Medical Consultant Report
(To be completed by medical consultant)

Medical Consultant Name: Ronald E. Goans, PhD, MD, MPH
Report Date: 12/07/2006

Signature Ronald E Goans MD 12/8/2006

Licensee Name: Saint Luke's Hospital of Kansas City; Saint Luke's Health System.

License No. 24-00889-01
Event No. 42941
Docket No. 030-02286

Facility Name: Radiation Oncology Department, Saint Luke's Hospital of Kansas City.

Incident Date: 10/26/06

Date of Notification: 10/27/06

Individuals' / Patient Physician Name and Address:

Susan Smith, MD
Department of Radiation Oncology
Saint Luke's Hospital of Kansas City
4401 Wornall Road
Kansas City, MO 64111

Individuals Contacted During Investigation:

Gregory Sackett, M.S., CHP; RSO
(816)-932-6296
gsackett@saint-lukes.org

Susan Smith, M.D., Radiation Oncologist
(816)-932-2575

John Erb, Ph.D., Chief Medical Physicist
(816)-932-2575

Records Reviewed: (General Description)

1. NRC Enclosure - Description of the Medical Event
2. Licensee Event Report
3. NRC Preliminary Notification of Event
4. NRC Medical Event Reporting and supporting literature
5. Saint Luke's correspondence to the NRC
6. Detailed review of patient radiation dose profile
7. HDR Treatment record
8. HDR Treatment procedures and protocols

Estimated Dose to Unintended Anatomic Region (see Figures 1-4):

Approximately 10,000 cGy to normal tissue, averaged over a 25 cm^3 region of breast tissue. As high as 400,000 -500,000 cGy to very small regions of breast tissue.

Probable Error Associated with Estimation: Determined by medical physics at Saint Luke's Hospital; ±20 % or less.

Prescribed Dose (Medical Misadministration Only):

2450 cGy

Method Used to Calculate Dose: Radiation medicine clinical dose profile and physical dosimetry. Dose computer for the HDR Mammosite® system. Approximate hand and computer calculations to confirm data from the treatment computer system.

Description of Incident:

The patient is a 67 year-old female with ductal carcinoma of the left breast, scheduled for HDR therapy with the Mammosite® system loaded with 3.9 Ci of Ir-192. On October 26, 2006, after 7 treatment sessions, the physicist noted that the most distal source was different than for previous treatments. On further investigation, it is noted that the usable catheter length was 93.0 cm, rather than the correct value of 95.0 cm. The error in catheter length was not noted during the first 7 treatments and it is thought that the treatment error results from a typographical error for the usable catheter length when entered into the treatment computer.

This error involving input to the treatment computer resulting in a tissue-averaged dose of approximately 10,000 cGy given to normal breast tissue instead of the expected dose of 2450 cGy.

The root cause of the incident is believed to be related to a simple typographical error initiated when entering the usable catheter length into the treatment planning computer. The error was not noted when performing pre-treatment checks until the dwell positions changed between treatments.

Clinical Details (See Figures 1-4 for dose profile)

The treating radiation oncologist, Susan Smith, M.D., has elected to discontinue treatment to the patient. Due to the incorrect location of the source, the patient received less dose than prescribed to the distal site of the Mammosite balloon, approximately 700-1000 cGy instead of the prescribed 3400 cGy. The proximal site received a significant overdosage as note above.

Assessment of Probable Deterministic Effects of the Radiation Exposure on the Individual:

It is expected that there will fat necrosis in the overexposed region in 2-4 months. Fortunately, neither the skin, muscle, nor surface of the heart received significant dose.

The tolerance dose $T_{x/5}$ (D) in radiation therapy is defined as the dose D to give x% complications in an organ in 5 years. According to Mettler and Upton (1995), for adult breast, >5000 cGy is the $T_{5/5}$ (1-5% complications in 5 years) and the $T_{50/5}$ (25-50% complications in 5 years) is > 10,000

cGy. Given the dose levels shown in Appendix 1 and Figures 1-4, it is highly likely that the patient will experience breast atrophy and fat necrosis as delayed effects.

