**UNITED STATES**
**NUCLEAR REGULATORY COMMISSION**
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

October 4, 2000

Daniel F. Flynn, M.D.
Radiation Oncologist
Holy Family Hospital and Medical Center
70 East Street
Methuen, MA 01844-4597

Dear Dr. Flynn:

This letter is to confirm your telephone agreement with Mr. Tom Thomson on September 24, 2000, that you will assist this U.S. Nuclear Regulatory Commission regional office by serving as a physician consultant with respect to two misadministrations described in Enclosure 1. A Charter detailing the tasks that should be completed under this contract is provided as Enclosure 2. Please note that you should not evaluate the appropriateness of the prescribed treatment or its medical effectiveness. If you encounter difficulty in completing these tasks or identify additional tasks that should be performed, please contact Neelam Bhalla, the NRC office contact for this matter, at (610)337-5188.

Ms. Bhalla 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. Also, please notify Ms. Bhalla if you are performing work for other Federal departments or agencies.

It is our understanding that you will not conduct an onsite visit. Your evaluation of the incident shall include a review of all pertinent documents available, regardless of whether an onsite visit is conducted.

The licensee, Sibley Memorial Hospital, has been notified by our office of your participation in this incident evaluation and has been asked to contact the individual's physician and/or the referring physician, regarding your involvement in NRC activities.

Enclosure 5 contains a brief summary of the U.S. Department of Energy (DOE), Office of Epidemiology and Health Surveillance Long-Term Medical Study Program. DOE sponsors this lifetime morbidity study of personnel involved in radiation accidents through the Radiation Emergency Assistance Center/Training Site (REAC/TS) of the Oak Ridge Institute of Science and Education (ORISE). NRC will provide information on the Study to the individual's physician or referring physician, after NRC has investigated the incident. However, you may want to discuss this information with the individual's physician or referring physician.

Please inform Ms. Bhalla when you have completed the tasks specified in the Charter. A report of your findings and conclusions shall be provided to us within 30 calendar days, of the completion of the case review, unless there are extenuating circumstances which have been discussed with Ms. Bhalla before the 30 day period ends.

Please follow the instructions provided in the Charter when preparing and submitting claims for reimbursement. These claims should be submitted on a monthly basis (Enclosure 7) but no later than 30 days after the completion of your report. You should submit your voucher to Ms. Bhalla.

Thank you for your assistance in this matter. I can be reached by telephone at (610)337-5209 or by facsimile at (610)337-5269.

Thank you for your cooperation.

Sincerely,

***Original signed by Mohamed M. Shanbaky***

Mohamed M. Shanbaky, Chief
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

Enclosures:
1. Description of the Incident, and the licensee's incident report
2. Charter for Physician Consultants
3. Medical Consultant Liability
4. Restrictions on Service with Other Federal Departments and Agencies
5. Summary of U.S. Department of Energy Office of Epidemiology and Health Surveillance Long-Term Medical Study Program
6. Medical Consultant Report
7. NRC Form 148, "Voucher for Professional Services"

Distribution: w/encl 1 only
Susan Greene, NMSS/ Misadministration Coordinator
Robert Gross, DRM, Region 1

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# Enclosure 1

DESCRIPTION OF THE INCIDENTS

NRC Regional Office: Region I
King of Prussia, PA

Date of The Incidents: September 15-20, 2000

Medical Consultant: Daniel F. Flynn, M.D.
Specialty: Radiation Oncology

Description of The Incident:

Licensee: Sibley Memorial Hospital
Division of Radiation Oncology
5255 Loughboro Road, N.W.
Washington, D.C. 20016

License No.: 08-07398-03
Docket No.: 030-14754

Contact: Gregory S. Sibley, M.D., Radiation Oncologist, @ (202) 537-4788
Sonya Cong, Ph.D., Medical Physicist, @ (202) 537-4787

SUBJECT: TWO MISADMINISTRATIONS INVOLVING I-125 EYE PLAQUE BRACHYTHERAPY IMPLANTS

On September 22, 2000, the licensee notified NRC Region I that it identified two potential misadministrations involving two patients that were treated with Iodine-125 (I-125) temporary brachytherapy eye implants. Both patients were prescribed a dose of 7000 centiGray (cGy) and their treatments started on September 15, 2000. On September 20, 2000, the eye plaques were removed at the conclusion of the treatment. The licensee reported that due to a calculation error, both patients received higher than the planned dose of 7000 cGy. The error resulted in an administered dose of 11,470 cGy to one patient and 10,866 cGy to the other patient. The error was made in converting the Air-Kerma strength of the I-125 sources to millicuries. The licensee's treatment planning system is in Air-Kerma units, whereas the vendor requires the order to be placed in millicuries. The licensee stated that to convert I-125 source strength from Air-Kerma to millicuries, Air-Kerma value is divided by a conversion factor of 1.27. However, the dosimetrist erroneously multiplied the conversion factor to obtain the source strength and that resulted in the two misadministrations. The error was identified on September 22, when the physicist recognized that the dosimetrist was ordering seeds for an upcoming case with an activity that was higher than expected. The conversion error was recognized and all I-125 cases were reviewed. The review process identified the two misadministrations and three recordable events (described below).

The licensee stated that it has suspended future treatments with this modality until further notice. The licensee, in its written report dated September 25, 2000, (as required by 10 CFR 35.33) has submitted its planned corrective actions to prevent potential errors in the future.

The NRC performed an inspection to evaluate the circumstances under which the misadministrations occurred. In its review of the program, the inspector noted that the licensee identified three recordable events involving the eye plaque treatments that were performed in April 2000. The recordable events occurred when the patients were planned to be treated for five days (120 hours), however, the implants were removed after four days of treatment. The error that Monday-Friday treatment would be a four-day treatment (implants started during the day on Monday, April 24, 2000 and explanted during the day on Friday, April 28, 2000) instead of the required five day (120 hours) treatment was not identified by the authorized physician or the support staff (physicist and dosimetrist) until September. A QMP audit in September 2000, identified the error and the consequent under-dosing of the patients by 12-15 percent of the prescribed dose.