MEDICAL CONSULTANT REPORT (SHORT FORM)
(To be completed by medical consultant, if site visit is not necessary)

Medical Consultant Name: Subir Nag, MD **Report Date:** June 10, 2015

Signature: _____

Licensee's Name: Paul G. Kocheril, M.D., McLaren Medical Center, Bay City, MI.

License No. 21-18585-01 **Docket No.:** 030-13900

Facility Name: McLaren Medical Center, Bay City, MI. **Incident Date:** 2/6/2015

Estimated Dose to Individual or Target Organ: 2.6 Gy to < 1 cc of right thigh

Probable Error Associated with Estimation: Minimal

Prescribed Dose (Medical Event Only): 22 Gy

Method Used to Calculate Dose: Treatment Planning Computer

General Description of Records Reviewed: Incident report, photographs of the applicator

Individuals contacted during investigation: Paul G. Kocheril, M.D. (AU)

Description of Incident: The licensee treated a 50 year old female diagnosed with endometrial cancer with pelvic external beam radiation and HDR brachytherapy boost. The authorized user prescribed a treatment using Ir-192 in a Varian Varisource HDR remote afterloading unit using a vaginal cylinder for a prescribed total dose of 22 Gray, in four fractions at 5.5 Gray per fraction. During the second fraction, dummy source train was placed in the cylinder and fluoroscopy was obtained to confirm position. However, the licensee staff positioned the HDR transfer tube assembly within the cylinder at distance of approximately 15cm proximal from the prescribed treatment position and CT scan was obtained without the dummy source train. The licensee does not measure the part of the transfer tube assembly sticking out of the cylinder. This mispositioning of the transfer tube within the cylinder during the second fraction resulted in a medical event, in which an unintended area of about one cubic centimeter of skin on the patient's right upper thigh, received a dose of 2.6 Gray and the treatment site did not receive the prescribed dose during this second fraction. The staff and licensee immediately recognized the error and reported the medical event. An additional fraction was added to the written directive to correct for the lost dose. The patient and the referring physician were informed of the medical event.

The medical event occurred because the transfer tube catheter was not fully seated inside the vaginal cylinder. Although there was a policy to verify the position of the cylinder and the length of the transfer tube catheter, there was not a policy or procedure in place to definitively verify the catheter position prior to treatment.

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 (partly).**

2. In areas where you do not agree with the licensee's evaluation, provide the basis for your opinion:

The licensee has developed a new policy which requires placement of a radio-opaque marker wire inside the catheter prior to imaging and sign off by the authorized user that the position of the catheter was verified. A check was added to a "time-out" sheet to verify that the authorized user has signed off on the catheter position prior to starting treatment. All nursing and support staff were trained of the new policy.

I would advise that the licensee measure and record the part of the transfer tube assembly sticking out of the cylinder as an additional check.

Why Site Visit is Not Required:

1. The description and cause of the medical event are clear.
2. I have talked with the authorized user involved in the case and have obtained dosimetric and photographic information. I have reviewed and confirmed the medical event on this patient.
3. The licensee has informed the appropriate persons/officials.

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

No significant adverse effect have occurred (nor is expected to occur) on the thigh. An additional treatment fraction was given subsequently so that the total biological dose and the patient treatment were not compromised.