

 **KAISER PERMANENTE®**
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Director of Brachytherapy Services

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November 8, 2007

Stevens A Reynolds, Director
Division of Nuclear Materials Safety
U. S. N. R. C., Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Mr. Reynolds:

I thank you for the opportunity to review the medical event incident at Clarian Arnett Health, Oncology Institute of Greater Lafayette. I am enclosing my final report of the medical event incident. Kindly do not hesitate to contact me if you require any further information or recommendations.

Sincerely yours,



Subir Nag, M.D.
Director of Brachytherapy Services
Member, ACMUI

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Enclosure 6

MEDICAL CONSULTANT REPORT

(To Be Completed By Medical Consultant)

Official Use Only

Medical Consultant Name: Subir Nag, MD

Report Date: 11/8/07

Signature: _____



Licensee Name: Clarian Arnett Health, Oncology Institute of Greater Lafayette

License No. 13-32087-01 **Docket No.:** 030-34812

Facility Name: Clarian Arnett Health, Oncology Institute of Greater Lafayette

Incident Date: Aug 14 – Sept 11, 2007

Discovery date: Oct 16, 2007

Prescribing Physician's Name: Loubna Scally, MD

Referring Physician's Name: Leon McNealy, MD
(Medical Event only)

Individuals contacted during investigation: Loubna Scally, MD, - A.U.
Phil Dittmer, PhD – A.M.P.

Records reviewed: (General Description)

The following were reviewed:

Medical event report, patient medical records, patient dosimetry.

Estimated Dose to Individual or Target Organ: 0.4 to 33.4 Gy to vagina

Probable Error Associated with Estimation: Minimal

Prescribed Dose (Medical Event Only): 7 Gy x 3 = 21 Gy

Method Used to Calculate Dose: Treatment Planning Computer

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

A patient of endometrial cancer had a small recurrence in the posterior wall of the mid-vagina 3 cm from apex. Pt had received 45 Gy external beam. The HDR plan was for 7 Gy per fraction x 3 fractions to 6.5 cm of vagina using a 4 cm diameter vaginal cylinder. The plan was to use 13 dwell positions spaced 5 mm apart to treat a length of 6.5 cm. However, 13 dwell positions spaced 2.5 mm apart was used to treat a length of 3.25 cm. Also, shielding was used to shield the posterior vaginal wall to reduce dose to the rectum. This also reduced the dose to the tumor.

This resulted in a 30% overdosage to the vaginal apex and anterior superior vagina. Additionally, there was a 50-98% underdosage to the inferior posterior vaginal wall (which contained tumor) when shielding is taken into consideration. This fulfils the requirements for classifying this as a medical event.

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

1. The overdose to the vaginal vault is unlikely to cause vaginal vault necrosis.
2. The underdosage to part of the tumor area increases the risk of tumor recurrence.

Briefly describe the current medical condition of the exposed individual:

No adverse effect seen at present.

Was individual or individual's physician informed of Department of Energy Long-term medical study program? No.

If yes, would the individual like to be included in the program? Not applicable.

1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to the Nuclear Regulatory Commission (NRC), pursuant to 10 CFR 20.2205 or 35.3045, in the following areas:

- a. **Why the event occurred: Yes**
- b. **Effect on the patient: Yes**
- c. **Licensee's immediate action on discovery: Yes**
- d. **Improvements needed to prevent recurrence: Yes.**

2. In areas where you do not agree with the licensee's evaluation (report submitted under 10 CFR 20.2205 or 35.3045), provide the basis for your opinion:

The licensee reports this as a medical event but notes that they are not altogether certain that this error meets the definition of a medical event as specified in 10 CFR 35.3045. The error resulted in a 30% overdosage to the vaginal apex and anterior superior vagina which could result in a small risk of vaginal vault necrosis. This was unintended. However, more importantly, there was a 50-98% underdosage to the inferior posterior vaginal wall, which contained tumor. This too was unintended and could result in a tumor recurrence. I would therefore classify this as a medical event.

3. Did the licensee notify the referring physician of the medical event? Yes.

Did the licensee notify the individual or responsible relative or guardian? Yes

4. If the individual 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 35.3045?

Not applicable.

Briefly explain the licensee's response:

Not applicable.

5. Provide an opinion of the licensee's plan for exposed individual follow-up, if available:

Patient will be clinically followed up at regular intervals to check for radiation morbidity and or tumor recurrence. This follow up is appropriate.

Why Site Visit is Not Required:

1. The description and cause of the adverse event is clear.
2. I have talked with the physicist involved in the case and have obtained additional dosimetric information. I have reviewed the dosimetry on this patient and confirmed the medical event.
3. I have also talked with the authorized user involved in the case and have obtained additional clinical information.
4. The licensee has informed the appropriate persons/officials and has taken the appropriate corrective actions to minimize risk of reoccurrence.