October 21, 2008

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

Dear Dr. Goans:

This letter is to confirm our telephone agreement of October 21, 2008, that you will assist this U.S. Nuclear Regulatory Commission (NRC) regional office by serving as a physician consultant with respect to the incident described in Enclosure 1. It was our understanding that you will provide additional consultation assistance to this office and expand your review of ten additional reported medical events. It was also agreed that your continued services are an addendum to our original request as described in our letter to you dated September 23, 2008. A Charter detailing the tasks that should be completed under this contract is provided in 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 your NRC regional contact for this matter. This individual 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 restrictions on service with other Federal departments or agencies. Please notify your NRC regional contact if you are currently performing work for other Federal departments or agencies.

It is our understanding, based on our telephone agreement of October 21, 2008, that it may not be necessary to 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.

Department of Veterans Affairs Medical Center, Philadelphia, Pennsylvania 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.

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 and Criteria for Selection of Cases for Long-term Medical Study Program. 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. 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 your NRC regional contact when you have completed the tasks specified in the Charter. A report of your findings and conclusions (Enclosure 7) shall be provided to us within 30 calendar days of the completion of the case review and/or site visit, unless there are extenuating circumstances that have been discussed with your NRC regional 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. Thus, 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.

Thank you for your assistance in this matter. The NRC regional contact for this case is Darrel Wiedeman. Mr. Wiedeman can be reached by telephone at (630) 829-9808, by FAX at (630) 515-1259, or by e-mail at Darrel.Wiedeman@nrc.gov.

Sincerely,

/RA/

Patricia J. Pelke, Chief
Materials Licensing Branch

License No.: 03-23853-01VA
Docket No.: 030-34325

Enclosures:
1. Preliminary Description of Incident Form
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. Criteria for Selection of Cases for Long-Term Medical Study Program
7. Medical Consultant Report
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. SF1034, Public Voucher for Purchases and Services Other Than Personal
12. Chronology for Medical Events

DOCUMENT NAME: G:\SEC\Work in progress\VA- Med Consult letter.doc
□ Publicly Available X Non-Publicly Available X Sensitive □ Non-Sensitive
To receive a copy of this document, indicate in the concurrence box "C" = Copy without attach/encl "E" = Copy with attach/encl "N" = No copy

OFFICE	RIII		RIII		RIII		RIII	
NAME	DGWiedeman:mb		CFFrazier by PJP for		PJPelke			
DATE	10/21/08		10/21/08		10/21/08			

OFFICIAL RECORD COPY

PRELIMINARY DESCRIPTION OF INCIDENT FORM
(provide additional information on separate sheet)

********IMPORTANT********
REDACT INFORMATION FROM DOCUMENT
(WHICH IS EXEMPT FROM DISCLOSURE UNDER 10 CFR 2.790)
THEN RELEASE THE DOCUMENT

Nuclear Regulatory Commission Regional Office: **RIII**

Date of Incident: 2/25/2002 through 5/06/2008
Date of Notification: (initial) 5/15/2008, updated on 10/02/2008

NRC Inspector (Regional Contact): Darrel Wiedeman
Telephone number: (630) 829-9808

Medical Consultant: Ronald Goans, Ph.D., M.D.
Specialty:

Licensee Involved (If more than one licensee is involved, provide a separate enclosure for each):

Name: Department of Veterans Affairs
Medical Center, Philadelphia, PA

Amit Maity, M.D., Radiation Oncologist

Address: 3900 Woodland Ave.
Philadelphia, PA

Telephone: (215) 823-5855
AMP: Paula Salanitro, M.S.
Telephone: (610) 237-5071 (Tues-Friday)
Cell Phone: (484) 678-3431

RSO: Mary Moore
Telephone Number: (215) 823-6009

NRC License No. 03-23853-01VA Docket No. 030-34325

Name and Title of Licensee contact: Mary Moore, RSO
Telephone Number: (215) 823-6009

Provide a preliminary description of the incident(s) and a summary of the known circumstances resulting in radiation exposure, including all known radionuclides and activities:

DESCRIPTION OF EVENT:

This licensee is a Department of Veterans Affairs Master Materials License (MML) that is administered through the VA National Health Physics Program (NHPP). The VA Medical Center Philadelphia is one of many permits issued under the MML.

The licensee notified NRC that an additional 37 medical events were identified. Thirty-five (35) of these additional reported medical events involve a dose to an organ or tissue other than the treatment site that exceeds 50 rem to an organ or tissue and 50 percent or more of a dose

expected from the administration as defined in the written directive. Specifically, these reported medical events involve excessive doses to either the rectum, perineum and /or bladder. As of October 2, 2008, the permittee has identified 57 medical events due to under dosing the prostate and 35 additional medical events due to excessive doses from misplaced implanted seeds. This brings the total number of reportable events to 92 cases. This VA Medical Center suspended its prostate brachytherapy program on June 11, 2008. Patient pre-treatment and post-treatment brachytherapy plans for the following patients will be forwarded to you under separate cover:
XRT 011, 012, 018, 019 022, 067, 088, 089, 092 and 103.

