DCD

January 22, 1998

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

Dear Dr. Flynn:

This letter is to confirm the telephone agreement of January 16, 1998, that you will assist the U.S. Nuclear Regulatory Commission (NRC) Region III Office by serving as a physician consultant with respect to the event described in Enclosure 1. A Charter detailing the tasks that should be completed under this contract is provided as Enclosure 2. Please be advised that you should not evaluate the appropriateness of the prescribed treatment or its medical effectiveness.

If you encounter difficulty in completing the tasks outlined in the enclosed Charter or identify additional tasks that should be performed, please contact me regarding this matter. I 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 me if you are currently performing work for other Federal departments or agencies.

Your evaluation shall include a review of any pertinent documents available, regardless of whether an onsite visit is conducted.

The licensee, Washington University and Medical Center, St. Louis, Missouri, has been notified by our office of your participation in this incident evaluation and has been asked to contact the physician(s) of the individual in question 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 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 physician(s) after the NRC has investigated the incident. However, you may want to discuss this information with the individual's physician(s) as well.

Please inform Thomas Young of this office 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 Mr. Young 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 to me on a monthly basis (Enclosure 6) but no later than 30 days after the completion of your report.

280048

IE07

Thank you for your assistance in this matter. Mr. Young can be contacted at (630) 829-9835. Our fax number is (630) 515-1259.

Sincerely,

Original signed by

Geoffrey C. Wright, Chief
Materials Inspection Branch 2

License No. 24-00167-11
Docket No. 030-02271

Enclosures: As stated

bcc w/encls: PUBLIC IE07
Dennis Serig, NMSS

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NAME	YOUNG:dp	E-Y	WRIGHT			
DATE	01/27/98		01/27/98			

OFFICIAL RECORD COPY

Enclosure 1

PRELIMINARY DESCRIPTION OF INCIDENT

NRC Regional Office Region III **Date of Incident** January 15, 1998

NRC Inspector Thomas Young **Phone** (630) 829-9835

Physician Consultant Daniel F. Flynn, M.D. **Phone** (508) 683-9209
Specialty Radiation Therapy

Name, address, and phone number of organization involved:

Washington University and Medical Center
P.O. Box 8053
660 S. Euclid Avenue
St. Louis, Missouri 63110-1093

License No. 24-00167-11
Docket No. 030-02271

Name, phone number, and title of licensee contacts:

John Eichling, Ph.D
Radiation Safety Officer
(314) 362-2988

Jeffrey F. Williamson, Ph.D.
Chief of Brachytherapy Medical Physics
Barnes Hospital, Radiation Oncology Center
(314) 362-2267

Carlos Perez, M.D.
Radiation Oncologist
(314) 362-9700 or -8542

Gill Nussbaum, Ph.D.
Brachytherapy Medical Physicist
(314) 362-2635

John LaSala, M.D.
Cardiologist
(314) 362-3940

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

See attached Preliminary Notification, PNO-III-98-008

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PNO-III-98-008

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by Region III staff (Lisle, Illinois) on this date.

Facility
WASHINGTON UNIVERSITY AND MEDICAL CENTER
Washington University And Medical
St. Louis, Missouri
License No: 24-00167-11

Licensee Emergency Classification
Notification of Unusual Event
Alert
Site Area Emergency
General Emergency
X Not Applicable

Subject: BRACHYTHERAPY MISADMINISTRATION (WRONG TREATMENT SITE)

On January 15, 1998, the licensee treated a patient to prevent restenosis of a coronary artery. The licensee used 12 pellets of strontium-90 (35 millicuries, total) [1.3 gigabecquerels, total] to deliver a radiation dose of 1,400 centigray to the outer wall of the coronary artery at the treatment site. The delivery system consisted of a syringe used to apply hydraulic pressure to saline solution within the double catheter that was used to transport the pellets to the treatment site.

The normal transit time of the pellets from the storage device to the treatment site was three to five seconds. After the three minute treatment time, the physician encountered difficulty in returning the pellets to the storage device so the physician removed the entire catheter containing the pellets from the patient and placed the catheter into a shielded container.

The licensee estimated that the pellets were in the patient about an additional 60 to 90 seconds. The licensee estimated that during the normal transit time, the outer wall of the artery received a radiation dose of about 1 centigray. The licensee estimated that during the additional minute to remove the catheter from the patient, the outer wall of the artery received about 300 centigray. The licensee is still in the process of investigating the cause of this event.

The licensee will notify the treating physician and referring physician and patient.

NRC Region III (Chicago) contacted the NRC Office of Nuclear Materials Safety and Safeguards and the State of Missouri. A medical consultant has agreed to review this matter. An NRC inspector will complete a special inspection of the event within a week. The information in this

preliminary notification was reviewed with licensee management.

NRC Operations Center was notified of this event at 1:30 p.m. ET on January 16, 1998.

This information was current as of 9:00 a.m. (CST) on January 20, 1998.

Contact: THOMAS YOUNG (630)829-9835 JOHN JONES (630)829-9832

Enclosure 2

PHYSICIAN CONSULTANT CHARTER

A. GENERAL INFORMATION

The U.S. Nuclear Regulatory Commission'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 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 physician consultant shall not do the following:

   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 physician 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 physician 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.

f. Volunteer advice about corrective actions to be taken by the licensee.

