ENCLOSURE 9

MEDICAL CONSULTANT REPORT

Medical Consultant Name: Edward B. Silberstein **Report Date:** 4/22/17
Signature: Edward B. Silberstein

Licensee Name: Washington University in St. Louis
License No. 24-00187-11 **Docket No.** 030-02271
Facility Name: Washington University in St. Louis

Incident Date: 04/08/16

Individual's Physician Name: Perry W. Grigsby M.D.
Address: 660 S. Euclid Ave.
Campus Box 8053
St. Louis, MO. 63110-1093

Referring Physician's Name: Darrel Zuckerman, M.D
(Medical Event Only)
Address: 660 S. Euclid Ave.
St. Louis, MO 63110

Individuals Contacted During Investigation: RSO; Sue Langhorst,
(Name and Title) " John Smith
Physicist Isaca Mutic

Records Reviewed: (General Description)
NRC description reviewed, and reconfirmed as well with Sasa Mutic.

Estimated Dose to Individual or Target Organ: (R) lobe of liver, 212 Gy
Probable Error Associated with Estimation: +/- 10%
Prescribed Dose (Medical Event Only): not provided for (L) lobe
Method Used to Calculate Dose: formula from manufacturer

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

Full † described by Robert Gottone, NRC, in terms of Y-90 Therasphere treatment. The therapist injected 95% of fraction 2, meant for the left lobe, into the right lobe. The invasive radiologist positioned the catheter in the lobe where the dose was to be given (left) and confirmed this with a contrast angiogram. Fluoroscopic monitoring showed the catheter's position while the radiation oncologist obtained the Y-90 Therasphere container, hooked it up to the catheter and administered the dose. About 1-2 minutes passed between completion of the angiogram and completed Y-90 Therasphere administration according to RSO Sue Langhorst and Asst RSO John Smith, although Sasa Mutic, physicist, thought the interval was closer to 5 minutes.

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

Side effects to the irradiated liver have been described in attached Refs 1-8. The uncertainty in this case is over because there are no data on the effects of consecutive Y-90 related hepatic doses separated by only a month of 11,800 rads & 9250 rads. If there were complete recovery of normal tissue from the first dose, atrophy with focal fibrosis would be far less likely than if the doses were additive (21,180 rads) & aberrant abnormalities have been described (Grade 3-4) with approximate thresholds of 40,000 - 280 equivalent rads (5, 7, 9, 11, 12). Patient suffered no effects

Briefly describe the current medical condition of the exposed individual:

I was told the patient was alive

Was individual or individual's physician informed of Department of Energy (DOE) Long-Term Medical Study Program? Yes (No) The patient has incurable cancer.

If yes, would the individual like to be included in the Program? Yes No

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

a. Why the event occurred: (Yes) No

b. Effect on the individual: (Yes) No

c. Licensee's immediate actions on discovery: (Yes) No

d. Improvements needed to prevent recurrence: (Yes) No

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

No patient intervention was observed, so I am forced to agree with the Wash. Univ. report. However, the only time interval where a timed administration can occur is between completion of angiography and t-96 injection an interval in this case of at least 12 minutes. The average adult breather about 12 Times / minute with the Liver motion 5-7 cm, more with a deep sighs by interval.

3. Did the licensee notify the referring physician of the medical event ?
(Yes) No

Did the licensee notify the individual or responsible relative or guardian? (Yes) No

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? Yes No

Briefly explain the licensee's response:

N/A

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

The patient is followed by his oncologist.