END

Enclosure 1

********IMPORTANT********

REDACT INFORMATION FROM DOCUMENT
(WHICH IS EXEMPT FROM DISCLOSURE UNDER 10 CFR 2.790)
THEN RELEASE THE DOCUMENT

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 an 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 <u>may consider</u> 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

MEDICAL CONSULTANT LIABILITY

Medical consultants who are appointed as Special Government Employees are considered to be Federal employees. When a Federal employee is personally sued for a common law tort committed within the scope of employment, the United States will be substituted as the defendant pursuant to the Federal Tort Claims Act. Government counsel will defend the suit on behalf of the United States. The United States will be responsible for any damages that might be awarded. In addition, the consultant would have absolute personal immunity for injury or damage arising from common law torts. A Federal employee (including present and former employees) may also be provided personal representation by the Government in a proceeding in which he or she is sued, subpoenaed, or charged in his or her individual capacity, provided the actions for which representation is requested reasonably appear to have been performed within the scope of the employee's appointment, and representation is in the interest of the United States.

The consultant's provision of professional opinions and recommendations to the U.S. Nuclear Regulatory Commission does not constitute "practice of medicine" within the scope of State licensing laws, provided the consultant does not enter into a physician-patient relationship with the patient [omit this paragraph for non-medical events].

END

RESTRICTIONS ON SERVICE WITH OTHER FEDERAL DEPARTMENTS OR AGENCIES

An employee who serves two or more Federal Departments or agencies is required to inform each of his or her arrangement(s) with the other. If the individual's appointments are made on the same date, the aggregate of the estimates of the days of services will determine the decision, by each agency, as to whether the individual is "Regular" or "Special." If, after being employed by one department or agency, a Special Government Employee is appointed by another agency, the second agency must make an estimate of the individual's days of service for the remaining portion of the 365-day period which was initiated by the first appointment. The sum of the estimate and of the actual number of days of service to other departments or agencies, during the prior portion of such 365-day period, will determine whether the individual is "Regular" or "Special." Close coordination between the agencies and the appointee must be maintained to ensure that the 130-day limitation is not inadvertently exceeded.

END

SUMMARY OF U. S. DEPARTMENT OF ENERGY, OFFICE OF EPIDEMIOLOGY AND HEALTH SURVEILLANCE'S LONG-TERM MEDICAL STUDY PROGRAM

The Office of Epidemiology and Health Surveillance of the U. S. Department of Energy (DOE) sponsors a voluntary life-time morbidity study of personnel involved in radiation incidents, which is maintained by the Radiation Emergency Assistance Center/Training Site (REAC/TS). This study includes the gathering of clinical and epidemiological data at an early stage, after a significant exposure to radiation, and continues throughout the lifetime of the individual involved. The purpose of this study is to compile the best human radiobiological data available for improving immediate medical care, to develop the best prophylactic and anticipatory care for possible late effects, and to upgrade the basis for radiation risk estimates.

Personnel sought to participate in the study are those involved in a radiation incident or medical event during which one or more persons received radiation exposure that equals or exceeds the selection criteria listed in the accompanying table. If an individual is willing to participate in the study, direct contact with the individual will be made by the DOE contractor, at which time the details of the program will be explained fully, a consent form will be signed, and a schedule for future contacts will be arranged.

Generally, the follow-up program will consist of obtaining copies of all medical records associated with the treatment of the individual immediately after the incident and then annual contacts with the individual to follow his/her medical history. Initially, the types of information sought will include a complete medical history before and after the incident or medical event and copies of all relevant hospital, laboratory, and physicians' records covering the period of observation. The annual contact will be made to determine whether the individual has had any illnesses or physical examinations during the year and to obtain additional medical records as they appear to relate to the radiation exposure.

Participation in the follow-up program is totally voluntary and individuals may stop their participation at any time. The medical information obtained during participation is covered by legal constraints to protect the identity and privacy of living participants. Any expenses involved in providing medical records to the follow-up program are borne by the DOE long-term medical study program, not the individual. Any expenses for either short- or long-term medical care of the individual are the responsibility of the program participant and not the responsibility of DOE, Oak Ridge Institute for Science and Education, or REAC/TS.

REAC/TS Contact: Dr. Robert C. Ricks, Director REAC/TS
(865) 576-3131

CRITERIA FOR SELECTION OF CASES FOR LONG-TERM MEDICAL STUDY PROGRAM

Condition	Criteria
Dose to whole body, active blood-forming organs or gonads	Greater than or equal to 0.25 Sievert (Sv) (25 rem).
Dose to skin of whole body or extremities	Greater than or equal to 6 Sv (600 rem).
Dose to other tissues or organs from external source	Greater than or equal to 0.75 Sv (75 rem).
Internal burdens	Greater than or equal to 50% of NCRP* Permissible Body Burden.
Medical Event	Medical Events as defined in 10 CFR 35.2 where the patient has received an administered dose greater than that prescribed.

*National Council on Radiation Protection and Measurement

END