

November 4, 1999

Richard Whittington, M.D.
Department of Radiation Oncology
Hospital of the University of Pennsylvania
3400 Spruce Street, 2 Donner
Philadelphia, PA 19104

Dear Dr. Whittington:

In our September 20, 1999, letter to you regarding your serving as a physician consultant, we included as Enclosure 2, a copy of the Charter for Physician Consultants. We recently discovered that we sent you the wrong charter and have enclosed a copy of the correct charter. Please refer to this charter for any further actions associated with the Northern Virginia Radiology and Nuclear Medicine, Inc. case.

Thank you for your assistance in this matter. If you have any questions, Thomas Decker, (404) 562-4721, is the NRC Regional Office contact for this case. Alternatively Jay Henson, (404) 562-4738, may also be contacted.

Sincerely,

Douglas M. Collins, Director
Division of Nuclear Materials Safety

Enclosure: Charter for Physician Consultants

cc w/encl:
Commonwealth of Virginia
Gary Purdy, NMSS

Distribution w/encl:
PUBLIC
RII Docket File, DNMS
D. Collins, RII
C. Hosey, RII
T. Decker, RII
J. Henson, RII

| | | | | | | | |
|--------------|---|---|--|--|--|--|--|
| OFFICE | RII:DNMS | RII:DNMS | | | | | |
| SIGNATURE | | | | | | | |
| NAME | J. Henson | T. Decker | | | | | |
| DATE | 11/4/99 | 11/4/99 | 11/ /99 | 11/ /99 | 11/ /99 | 11/ /99 | 11/ /99 |
| E-MAIL COPY? | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO | <input type="checkbox"/> YES <input type="checkbox"/> NO |

OFFICIAL RECORD COPY

DOCUMENT NAME: G:\NMSSI\DNMS\MLIB1\Whtngtn2.wpd

1207

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 doses 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.

Enclosure

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. Evaluate the medical data provided by each patient's physician and interpret the results for the NRC regional office staff; keep the appropriate NRC regional or Headquarters staff informed of any issues that may be relevant to the medical condition of the individuals involved as a result of the use of mixed isotopes to treat these patients.
 - 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 medical history, written directive, physical examinations, and other pertinent laboratory work, etc.
 - d. Evaluate the information provided in the written directives and other records for each patient treatment and determine if a misadministration occurred because either:
 - (1) the dose was delivered to the wrong treatment site (excluding seeds that were implanted in the correct site but migrated outside the treatment site); or
 - (2) the calculated administered dose differed from the prescribed dose by more than 20 percent of the prescribed dose.
 - e. Gather information regarding the radiation dose actually received by the patients, as compared with the prescribed dose, to determine whether any potential misadministrations were medically or biologically significant.
 - f. Assess any probable deterministic effects on the exposed individual/patient.
 - g. Gather information regarding the circumstances surrounding any identified misadministrations to assist in determining the root cause(s).
 - h. 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.

- i. 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.
 - j. 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.
 - k. 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.
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.)

END