Briefly describe the current medical condition of the exposed individual:

In a discussion with Dr. Smith, I understand the patient is doing well. A general surgeon, Lon McCroskey, M.D., has been retained, should excision of necrotic breast tissue be necessary in the next few months.

It will also be important to exercise medical vigilance for breast cancer recurrence, since there was an underdosage in part of the breast. There are no additional co-morbid conditions that would be expected to complication the process.

References

LF Fajardo L-G, M Berthrong, and RE Anderson. *Radiation Pathology*. Oxford Press. 2001.

GH Fletcher. Textbook of Radiotherapy. 3rd edition. Lippincott, Williams & Wilkins. 1980.

FA Mettler, AC Upton. Medical Effects of Ionizing Radiation. 2nd Edition. Saunders. 1995.

Was individual or individual's physician informed of DOE Long-term Medical Study Program?

Yes

If yes, would the individual like to be included in the program?

No

COMPLETE FOR MEDICAL MISADMINISTRATION
(To be completed by Medical Consultant)

1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to the NRC pursuant to 10 CFR 35.33 in the following areas:

a. Why the event occurred – Yes. Circumstances of this event were human error in data input at Saint Luke's Hospital Radiation Oncology Department.

b. Effect on the patient – Yes.

My independent dose estimates generally agree with those provided by the hospital.

c. Licensee's immediate actions upon discovery – There was immediate reporting of the event to the NRC.

d. Improvements needed to prevent recurrence - Yes.

This is a human factors issue, correctable by education and improved procedures. The issue was also addressed through the hospital Radiation Safety Committee. Appendix 2 and 3 show the current therapy sheet and revised procedures, respectively.

2. In areas where you do not agree with the licensee's evaluation (report submitted under 10 CFR 35.33, provide the basis for your opinion: N/A

3.

Did the licensee notify the referring physician of the misadministration? Yes

Did the licensee notify the patient's or the patient's responsible relative or guardian? Yes

If the patient 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 35.33? N/A

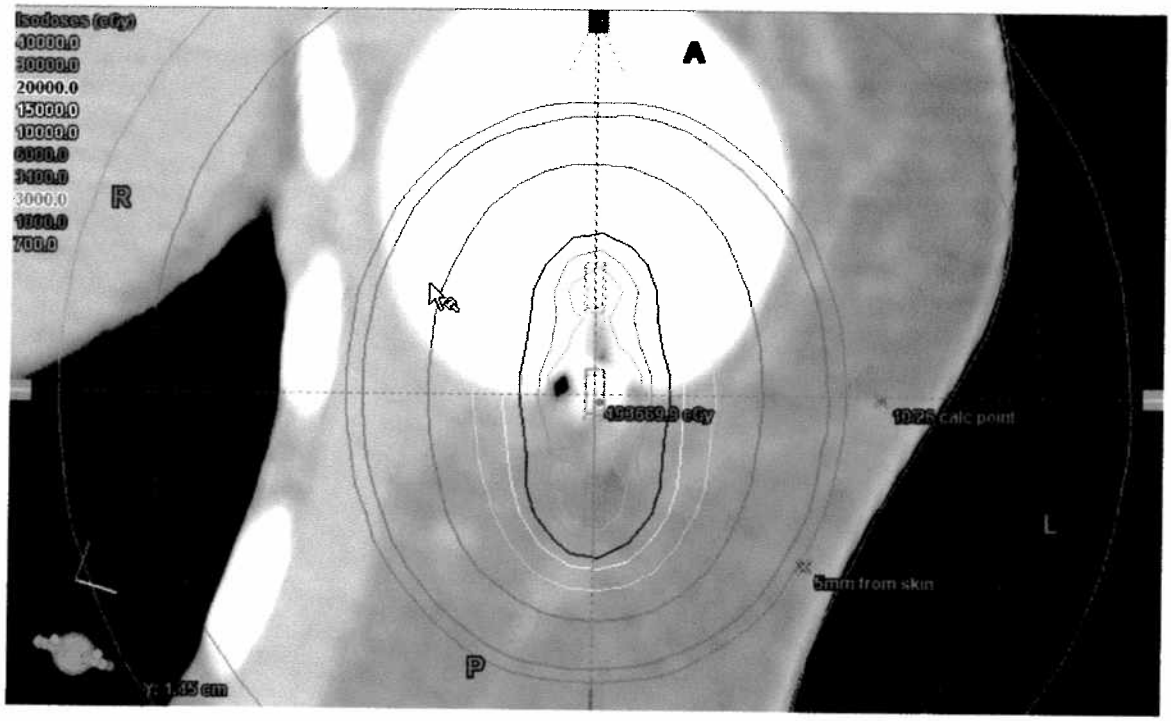
Explain rationale for response.

