

10/21/11

MEMORANDUM TO: File
Washington University of St. Louis
License No. 24-00167-11
Docket #: 030-02271

FROM: Robert G. Gattone, Jr., Senior Health Physicist, Materials Inspection
Branch, Region III *Robert G. Gattone, Jr.*

SUBJECT: Notice to Next Inspector

Please review the issues summarized in the attached documents during the next routine inspection.

2:15 pm_10/19/11

CONVERSATION RECORD

|TIME |DATE

VISIT

CONFERENCE

TELEPHONE
10/19/11

INCOMING
 OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT

ORGANIZATION (OFFICE, DEPT. ETC.)

TELEPHONE NO.

Sue Langhorst, RSO

Washington University of St. Louis

314-362-3476

SUBJECT

Notification of Unintended Gamma Stereotactic Radiosurgery (GSR) Shot

SUMMARY

The inspectors contacted the RSO after the NRC was notified that she was unsure if a finding that was discovered on 10/19/11 should be reported as a medical event. The RSO explained that on 10/6/2011, a patient with metastatic brain cancer underwent GSR treatment. The written directive prescribed a total of 21 shots to treat 5 sites. The 5 sites were treated with a total of 21 shots in accordance with the written directive and the associated treatment plan. However, during a post-treatment check, the authorized user identified that the 21st shot location was in an area that was unintended (i.e., an erroneous written directive/treatment plan was inadvertently approved by the authorized user and administered without error).

The RSO stated that she does not believe the treatment resulted in a medical event because it was administered in accordance with the written directive and the treatment plan.

ACTION REQUIRED

Place in ADAMS.

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Claire Wellinghoff

Claire Wellinghoff

10/21/2011

Bob Gattone

Robert B. Gattone, Jr.

10/21/11

ACTION TAKEN

The inspectors requested that the licensee provide the report of its extent of condition review. The licensee agreed to provide the report by 11/3/11. The RSO stated that there were no adverse effects to the patient. She also stated that the 21st shot gave a dose of 20 Gy at the 80% dose line. The RSO also stated that the authorized user has delivered the same dose to the same area of the brain of other patients without adverse effects. The authorized user informed the RSO that due to the location of the shot, which was administered to a motor part of the brain, there is a 1% chance of an adverse effect, which could be weakness of the patient's right leg.