

MEDICAL CONSULTANT REPORT
(To Be Completed By Medical Consultant)
~~Official Use Only~~

Medical Consultant Name: Lois Potters, MD Report Date: 1/27/11
Signature: M.P. As MD

Licensee Name: Patrick W. McLaughlin MD
License No. 21-02802-03 Docket No. 030-02022
Facility Name: Providence Hospital
Incident Date: 8/30/10
Individual's Physician Name: Patrick W. McLaughlin MD
Address: PROVIDENCE HOSPITAL
47601 GRAND RIVER AVE
NOVI, MICHIGAN
Referring Physician's Name: Al. McKendrick MD
(Medical Event Only)
Address: _____

Individuals Contacted During Investigation: Patrick McLaughlin MD
(Name and Title) _____

Records Reviewed: (General Description)
ENTIRE RADIATION ONCOLOGY CHART in copy form

Estimated Dose to Individual or Target Organ: Between 2 & 7.5 Gy
Probable Error Associated with Estimation: _____
Prescribed Dose (Medical Event Only): 90 Gy
Method Used to Calculate Dose: Copies of X-RAY/CT scans in treatment
planning software (BRACHY version 361-36A)

Factual Description of Incident:

(Attach a copy of any reports, documents, etc. used/referenced in this description.)

The patient, an 86 yo ♂ had a diagnosis of Rectal cancer. He received pre-operative xRT (external beam radiation) and chemotherapy. There was not a favorable response and the patient needed a diverting colostomy. The local, rectal tumor continued to progress and palliative brachytherapy was planned with permanent low dose rate I-125. Preplanning was performed based on CT & PET images on 8/30/10. The patient was taken to the OR later on 8/30/10 and the clinical exam indicated further progression and a need for more sources. Needles that were preloaded were placed percutaneously into the peri-anal/Rectal cancer. The OR reports that the tumor was "hard & difficult to penetrate". The seeds were then dropped after reviewing on fluoroscopy. Post-operative imaging studies identified from 9/1/10, that identified that many of the 32 implanted sources were not in proximity to the target - peri-anal tumor. Cystoscopy was performed to remove 12 seeds from the bladder and 20 seeds remained in the patient. Doses to target were 2-7.5 Gy relative to R dose of 90 Gy. The patient had subsequent Stereotactic radiation to control his tumor. He developed metastatic disease and has passed. There was no clinical sequelae from this misadministration.

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

Without markers that would have defined the tumor/target on fluoroscopy, there was no way the physicians could know w/certainty the placement of the needles before the sources were passed.

The radiation from the sources within the pelvis area/were not likely to manifest any clinical sequelae, either acute or chronic.

Briefly describe the current medical condition of the exposed individual:

The patient had no clinical activity from the implant. His local tumor progressed and he received local Stereotactic Radiation. He had progression of his disease with metastasis, unrelated to the brachytherapy event.

Was individual or individual's physician informed of Department of Energy (DOE) Long-Term Medical Study Program? Yes No

If yes, would the individual like to be included in the Program? Yes No

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<p>1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to Nuclear Regulatory Commission (NRC), pursuant to 10 CFR 20.2205 or 35.3045, in the following areas:</p> <p>a. Why the event occurred: <input checked="" type="radio"/> Yes No</p> <p>b. Effect on the individual: <input checked="" type="radio"/> Yes No</p> <p>c. Licensee's immediate actions on discovery: <input checked="" type="radio"/> Yes No</p> <p>d. Improvements needed to prevent recurrence: <input checked="" type="radio"/> Yes No</p>
<p>2. In areas where you do not agree with the licensee's evaluation (report submitted under 10 CFR 20.2205 or 10 CFR 35.3045), provide the basis for your opinion:</p> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
<p>3. Did the licensee notify the referring physician of the medical event ? <input checked="" type="radio"/> Yes No</p> <p>Did the licensee notify the individual or responsible relative or guardian? <input checked="" type="radio"/> Yes No</p>
<p>4. If the individual or responsible relative or guardian was <u>not</u> notified of the incident, did the licensee provide a reason for not providing notification, consistent with 10 CFR 35.3045? Yes No</p> <p>Briefly explain the licensee's response:</p> <hr/> <hr/> <hr/> <hr/>
<p>5. Provide an opinion of the licensee's plan for exposed individual follow-up, if available.</p> <p><i>There was subsequent care provided and unrelated to the event, his disease progressed and no further radiation therapy was needed. No clinical sequelae have occurred.</i></p> <hr/> <hr/> <hr/> <hr/>