JUN 17 1994

Daniel F. Flynn, M.D.
Holy Family Medical Center
70 East Street
Methuen, MA 01844

Dear Dr. Flynn:

This letter is to confirm our telephone agreement of June 16, 1994, that you will assist the NRC Region III Office by serving as a physician consultant with respect to the matter described in Enclosure 1. A Charter detailing the tasks that should be completed under this contract is provided as Enclosure 2. If you encounter difficulty in completing these tasks or identify additional tasks that should be performed please contact John D. Jones, the Region III contact for this matter. In addition, please note the information in Enclosure 3 regarding service with other Federal Departments or Agencies. Please notify Mr. Jones if you are currently performing work for other Federal Departments or Agencies.

Your evaluation shall include a review of any pertinent documents available. Please contact Mr. Jones if, in your opinion, an on-site visit is warranted.

The licensee, Lucie Lee Hospital at Popular Bluff Missouri, has been notified by our office of your participation in this incident evaluation and has been asked to contact the physicians of the individual in question regarding your involvement.

Enclosure 4 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 life-time morbidity study of personnel involved in radiation incidents 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 physicians after the NRC has investigated the incident. However, you may want to discuss this information with the individual's physicians.

Please inform Mr. Jones 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 tasks. In order to expedite payment, please follow the enclosed instructions in preparing and submitting claims for reimbursement. These claims should be submitted on a monthly basis. You should submit your voucher to Mr. Jones at the Region III Office.

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Thank you for your assistance in this matter. Mr. Jones can be contacted at 708/829-9832. His fax number is 708/515-1259.

Sincerely,

Original Signed by Roy J. Caniano

W. L. Axelson, Director
Division of Radiation Safety
and Safeguards

Enclosures:
1. Description of Incident
2. Charter for Physician Consultants
3. Restrictions on Service with Other Federal Departments or Agencies
4. Summary of U.S. Department of Energy Office of Epidemiology and Health Surveillance Long Term Medical Study Program
5. NRC Form 148, "Voucher for Professional Services"

cc w/enclosures:
Dennis Serig, NMSS/IMOB

RIII	RIII	RIII	RIII
Jones/jaw	Grobe 6/17/94	Caniano	Axelson

Enclosure 1

PRELIMINARY DESCRIPTION OF INCIDENT

NRC Regional Office Region III Date of Incident 6/14/94

Medical Consultant Daniel F. Flynn, M.D.

Specialty Radiation Therapy

Name, address, and phone number of organization involved:

Blodgett Memorial Medical Center License No. 21-01424-03
Midland, MI

Docket No. 030-02008

Name, phone number, and title of licensee contacts:

Armond Lasorsa, M.D.
616-774-7845
Radiation Safety Officer

Preliminary description of incident and summary of known circumstances resulting in radiation exposure including all known radionuclides and activities.

On June 14, 1994, a misadministration occurred during the second of a series of three treatments to a eye surface lesion using a strontium-90 eye applicator. The applicator contains a sealed source of 50 millicuries of strontium-90. The patient was to receive 2550 rads (25.5 gray) in a series of three equal treatments. The first treatment was performed as intended. During the second treatment, the treatment time of 19.1 seconds in the written directive was misread, and the patient received treatment for 1 minute and 9 seconds.

The second treatment dose was 3068 rads (30.68 gray) instead of the intended 850 rad (8.5 gray) dose. The third treatment was not administered. Therefore, the patient's eye received a total dose of 3918 rads (39.18 gray), which was 53.6 percent above the total intended dose.

The patient and referring physician have been informed. The licensee states that it does not expect any adverse medical consequences of the misadministration.

Enclosure 2

PHYSICIAN CONSULTANT CHARTER

A. GENERAL INFORMATION

The Nuclear Regulatory Commission's (NRC) authority and responsibility for conducting special inspections of radiation exposure incidents are provided under of 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 short-term medical care to exposed persons, evaluating corrective actions taken by the licensee to preclude future similar incidents, verifying or estimating dose to the exposed individual(s), evaluating biological effects of the exposure, evaluations of licensee's patient notification and follow-up plan, if available, and gathering evidence to support any necessary enforcement actions by the NRC.

B. SPECIFIC GUIDANCE AND TASKS TO BE PERFORMED

1. The physician consultant <u>shall not</u> do the following:

   a. Volunteer medical advice to the licensee, the individual(s), or the individual's physician. However, consistent with medical ethics, if it appears that the services of an expert in the medical care of radiation injuries are advisable, the physician consultant may recommend experts. The consultant must obtain written approval from NRC prior to recommending services of an expert, to the licensee or to the patient's physician.

   b. Divulge or make known to the licensee, exposed individual(s), or individual's physician, or any other person or individual, any official findings or conclusions resulting from the NRC inspection without the express, written permission of the NRC.

   c. Evaluate the appropriateness of the prescribed treatment, or its medical effectiveness.

   d. Volunteer advice regarding corrective actions to be taken by the licensee.

2. The physician consultant <u>shall</u> do the following:

   a. If an on-site visit will be performed, the consultant shall provide the date of the on-site visit to the NRC regional contact as soon as the visit has been scheduled.

   b. Gather information regarding the radiation dose and medical condition of the individual through discussions with appropriate physicians and support personnel <u>and</u> a review of applicable records. 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.

c. Gather information regarding the circumstances surrounding the incident to determine the root cause; evaluate the licensee's immediate actions in response to the incident and corrective actions to prevent recurrence; evaluate the licensee's notification to the exposed patient or the patient's responsible relative or guardian, and evaluate the licensee's plan for patient follow up, if available.

d. Provide an opinion on whether this incident constitutes a misadministration pursuant to the definition in 10 CFR 35.2.

e. Assess any short term (i.e., 6 months) and any long-term effects on the patient. Evaluate how long the patient should be followed to determine direct effects.

f. Review and evaluate report(s) submitted by the licensee.

