KAISER PERMANENTE®
Subir Nag, MD, FACR, FACRO
Director of Brachytherapy Services

Kaiser Permanente Radiation Oncology
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November 5, 2007

Robert G. Gattone, Jr
Senior Health Physicist
Material Inspection Branch, DNMS
U. S. N. R. C., Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Mr. Gattone:

I thank you for the opportunity to review the medical event incident at Clarian Arnett. 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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MEDICAL CONSULTANT REPORT (SHORT FORM)

(If site visit is not necessary)

Medical Consultants Name: Subir Nag, MD
Report Date: 11/5/07

Signature: 

Licensee's Name: Clarian Arnett Health. Lafayette, IN

License No. 13-32087-01
Docket No.:
Facility Name: Clarian Arnett Health. Lafayette, IN
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, Phil Dittmer, PhD

Records reviewed: Medical event report, patient medical records, patient dosimetry.

Estimated Dose to Individual or Target Organ:
Probable Error Associated with Estimation:
Prescribed Dose (Medical Event Only): 7 Gy x 3 = 21 Gy
Method Used to Calculate Dose: Treatment Planning Computer

Description of Incident:
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. However, this also reduced the dose to the tumor. This resulted in a 30% overdosage to the vaginal apex and anterior superior vagina. However, more importantly, there was a 50-98% underdosage to the inferior posterior vaginal wall (which contained tumor) when shielding is taken into consideration. I would therefore classify this as a medical event.

Based on your review do you agree with the licensee's written report that was submitted to the Nuclear Regulatory Commission (NRC) in the following areas:

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

Did the licensee notify the referring physician: Yes.

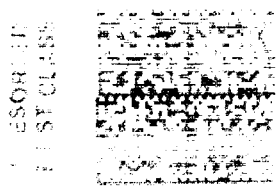
Did the licensee notify the individual or responsible relative or guardian? Yes

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.

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.

Subir Nagpal
Kaiser Permanente Medical Center-CTC
3800 Homestead Road
Santa Clara, CA 95051



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