ST JOHN PROVIDENCE HEALTH SYSTEM

ST. JOHN MACOMB-OAKLAND HOSPITAL

July 24, 2012

U.S. Nuclear Regulatory Commission
Office of Federal and State Materials and Environmental Management Programs
ATTN: Document Control Desk, Director
Washington, DC 20555–0001

Re: Event #48085

Please allow the following to serve as the written report in follow up to the initial July 10, 2012 notification to the United States Nuclear Regulatory Commission ("USNRC"), by St. John Macomb-Oakland Hospital - Macomb Center ("the Hospital") regarding the above-referenced event number.

Licensee Name
St. John Macomb Oakland Hospital - Macomb Center – NRC License #21-01190-05

Prescribing Physician
Paul Chuba, M.D.

Description of Event
On 7/9/12, a patient presented to the Hospital's radiation oncology department for a High Dose Rate Afterloader (HDR) procedure. At the beginning of the 3 catheter HDR procedure, the physicist connected a transfer tube to the endobronch catheter. The physicist should have connected the endobronch catheter directly to the HDR unit, thus resulting in the source not being delivered to the patient's treatment site. This event was not discovered until later that evening after the patient was discharged.

Upon discovery of the event, the radiation safety officer/physicist recreated the procedure with 2 other physicists and the nurse that assisted during the actual HDR treatment, confirming that the source did not make it to the patient's treatment site. The delivery stopped outside the patient's body and confirmed not to be in direct contact with the skin since proper barriers were utilized during the procedure to prevent skin contact. A farmer chamber, MOSfet, and Ion chambers were placed in locations determined to represent the highest possible patient skin dose measurements. Measurements were calculated and resulted in the highest potential skin dose to be 1.8cGy/1.8rem to the patient's left arm/shoulder area.

Since the dose received varied from the dose prescribed, it was concluded that a possible medical event had occurred. On 7/10/12, the radiation safety officer for the Hospital notified the USNRC Operations Center regarding the event and received the event number 48085.

Why the Event Occurred
The Hospital believes that the event occurred due to transfer tubing of about 1 meter in length being connected to the endobronch catheter, creating a distance greater than intended between the treatment site and the HDR unit source.

The Effect on the Patient
Through patient observation, there are no effects to report or expect other than the patient did not receive the intended treatment at that time.

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Action Taken/Planned to Prevent Recurrence

Effective immediately, Policy 1637.24, Radiation Oncology Time Out Procedures, Section 4(A)(i) was reviewed by the Hospital's radiation safety officer and revised to include a timeout to confirm that the correct HDR connections are in place for the specific treatment being performed. During the timeout, the physicist will verbally voice assurance to present secondary staff that connections to the HDR unit are proper. The long term action planned is to train qualified staff to perform this secondary check and confirmation of the correct connections during the HDR Time Out procedure. In addition, the Hospital has notified the manufacturer, Nucletron, of the event and provided it with suggestions regarding specificity of tube connections with procedures programmed in the HDR unit.

Notification to Patient

The prescribing physician notified both the referring physician and the patient in accordance with 10 CFR Part 35.3045.