4. Provide an opinion of the licensee's plan for patient follow-up. If available.

The patients will be followed clinically by private physicians as indicated. I believe that the hospital system and specifically, the radiation oncology department, will institute an effective program to prevent a recurrence of this event. The information in the preliminary notification has also been reviewed with licensee management.

Appendix 1 (Isodose curves; projection noted in lower left corner)

Figure 1



Central area of highest dose: 493669.9 cGy

Figure 2

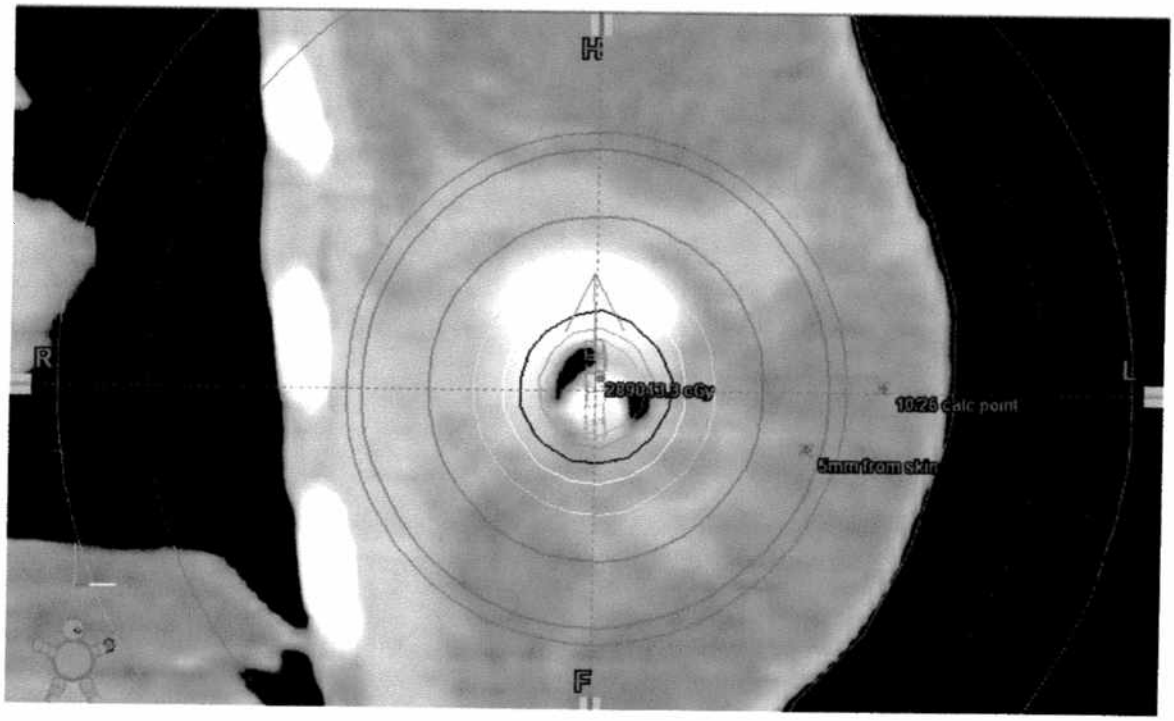


Figure 3

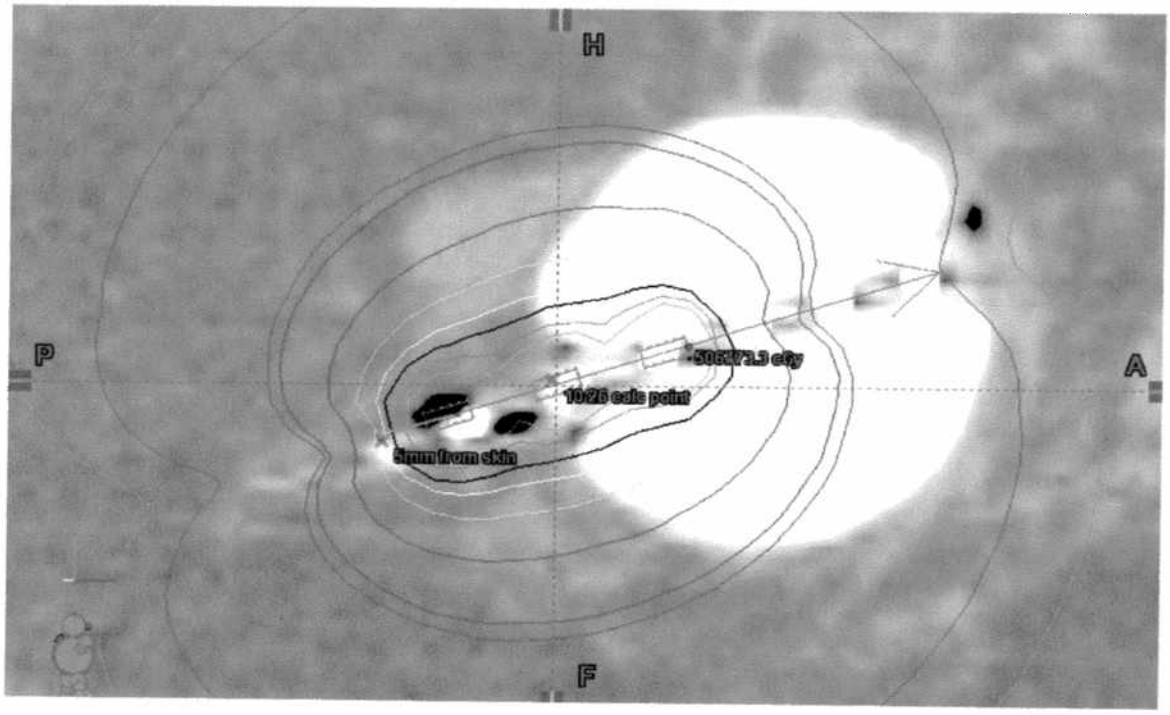
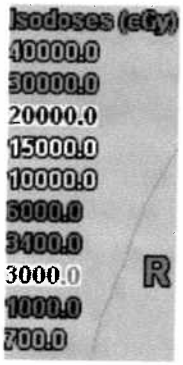


Figure 4 - Isodose contour lines



Appendix 2 - Revised HDR treatment record (12/4/2006)

SAINT LUKE'S CANCER INSTITUTE

HDR BRACHYTHERAPY PATIENT TREATMENT RECORD

Patient: _____ Fraction No. _____ of _____

Med. Rec. No.: _____ Treatment Start Date / Time: _____/_____

Authorized User Present: _____ Physicist Present: - _____

(signature): _____ (signature) _____

Patient I.D. Confirmation: Picture ___ Name ___ DOB ___ Other _____

Check mechanical integrity of applicator with source guide tube(s) and connectors. Pass__ Fail__ AU Initials_____

Confirm the length of source transfer tube and apparatus. Measured _____cm* Expected _____cm

Plan and independent "hand" calculation of dose point agree within 10%. Physicist Initials_____

Pre-treatment Survey:

Room Bkgd: _____mR/hr Patient: _____mR/hr

Afterloader Top: _____mR/hr Expected: _____mR/hr.

