



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

September 14, 2009

Willis E. Brumley, M.S.
Radiation Safety Officer
Missouri Cancer Associates, LLC
1705 East Broadway
Columbia, MO 65201

**SUBJECT: NRC INSPECTION REPORT NO. 030-37082/2009-001(DNMS) –
MISSOURI CANCER ASSOCIATES, LLC**

Dear Mr. Brumley:

On May 13, 2009, a Nuclear Regulatory Commission (NRC) inspector conducted an inspection at your Columbia, Missouri facility, with continuing in-office review through August 20, 2009. During the inspection, the inspector examined activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. Office review included review of the medical consultant's report and other documents associated with the oncology treatment discussed below.

During the inspection, the inspector interviewed personnel and reviewed records concerning a patient in radiation oncology, who showed a greater than expected skin effect from a breast cancer treatment. The NRC contracted with a medical consultant to review and make an independent assessment of the case. The medical consultant discussed the treatment with you, your staff, and another independent radiation oncologist. The medical consultant's report is enclosed for your review. Based on the inspector's and the medical consultant's reviews of the treatment, the NRC has determined that the treatment was not a medical event. No violations of NRC regulatory requirements were identified as a result of this inspection.

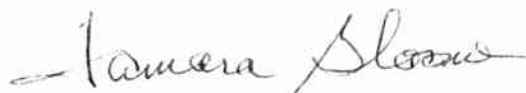
In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public

W. Brumley

-2-

Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

A handwritten signature in cursive script that reads "Tamara Bloomer".

Tamara E. Bloomer, Chief
Materials Inspection Branch

Docket No. 030-37082
License No. 24-32604-01

Enclosure:
NRC Medical Consultant's Report

DISTRIBUTION:

Docket File
C. Pederson, RIII
S. Reynolds, RIII
S. Orth, RIII
J. Choe, RIII
P. Pelke, RIII

Medical Consultant Report
(To be completed by medical consultant)

Medical Consultant Name: Ronald E. Goans, PhD, MD, MPH
Report Date: 8/10/2009

Signature



Licensee Name Missouri Cancer Associates, LLC
1705 East Broadway, Suite 100
Columbia, MO 65201

License No. 24-32604-1
Docket No. 030-37082

Facility Name: Missouri Cancer Associates, LLC
1705 East Broadway, Suite 100
Columbia, MO 65201

Incident Date: 2/21/2008 through 2/27/2008
Date of Notification Has not been reported as a medical event; it is furthermore determined that this does not rise to the level of a medical event.

Individual's / Patient Physician Name and Address:

Mark Bryer, MD, Radiation Oncology

Missouri Cancer Associates, LLC
1705 East Broadway, Suite 100
Columbia, MO 65201

Individuals Contacted During Investigation:

Willis Brumley, MS, RSO
(573) 441-3710

Mark Bryer, MD, Radiation Oncology
(573) 442-5525

Missouri Cancer Associates, LLC
1705 East Broadway, Suite 100
Columbia, MO 65201

Records Reviewed: (General Description)

1. NRC Enclosure - Description of the Medical Event
2. NRC Preliminary Notification of Incident

Estimated Dose to Individual or Target Organ: Mammosite HDR system, 340 cGy at 1 cm from the balloon, twice daily for 10 days.

Probable Error Associated with Estimation: Estimated < 5%.

Prescribed Dose (Medical Misadministration Only): 340 cGy at 1 cm from the balloon, twice daily for 10 days.

Method Used to Calculate Dose: Dose estimates from Missouri Cancer Associates Mammosite HDR regimen.

Description of Incident:

The patient is a 45-year old female found to have a 6 mm lesion in the breast. A biopsy on January 22, 2008 indicated a well differentiated intraductal carcinoma. A lumpectomy was performed 2/14/2008 and the sentinel lymph node was found to be negative; four additional nodes were negative. The patient was prescribed Mammosite HDR therapy, 340 cGy at one cm BID x 10 days. The tumor classification was T1BN0M0.

The patient was noted to be at high risk for complications because of her thin stature and a history of heavy smoking with likely vascular compromise and the potential for poor surgical wound healing. THE AU prepared and signed a written directive for the noted treatment and the AMP prepared a treatment plan, which was reviewed by the AU and approved. The treatment plan was marginal since the skin margin was approximately 6 mm and the catheter was not perfectly centered in the balloon, but within specifications.

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

Likely minimal.

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.

RE Goans. Clinical Care of the Radiation Accident Patient: Patient Presentation, Assessment, and Initial Diagnosis. In *The Medical Basis for Radiation-Accident Preparedness. The Clinical Care of Victims*. Eds. Robert C. Ricks, Mary Ellen Berger, and Frederick M. O'Hara, Jr. Proceedings of the Fourth International REAC/TS Conference on the Medical

Basis for Radiation-Accident Preparedness, March 2001, Orlando, FL. The Parthenon Publishing Group, 2002.

Briefly describe the current medical condition of the exposed individual:

The patient has had a surgical dehiscence of the lumpectomy site as noted in Figure 1. One month after treatment, the patient showed skin effects more extensive than expected from the treatment. Several months later, a new RSO reviewed the treatment plan and again concurred that all treatment was within protocol.

