

November 6, 2007

Subir Nag, M.D.
[HOME ADDRESS DELETED
UNDER 10 CFR 2.390]

Dear Dr. Nag:

This letter is to confirm your agreement during a November 1, 2007, telephone call with Mr. Robert Gattone of my staff, to assist the U.S. Nuclear Regulatory Commission (NRC) Region III Office by serving as a physician consultant with respect to the incident described in Enclosure 1. A Charter detailing the tasks that should be completed under this contract is provided in Enclosure 2. Please note that it is not the NRC's intent through this contract or 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 the tasks outlined in the Charter or identify additional tasks that should be performed, please contact Mr. John Madera, the NRC regional contact for this matter. Mr. Madera 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. Madera if you are currently performing work for other Federal departments or agencies.

It is our understanding, based on the telephone agreement of November 1, 2007, that you will not conduct an on-site visit. Your evaluation of the incident shall include a review of all pertinent documents available, regardless of whether an on-site visit is conducted. The licensee (Oncology Institute of Greater Lafayette) has been notified by our office of your participation in this incident evaluation and has been asked to contact the individual's physician(s) 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'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. Madera when you have completed the tasks specified in the Charter. A report of your findings and conclusions (Enclosure 6) 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 Mr. Madera before the 30-day period ends. Please note that your report will be an official Agency record, and will be released to the public. Thus, it is important that all confidential information be kept out of your report.

S. Nag

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

Thank you for your assistance in this matter. Mr. Madera can be reached by telephone at (630) 829-9834, FAX (630) 515-1259, or by e-mail at jrm4@nrc.gov.

Sincerely,

/RA by K. O'Brien Acting for/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

License No.: 13-32087-01

Docket No.: 030-34812

Enclosures:

1. Summary of the Event
2. Medical Consultant Charter
3. Medical Consultant Liability
4. Restrictions on Service with Other Federal Departments or Agencies
5. Summary of U.S. Department of Energy, Office of Epidemiology and Health Surveillance's Long-Term Medical Study Program
6. Medical Consultant Report Form
7. NRC Procedure for Notifying the Referring or Individual's Physician of the U.S. Department of Energy Long-Term Medical Study Program
8. NRC Form 148, Voucher for Professional Services
9. NRC Form 64/64A/64B, Travel Voucher (non-local travel)
10. SF1164, Claim for Reimbursement for Expenditures on Official Business (local travel)
11. SF 1034, Public Voucher for Purchases and Services Other than Personal

bcc w/encls 1 & 2: Greg Morrell, NMSS

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OFFICE	RIII		RIII		RIII		RIII	
NAME	RGGattone		JRMadera		SAReynolds by K. O'Brien for			
DATE	11/06/07		11/06/07		11/06/07			

OFFICIAL RECORD COPY

SUMMARY OF THE EVENT

POTENTIAL MEDICAL EVENT

A patient received a series of three vaginal cylinder HDR treatments on August 14, 2007, August 28, 2007, and September 11, 2007, at the Arnett Cancer Care Center (also known as the Oncology Institute of Greater Lafayette, which is the name on their license). The treatment was planned with a source spacing of 5 millimeters. The electronic transfer of source spacing from the treatment planning computer to the treatment unit did not function properly and the source spacing information was entered into the treatment console manually. As a result, an incorrect source spacing of 2.5 millimeters was used. The dose distribution was different than planned due to the spacing difference, but the overall dose was correct. The prescribed dose per fraction was 700 cGray using an Ir-192 source with 13 dwell positions spaced 5 millimeters apart.

The physician has been notified and does not believe that there will be any adverse effects to the patient. At this time the patient has not been notified, but the licensee is attempting to contact her to inform her that the overall dose was delivered differently than planned.

The licensee has taken corrective action to set the device default spacing at 5 millimeters and they will be revising their procedures to prevent reoccurrence. An inspection by the NRC Region III inspector (Bob Gattone) on October 16, 2007, discovered the source spacing error.

A "Medical Event" may indicate potential problems in a medical facility's use of radioactive materials. It does not necessarily result in harm to the patient.

MEDICAL CONSULTANT CHARTER

A. GENERAL INFORMATION

The U. S. Nuclear Regulatory Commission's (NRC's) authority and responsibility for conducting special inspections of radiation exposure incidents are provided under the Atomic Energy Act of 1954, as amended, and under the Energy Reorganization Act of 1974. The purpose of these inspections is to ascertain the facts and other related information surrounding the incident. This may involve the following tasks: determining the circumstances surrounding the incident and the root cause of the incident; evaluating the actions taken by the licensee at the time of the incident, in providing medical care to exposed persons; evaluating corrective actions taken by the licensee to preclude future similar incidents; verifying or estimating dose(s), to the exposed individual(s); evaluating the probable deterministic effects of the exposure; evaluating the notifications made by the licensee, and the licensee's follow-up plan, if available; and gathering evidence to support any necessary enforcement actions by NRC.

