April 12, 2011

Louis Potters, M.D.
Professor of Radiation Medicine
North Shore-LIJ Health System
270-05 76th Ave.
New Hyde Park, NY 11040

Dear Dr. Potters:

On March 19, 2011, the U.S. Nuclear Regulatory Commission (NRC) Region III office contacted you to assist us by serving as a physician consultant with respect to the incident described in Enclosure 1. This letter confirms the agreement reached via email on March 21, 2011, between Mr. Michael LaFranzo of my staff and yourself and provides the Charter detailing the tasks that should be completed under this assignment (Enclosure 2). It is not the intent of the Medical Consultant Program to evaluate the appropriateness of the prescribed treatment, its medical effectiveness, or provide an opinion as to how the facility should operate. If you encounter difficulty in completing these tasks or identify additional tasks that should be performed, please contact Mr. Michael LaFranzo, your NRC contact for this matter. Mr. LaFranzo should also be contacted if you believe that your involvement in the case would result in a possible conflict-of-interest situation. In addition, please note the information in Enclosures 3 and 4 regarding medical consultant liability and service with other Federal departments or agencies. Please notify Mr. LaFranzo if you are currently performing work for other Federal departments or agencies.

It is our understanding, based on the agreement of March 21, 2011, that you are reserving the right to conduct an on-site visit, if you deem it necessary. Your evaluation of the incident shall include a review of all pertinent documents available, regardless of whether an on-site visit is conducted.

Our office notified The Regents of the University of Michigan of your participation in this incident evaluation and asked them to contact the individual's physician(s) and/or the referring physician regarding your involvement in NRC activities.

Enclosures 5 and 6 contain a brief summary of the U.S. Department of Energy (DOE), Office of Epidemiology and Health Surveillance's Long-Term Medical Study Program. The DOE sponsors this life-time morbidity study of personnel involved in radiation incidents through the Radiation Emergency Assistance Center/Training Site of the Oak Ridge Institute of Science and Education. The NRC will provide information on the study to the individual's physician or referring physician, after it has investigated the incident; however, you may want to discuss this information with the individual's physician or the referring physician.

Please inform Mr. LaFranzo when you have completed the tasks specified in the Charter. A report of your findings and conclusions (Enclosure 7 and Enclosure 8) shall be provided to us within 30 calendar days of the completion of the case review, unless there are extenuating circumstances that have been discussed with your NRC contact before the 30-day period ends.

Please note that your report will be an official agency record, and will be released to the public; therefore, it is important that all confidential information be kept out of your report.
Please follow the instructions provided in the Charter when preparing and submitting claims for reimbursement. Please contact Mr. LaFranzo for this case if you decide to conduct an on-site visit as part of your evaluation of the incident. He can assist you in making travel arrangements through NRC's travel contractor.

Thank you for your assistance in this matter. You can reach Mr. LaFranzo by telephone at (630) 829-9865, FAX (630) 515-1259, or by e-mail at Michael.LaFranzo@nrc.gov.

Sincerely,

***/RA/***

Anne T. Boland, Director
Division of Nuclear Materials Safety

Enclosures:
1. Preliminary Description of Incident
2. Medical Consultant Charter
3. Medical Consultant Liability
4. Restrictions on Service with Other Federal Departments or Agencies
5. Long-Term Medical Study Program
6. Criteria for Selection of Cases for Long-Term Medical Study Program
7. Medical Consultant Report, Short Form
8. Medical Consultant Report
9. NRC Forms and Vouchers

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|---|---|---|---|---|---|---|---|---|
| NAME | MMLaFranzo:rj | | TEBloomer | | ATBoland | | | |
| DATE | 04/12/2011 | | 04/12/2011 | | 04/12/2011 | | | |

**OFFICIAL RECORD COPY**

**PRELIMINARY DESCRIPTION OF INCIDENT FORM**

Nuclear Regulatory Commission Regional Office: **Region III**

Date of Incident: **March 9, 2011** Date of Notification: **March 10, 2011**

NRC Inspector (Regional Contact): **Michael LaFranzo**
Telephone : **(630) 829-9865**

Medical Consultant: **Louis Potters, M.D.**
Specialty: **Radiation Therapy**

Licensee Involved:
Name: **The Board of Regents of the University of Michigan**
Address: **1239 Kipke Drive, Ann Arbor, Michigan**

RSO: **Mark L. Driscoll** Telephone: **(734) 647-2251**

Authorized User: **Mary Feng, M.D.** Telephone: **(734) 936-4300**
Authorized Medical Physicists: **Joann Prisciandaro, Ph.D.** Telephone: **(734) 936-4309**
Interventional Radiologist: **Paula Novelli, M.D.** Telephone: **(734) 615-2890**

NRC License No.: **21-00215-04** Docket No.: **030-01988**

Name and Title of Licensee contact: **Dennis Palmieri, Senior Health Physicist**
Telephone: **(734) 764-9182**

Description of Incident:

On March 9, 2011, the licensee performed an infusion of Yittrium-90 (Y-90) TheraSpheres, as a brachytherapy treatment, into the left lateral lobe of an adult male patient's liver. An incorrect liver volume was used to calculate the activity needed to deliver the dose to the left lateral lobe of the liver. Specifically, the licensee had intended to deliver 60.5 millicuries of Y-90 to the left lateral lobe of the liver with a volume of 1333.64 cc. However, the actual left lateral lobe of the liver had a volume of 637 cc. The intended radiation dose was 74.4 Gray (Gy) to the left lateral lobe of the liver. The actual dose delivered to the left lateral lobe of the liver was estimated at 159.4 Gy.

The licensee believes there were four reasons for the error: 1) the patient had received more than one Y-90 treatment and the Interventional Radiologist Worksheet was not adequate to address multiple Y-90 treatments for the same patient; 2) the patient lived a significant distance from the hospital and was substantially ill; this caused the licensee to perform the multiple treatments with a single preparatory evaluation; 3) the prescribing physician (authorized user) and medical physicist communicated informally and without sufficient detail regarding the site and parameters relevant to the intended treatment; and 4) a failure of the prescribing physician and second medical physicist to comprehensively review the draft written directive in its entirety.

Patient and referring physician have been informed of the incident.