

November 1, 2006

Ronald E. Goans, Ph.D., M.D.  
[HOME ADDRESS DELETED  
UNDER 10 CFR 2.390]

Dear Dr. Goans:

This letter is to confirm your agreement during an October 30, 2006, telephone call with Mr. Darrel Wiedeman 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. Kenneth Lambert, the NRC regional contact for this matter. Mr. Lambert 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. Lambert if you are currently performing work for other Federal departments or agencies.

It is our understanding, based on our telephone agreement of October 30, 2006, 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 (St. Lukes Hospital of Kansas City) 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. Lambert 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. Lambert 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.

R. Goans, M.D.

-2-

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. Lambert.

Thank you for your assistance in this matter. Mr. Lambert can be reached by telephone at (630) 829-9633, FAX (630) 515-1259, or by e-mail at [kjl@nrc.gov](mailto:kjl@nrc.gov).

Sincerely,

*/RA/*

Steven A. Reynolds, Director  
Division of Nuclear Materials Safety

License No.: 24-00889-01  
Docket No.: 030-02286

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, 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

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OFFICE	RIII	RIII	RIII	RIII
NAME	DGWiedeman:mb	KJLambert	SAReynolds	
DATE	10/31/06	10/31/06	11/01/06	

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## SUMMARY OF EVENT

### DESCRIPTION:

The licensee notified the NRC that on October 27, 2006, they discovered a medical event involving a high dose-rate remote afterloader (HDR) breast therapy (MammoSite®). At the time of the event the HDR contained approximately 3.9 curies of iridium-192. The physicist noted that the first (most distal) source position was different from previous treatments. A subsequent investigation by the licensee into the differences in the source positions, revealed that the usable catheter length entered into the treatment planning computer was 93.0 cm rather than the correct value of 95 cm. This error in catheter length was used for the first seven treatments until the error was discovered. It is currently believed that a typographical error occurred in entering the usable catheter length into the treatment planning computer. The licensee's calculations indicate that the area proximal to the treatment site received a dose of 10,000 cGy rather than the expected dose of 2,450 cGy. Both the patient and the referring physician have been notified of the error.

### Licensee Contact Information:

Gregory Sackett, M.S., Radiation Safety Officer  
Phone No. (816) 932-2000

Susan Smith, M.D., Radiation Oncologist  
Phone No. (816) 932-2575

John Erb, Ph.D, Chief Medical Physicist  
Phone No. (816) 932-2575

## 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.

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.
  - 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 misadministration 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 misadministration.
  - 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.

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.

- n. Promptly prepare and submit NRC Form 148, "Voucher for Professional Services," to the NRC regional contact, indicating days/hours claimed. Per NRC Management Directive 10.6, "Use of Consultants and Experts," these vouchers should be submitted monthly when work is performed.
- o. 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).

- p. 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.
- q. 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 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.