2. The physician consultant shall do the following:

a. Provide the date of any onsite visits at the licensee's facility, to the NRC regional contact, as soon as a visit has been scheduled.

b. Gather information regarding the circumstances surrounding the incident, to assist in determining the root cause(s).

c. Provide an estimate of the radiation dose to the patient/exposed individual, 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.

d. Assess any probable deterministic effects on the exposed individual/patient.

e. Evaluate the medical data provided by each exposed individual's/patient'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.

f. Evaluate the promptness and effectiveness of the licensee's immediate actions, in response to the incident, and corrective actions to prevent recurrence.

g. 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 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.

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

i. Prepare and submit NRC Form 64/64A, "Travel Voucher," 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.)

j. 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.

k. Evaluate the licensee's notification to the exposed patient or patient's responsible relative or guardian, or, alternatively, the licensee's reason for not informing the patient or patient's responsible relative of the misadministration.

l. Review and evaluate the report submitted by the licensee under 10 CFR 35.33, 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 patient.

m. Evaluate the licensee's plan for patient follow-up, if available.

3. The physician consultant may consider performing 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 (REAC/TS) of the Oak Ridge Institute of Science and Education (ORISE). 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.)

MEDICAL CONSULTANT REPORT

(To Be Completed By Medical Consultant)

Medical Consultant Name: _____ **Report Date:** / /

Signature: _____

Licensee Name: _____ **License No.** _____

Facility Name: _____

Individual's/Patient's Identification No.: _____

Incident Date: / /

Individual's/Patient's Physician Name and address: _____

_____

_____

Referring Physician Name and address: _____
(Medical Misadministration Only) _____ _____

Individuals Contacted During Investigation: _____
(Name and Title) _____

_____

Records Reviewed: (General Description)

Estimated Dose to Individual or Target Organ: _____
Probable Error Associated with Estimation: _____ **Prescribed Dose (Medical Misadministration Only):** _____ **Method Used to Calculate Dose:** _____

_____

Description of Incident:

Assessment of probable deterministic effects of the radiation exposure on the individual:

Briefly describe the current medical condition of the exposed individual:

Was individual or individual's physician informed of DOE Long-Term Medical Study Program?	Y	N
If yes, would the individual like to be included in the Program?	Y	N

COMPLETE FOR MEDICAL MISADMINISTRATION

(To Be Completed by Medical Consultant)

1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to NRC pursuant to 10 CFR 35.33 in the following areas:

a. Why the event occurred	Y	N
b. Effect on the patient	Y	N
c. Licensee's immediate actions upon discovery	Y	N
d. Improvements needed to prevent recurrence	Y	N

2. In areas where you do not agree with the licensee's evaluation (report submitted under 10 CFR 35.33), provide the basis for your opinion:

3. Did the licensee notify the referring physician of the misadministration? Y N

Did the licensee notify the patient's or the patient's responsible relative or guardian? Y N

If the patient or responsible relative or guardian was not notified of the incident, did the licensee provide a reason for not providing notification consistent with 10 CFR 35.33? Y N

Explain rationale for response.

4. Provide an opinion of the licensee's plan for patient follow-up, if available.

Enclosure 3

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.

Enclosure 4

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 a Commission Directive [1]. The following information is contained in the Directive and has direct implications for the physician and scientific consultant.

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 5

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 (OEHS) 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 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 the accompanying table. If a willingness is expressed by an individual 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 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 DOE long-term medical study program and 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.

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

	Condition	Criteria
1.	Dose to whole body, active blood-forming organs, or gonads	Greater than or equal to 25 rem (0.25 Sv)
2.	Dose to skin of whole body or extremities	Greater than or equal to 600 rem (6 Sv)
3.	Dose to other tissues or organs from external source	Greater than or equal to 75 rem (0.75 Sv)
4.	Internal burdens 50% of NCRP [1]	Greater than or equal to Permissible Body Burden
5.	Medical misadministration	Misadministrations as defined in 10 CFR 35.2 where the patient has received an overexposure

[1]National Council on Radiation Protection

Enclosure 6

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)

			AMOUNT CLAIMED	
CONTRACT:	NUMBER	DATE		
PERIOD COVERED: *(Dates)*	FROM	TO	DOLLARS	CENTS
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.

SERVICES PERFORMED

RATE OF COMPENSATION		PLACE (S) OF WORK PERFORMED
PER DAY $	PER HOUR $	

DATE	TIME WORKED OR IN AUTHORIZED STATUS *(Indicate which and a.m. or p.m.)*		
	FROM	TO	TOTAL HOURS

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e) (3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on Form NRC-148. This information is maintained in a system of records designated as NRC-20 and described at 40 Federal Register 45341 (October 1, 1975).

1. AUTHORITY 31 U.S.C. 21, 22, 24, 49, 54, and 66a. Solicitation of the social security number is authorized under Executive Order 9397 dated November 22, 1943.

2. PRINCIPAL PURPOSE(S) Information entered on this form is used to secure payment for authorized claims for compensation.

3. ROUTINE USES Information on this form is used for transmittal to the U.S. Treasury for payment. The information may also be disclosed to an appropriate Federal, State, or local agency in the event the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, and local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.

4. WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION The supplying of this information is voluntary on your part. Failure to supply the information, however, may result in the denial of your claim for compensation. Your social security number is used as an identifier and its use is necessary because of the large number of present and former Federal employees with similar names and birth dates.

5. SYSTEM MANAGER(S) AND ADDRESS Controller, Office of the Controller, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555