual's physician informed of DOE Long-term Medical Study Program?

Yes

If yes, would the individual like to be included in the program?

No

COMPLETE FOR MEDICAL MISADMINISTRATION

(To be completed by Medical Consultant)

1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to the NRC pursuant to 10 CFR 35.33 in the following areas:

a. Why the event occurred – Yes.

b. Effect on the patient – Yes.

My independent dose estimates generally agree with those provided by the hospital.

c. Licensee's immediate actions upon discovery – There was immediate reporting of the event to the NRC, once the incident was noted.

d. Improvements needed to prevent recurrence - Yes. This is a human factors issue, correctable by education and improved procedures. The issue was also addressed through the hospital Radiation Safety Committee. Pregnancy tests will be ordered on all women who could potentially be pregnant based on a review of the medical history. In addition, all pertinent clinical issues, including medications, will be documented.

2. In areas where you do not agree with the licensee's evaluation (report submitted under 10 CFR 35.33, provide the basis for your opinion: N/A

3.

Did the licensee notify the referring physician of the misadministration? Yes

Did the licensee notify the patient's or the patient's responsible relative or guardian? Yes

If the patient or responsible relative or guardian was not notified of the incident, did the licensee provide a reason for not providing notification consistent with 10 CFR 35.33? N/A

Explain rationale for response.

4. Provide an opinion of the licensee's plan for patient follow-up. If available.

The patients will be followed clinically by private physicians as indicated. I believe that the hospital system and, specifically the radiation oncology department, will institute an effective program to prevent a recurrence of this event. An NRC Region III inspector has reviewed issues regarding this occurrence at the licensee's facility. The NRC Office of Nuclear Materials Safety and Safeguards has also been notified. The information in the preliminary notification has also been reviewed with licensee management.