Afterloader Front: _____mR/hr Expected: _____mR/hr

Time:_____; Surveyed By: _____

Compare Catheter Treatment Length, Dwell Positions and Times in console with those in the Plan.

Catheter Length from Printout _____ cm + 1.5 cm (end factor) = Measured Length _____ cm*

Plan Total Time: _____sec. Console Total Time: _____sec

Activity (Plan): _____Ci Activity (Console): _____Ci Activity (Posted Table): _____Ci

Physicist: _____; Physician: _____

Compare Post-treatment printout of treatment time with those of plan.

Total Time Prescribed: _____sec; Total Time Delivered: _____sec. Physicist Initials: _____

Post-treatment Survey:

Room Bkgd: _____mR/hr Patient: _____mR/hr Meter Used: Model _____

Afterloader Top: _____mR/hr Expected: _____mR/hr. Ser. No. _____

Afterloader Front: _____mR/hr Expected: _____mR/hr

Time:_____; Surveyed By: _____

Appendix 3 - Revised HDR Treatment plans (12/4/2006)

THE CANCER INSTITUTE – ST. LUKE'S HOSPITAL OF KANSAS CITY

Procedures for HDR Treatment (Treatment Record) Revised 12-04-2006

Policy: A treatment record will be completed for each fraction of a treatment course. In addition to the patient's name and fraction number, this form will include documentation of the actions outlined below in the procedures. The physician (an authorized user) and the authorized physicist will be present during the entire treatment, and will signify such by signing the treatment record. The Treatment Record is attached.

Procedures: The following actions will be carried out during the delivery of a treatment fraction with HDR:

1. Before each fraction, the patient will be scanned on the CT-Simulator. The images will be transferred to the treatment planning computer for display to check positioning of the applicator, and to formulate a treatment plan in accordance with the written directive. While in simulation, the length of the transfer tube and the apparatus will be measured twice, once by the physicist and once by the sim therapist, and compared to the standard length of that combination. These values will be recorded as measured and expected values on the Sim sheet and the treatment record. There should be an agreement of +/- 1 mm. If the variation is 1.5 mm or greater, the location of the first dwell position will be adjusted.
2. The physician (authorized user) will review and approve the plan on the computer screen. An independent "hand-calculation" of one or more dose points will be made. Agreement between the plan and the "hand-calculation" should be within 5% and must be within 10%. The physicist will initial the treatment record that this requirement has been met.
3. With the patient in the treatment room, the patient's identification will be confirmed by two means. This will be documented on the treatment record.
4. The physicist will perform a pre-treatment survey. Room background will be measured as well as the radiation level near the surface of the patient. Measurements will be taken at the top and front of the HDR afterloader and compared with the expected. These values will be recorded on the treatment record, as well as the time of the survey and the signature of the physicist.
5. Immediately prior to the start of the treatment, the physician will check the catheter connection(s) and the location of the applicator. Once this is done and confirmed by the physician, the physician will indicate that the integrity of the applicator with the source guide tube(s) has passed on the treatment record, and will initial in the space provided.
6. The print-out from the treatment console is compared with the plan, relative to dwell positions and dwell times, total time and activity of the source. The catheter length from the printout plus 1.5 cm must equal the measured length in step 1 above (within 1 mm). These comparisons will be performed by the physicist and

the physician. Pertinent information is entered on the treatment record, and both the physicist and the physician will initial the record.

7. At the conclusion of the treatment, the print-out with the completed treatment time is compared to the plan. The total time prescribed, the total time delivered, and the physicist's initials are entered in the record.
8. The post-treatment survey is performed, prior to disconnecting the catheter from the afterloader. The same survey meter, used in the pre-treatment survey, should be used. The model and serial number shall be recorded on the treatment record. Room background will be measured as well as the radiation level near the surface of the patient. Measurements will be taken at the top and front of the HDR afterloader and compared with the expected. These values will be recorded on the treatment record, as well as the time of the survey and the signature of the physicist.