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 and the course of the short-term medical care being provided.

h. Prepare and submit to the NRC regional office a report of findings and conclusions within 30 calendar days of the completion of assigned duties. If information is discovered that is directly relevant to a potential violation of NRC regulations, it should be promptly communicated to the NRC.

   The report may be submitted on the enclosed report form. If the enclosed form is not used to submit the findings, you shall, at a minimum, address the items listed on the form.

i. Promptly prepare and submit NRC Form 148, "Voucher for Professional Services," to the NRC Regional Contact, indicating days/hours for which payment is claimed. Per NRC Manual Chapter 4139, "Utilization of Consultants and Experts," these vouchers should be submitted monthly when work is performed.

j. If appropriate, prepare an NRC Form 64/64A, "Travel Voucher," for expenses incurred during days/hours worked in the Region or Headquarters. The regional offices shall make travel arrangements through an NRC travel request (NRC Form-279). Vouchers should be forwarded to the NRC Regional Contact.

3. The physician consultant may consider performing the following:

a. Informing the individual's physician of the U.S. Department of Energy (DOE), 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 (REAC/TS) of the Oak Ridge Institute of Science and Education (ORISE). Information on the Study is attached to the confirmation letter.

Enclosure 3

RESTRICTIONS ON SERVICE WITH OTHER FEDERAL DEPARTMENTS OR AGENCIES

U.S. Nuclear Regulatory Commission policies and procedures for obtaining the services of consultants are defined in Commission Directives. The following information is contained in the Directive and has direct implications for the physician and scientific consultant[1].

Service with other 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 insure that the 130-day limitation is not inadvertently exceeded.

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[1]Information taken from U.S. Nuclear Regulatory Commission, Management Directive Chapter 4139, Utilization of Consultants, Members, and Other Advisory and Assistance Services, Part I, Appendix D, Paragraph 4.

Enclosure 4

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

The Office of Epidemiology and Health Surveillance (OEHS) of the Department of Energy (DOE) sponsors a voluntary life-time morbidity study of personnel involved in radiation incidents that 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 following 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 bases for radiation risk estimates.

Personnel sought to participate in the study are those involved in a radiation incident or misadministration during which one or more persons received radiation exposure that equals or exceeds the selection criteria listed in this Attachment. The NRC will provide a brief explanation of the program to the exposed individual's physician or the patient and determine whether the exposed individual is willing to participate. If a willingness is expressed, 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 following 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 misadministration 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 program and not the individual.

CRITERIA FOR SELECTION OF CASES FOR LONG-TERM MEDICAL FOLLOW-UP

Condition		Criteria
1.	Dose to whole body, active blood-forming organs, or gonads	> 25 rem (0.25 Sv)
2.	Dose to skin of whole body or extremities	> 600 rem (6 Sv)
3.	Dose to other tissues or organs from external source	> 75 rem (0.75 Sv)
4.	Internal burdens	> 10% NCRP Permissible Body Burden
5.	Medical misadministration	Misadministrations as defined in 10 CFR 35.2

NRC FORM 148
(4-76)
NRCM 4139

U.S. NUCLEAR REGULATORY COMMISSION

UNIT *(OC use only)*

VOUCHER FOR PROFESSIONAL SERVICES

INSTRUCTIONS

This form shall be completed by all NRC consultants for claiming compensation for official authorized personal services. A signed original and two copies should be submitted to the NRC office authorizing the service.

TO: U.S. Nuclear Regulatory Commission			FROM: NAME OF CLAIMANT		
ATTENTION: NRC OFFICE AUTHORIZING THIS SERVICE			STREET ADDRESS		
			CITY	STATE	ZIP CODE
CITY	STATE	ZIP CODE	SOCIAL SECURITY NUMBER		

DESCRIPTION OF CLAIM

(All blocks must be completed)

CONTRACT:	NUMBER	DATE	AMOUNT CLAIMED	
			DOLLARS	CENTS
PERIOD COVERED: *(Dates)*	FROM	TO		
SERVICES PERFORMED: *(Itemize on reverse)*	NUMBER OF DAYS	PER DAY @ $		
	NUMBER OF HOURS	PER HOUR @ $		
RETIRED ANNUITANT: YES ☐ NO ☐		TOTAL AMOUNT CLAIMED		

CERTIFICATION

I CERTIFY that the above account is just and true in all respects; that my statement of services correctly sets forth the services on official business; that the payment therefore has not been received; and that no compensation for any of the time shown above is payable from or will be claimed from any other source of the Federal Government or its cost reimbursable contractors.

(Claimant's Signature)

(Date of Certification)

OFFICE OF THE CONTROLLER USE ONLY

DIFFERENCE		
AMOUNT VERIFIED CORRECT		
SIGNATURE		

APPROVAL

I CERTIFY that the above claim is just; that the above services were officially requested and performed; and that the expenses claimed are authorized.

(Approving Officer's Signature)

(Date Approved)

NRC FORM 148 REPLACES FORM AEC 148 WHICH IS OBSOLETE AND EXISTING STOCK SHOULD BE DESTROYED.