I have consulted with another, independent radiation oncologist in Oak Ridge, TN and we agree that this incident does not rise to the level of a medical event. The surgical wound site is currently healing in a satisfactory manner.

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:**

Why the event occurred – Yes

Effect on the patient – Yes

Licensee's immediate actions upon discovery – Yes. The NRC was notified late of this incident, but the wound separation does not rise to the level of a medical event.

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: Please see above comments.**

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.

Adequate oversight and QA procedures appear to be in effect.



Figure 1

INSPECTION RECORD

Region III Inspection Report No. 2009-001

License No. 24-32604-01

Docket No. 030-37082

Licensee (Name and Address):

Missouri Cancer Associates, LLC
1705 East Broadway, Ste. 100
Columbia, MO 65201

Location (Authorized Site) Being Inspected

Same as above

Licensee Contact: Willis Brumley, M.S., RSO

Telephone No. 573-441-3710

Priority: 2

Program Code: 02230

Date of Last Inspection: May 20, 2008

Date of This Inspection: May 13 - Aug 20, 2009

Type of Inspection: () Initial () Announced (X) Unannounced
() Routine (X) Reactive

Next Inspection Date: No change () Normal () Reduced

Justification for reducing the routine inspection interval: N/A

Summary of Findings and Actions:

- (X) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
() Non-cited violations (NCVs)
() Violation(s), Form 591 issued
() Violation(s), regional letter issued
() Followup on previous violations

Inspector(s) Geoffrey M. Warren, Health Physicist (Name(s))

Date 9/10/09

[Signature] (Signature(s))

Approved Tamara E. Bloomer, Chief, MIB (Name)

Date 9/10/09

[Signature] (Signature)

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:
(License amendments issued since last inspection, or program changes noted in the license)

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
--------------------	-------------	----------------

None concerning subject of inspection.

2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

No violations were cited in previous inspections in April 2006 and May 2008.

3. INCIDENT/EVENT HISTORY:
(List any incidents, or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

None.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)

The licensee was a medical clinic located in Columbia, Missouri, which provided radiation oncology and diagnostic nuclear medicine (PET) services.

2. SCOPE OF INSPECTION:
(Identify the inspection procedure(s) used and focus areas evaluated. If records were reviewed, indicate the type of record and time periods reviewed)

Inspection Procedure(s) Used: 87132

Focus Areas Evaluated: 03.01, 03.02, 03.05, 03.06, 03.07

During the inspection, the inspector reviewed a High Dose Rate (HDR) remote afterloader breast cancer treatment which produced a greater than expected skin effect. The inspector interviewed personnel and reviewed records concerning this treatment, and reviewed additional HDR treatment and QC records.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

The inspector performed area surveys with a Ludlum-2401 survey meter calibrated in June 2009. Readings indicated radiation levels consistent with licensee postings and survey records.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

(State the requirement, how and when the licensee violated the requirement, and the licensee's proposed corrective action plan. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

No violations or other issues were identified.

The inspector reviewed a HDR breast cancer treatment which produced a greater than expected skin effect. The inspector discussed the treatment with the licensee's Radiation Safety Officer (RSO), the Physician Authorized User (AU), and the therapist involved with the treatment, and reviewed the licensee's records concerning the treatment. The RSO and the AU stated that, prior to the treatment, the patient was informed about the risk of increased skin effects from the patient being very thin, being a heavy smoker, and other factors, but that the patient chose to have the procedure done despite the increased risk. They stated that the distance between the surface of the skin and the balloon was approximately 6 millimeters and the catheter was slightly off-center in the balloon, but that both parameters were within acceptable ranges. In addition, they stated that the lesion resulting from the treatment healed completely.

The treatment was performed in February 2008. Licensee staff performed a full review of this case in March 2008 when the referring physician noted the effect of the treatment on the patient's skin and notified the AU. In October 2008, the incoming RSO performed a second review of the case when the concern was brought to his attention. In both reviews, the reviewers determined that the treatment was performed in accordance with the written directive and the treatment plan and that no medical event occurred.

The inspector's review of the records associated with the treatment indicated that (1) the AU properly completed the written directive and approved the treatment plan; (2) the Authorized Medical Physicist (AMP) prepared a treatment plan consistent with the written directive, performed additional calculations to verify the treatment plan, and performed the quality assurance checks to verify the HDR unit was working correctly; and (3) licensee staff performed the treatment in accordance with the written directive and the treatment plan.

The NRC contracted with a medical consultant to review this case and conduct an independent assessment of the treatment. The consultant discussed the incident with the licensee's RSO and the AU, as well as another independent radiation oncologist. Following these discussions, he determined that, despite the skin effects, the incident was not a medical event. He confirmed that based on his review, (1) the given risk factors would lead to an increased likelihood of complications, (2) the treatment plan was within appropriate specifications, and (3) the treatment was performed in accordance with the written directive and treatment plan.

5. PERSONNEL CONTACTED:
(Identify licensee personnel contacted during the inspection, including those individuals contacted by telephone.)

- #* Willis Brumley, M.S., RSO, AMP
 - * Mark Bryer, M.D., Radiation Oncologist, AU
- And other licensee personnel

Use the following identification symbols:

- # Individual(s) present at entrance meeting
- * Individual(s) present at exit meeting

-END-