B. SPECIFIC GUIDANCE AND TASKS TO BE PERFORMED

1. The medical consultant shall not do the following (as applicable to the specific situation):
 - a. Enter into a physician-patient relationship with the exposed individual.
 - b. Provide medical opinions or recommendations to anyone other than NRC, without NRC's written permission, unless compelled by legal process to do so. To minimize the risk of liability, any recommendations made by a medical consultant should be accompanied by a disclaimer that the recommendation is not a substitute for the professional judgment of any physician involved with, or responsible for, the patient's or individual's care.
 - c. Recommend a particular expert. The medical consultant may indicate that the services of an expert are needed, and if asked, the consultant may identify, after consultation with NRC management, sources for identification and location of such experts. Recommendations will be in accordance with 5 CFR 2635.702, which prohibits Federal employees from using public office for the endorsement of any product, service, or enterprise. Information on 5 CFR 2635.702 is available from the regional contact listed in the cover letter.
 - d. Divulge or make known to the licensee, individual, individual's physician, or referring physician any official findings or conclusions resulting from the NRC inspection, without NRC's permission.
 - e. Evaluate the appropriateness of the prescribed treatment or its medical effectiveness (medical events), or provide an opinion on how the facility should operate.
 - f. Volunteer advice to the licensee about corrective actions to be taken by the licensee.
 - g. Determine if an incident is a medical event.

2. The medical consultant shall do the following (as applicable to the specific situation):
 - a. Act for, and on behalf of, the Commission, to gather medical information for the evaluation of the effects of radiation exposure on those exposed to radiation.
 - b. Assist in NRC inspection/investigative activities related to radiation exposure incidents.
 - c. Provide the date of any on-site visits at the licensee's facility, to the NRC regional contact, as soon as a visit has been scheduled.
 - d. Gather information regarding the circumstances surrounding the incident, to assist in determining the root cause(s).
 - e. Provide a professional opinion/estimate on the magnitude of the radiation dose to the exposed individual(s), and the probable error associated with the estimation of the dose. If necessary, request that the licensee and/or individual's physician furnish information on bioassays, medical history, written directive, physical examinations, and other pertinent laboratory work, etc.
 - f. Assess any probable deterministic effects on the exposed individual(s).
 - g. Evaluate the medical data provided by each exposed individual's physician and interpret the results for the NRC regional office staff; keep the NRC regional or Headquarters staff informed (as appropriate) of the medical condition of the individual.
 - h. Evaluate the promptness and effectiveness of the licensee's immediate actions, in response to the incident, and corrective actions to prevent recurrence.
 - i. For medical events, gather information regarding the radiation dose actually received by the patient, as compared with the prescribed dose, to determine whether the medical event was medically or biologically significant.
 - j. For medical events, evaluate the licensee's notification to the exposed individual or individual's responsible relative or guardian or, alternatively, the licensee's reason for not informing the individual or individual's responsible relative of the medical event.
 - k. Review and evaluate the report (to individuals of exceeding dose limits) submitted by the licensee under 10 CFR 20.2205 (non-medical event) or 10 CFR Part 35 (medical event) to include an evaluation of the licensee's description of the incident, immediate actions taken in response to the incident, steps taken or proposed regarding long-term corrective actions to prevent recurrence, and the probable effects on the exposed individual.
 - l. Evaluate the licensee's plan for exposed individual follow-up, if available.
 - m. Prepare and submit, to the NRC regional office, a report of findings and conclusions, within 30 calendar days of completion of the case review and/or site visit, unless there are extenuating circumstances. These circumstances should be communicated to NRC regional management as soon as they are discovered. If information is discovered that is directly relevant to a potential violation of NRC regulations, it should be promptly communicated to NRC.

- n. The report may be submitted on the "Medical Consultant Report" form. If the form is not used to submit the findings, you shall, at a minimum, address the items listed on the form.
- o. By no later than noon on the second Thursday of each pay period, complete and sign NRC Form 148, "Voucher for Professional Services." Provide details of the work performed during the pay period on Form 148 or complete a separate additional sheet. Send Form 148 and the summary of work performed via FAX to the FSME Coordinator. Within three business days of sending out the FAX, the consultant should mail (regular mail) the original signed Form 148 to the designated timekeeper for permanent retention.
- p. Complete and sign the NRC Form 148, "Voucher for Professional Services," along with a detailed summary of work assignments. The summary of work performed may be detailed directly on NRC Form 148 or it may be submitted on a separate sheet. Fax the signed NRC Form 148 and summary of work performed to the to the NRC regional contact by noon on the second Thursday of the pay period for which the requested tasks were completed. Mail the original signed Form 148 to the designated NRC HQ timekeeper within three business days of sending the fax.
- q. Prepare and submit NRC Form 64/64A, "Travel Voucher" (non-local travel) or SF1164, "Claim for Reimbursement for Expenditures on Official Business" (local travel) to the NRC regional contact for expenses incurred during days/hours worked in the region or Headquarters.

NOTE: The regional offices shall make travel arrangements through an NRC travel request (NRC Form-279).

- r. Prepare and submit SF 1034, "Public Voucher for Purchases and Services Other Than Personal," to the NRC regional contact, for administrative expenses other than those associated with salary and travel.
 - s. Furnish expert testimony at inquiries or hearings and participate in selected conferences on bioeffects of radiation and radioactive materials.
3. The medical consultant may consider doing the following:

Informing the referring or individual's physician of the U.S. Department of Energy, Office of Epidemiology and Health Surveillance's Long-Term Medical Study Program. This life-time morbidity study of personnel involved in radiation incidents is maintained by the Radiation Emergency Assistance Center/Training Site of the Oak Ridge Institute of Science and Education. Information on the study is attached to the confirmation letter.

NOTE: NRC will make the referring or individual's physician aware of the study if the consultant does not inform the physician.

END