DEPARTMENT OF VETERANS AFFAIRS

Memorandum

Date: APR 23 2010

From: Director, VHA National Health Physics Program (NHPP) (115HP/NLR)

Subj: Radiation Safety Program Inspection - Inspection Report 583-10-I01

To: Director (583/00), Richard L. Roudebush VA Medical Center, Indianapolis, Indiana

1. Paul L. Yurko, NHPP, performed an announced reactive inspection on January 6, 2010, with continuing review until April 9, 2010. This inspection was focused entirely on a medical event and the Yttrium-90 microsphere therapy program and did not serve as a routine NHPP inspection.

2. Attached is the inspection report with no violations cited.

3. You are not required to respond to this memorandum.

4. Thank you for the courtesy and cooperation extended during the inspection. Please contact Mr. Yurko at 410-642-2411, extension 6288, if you have any questions about the inspection.

Gary E. Williams

Attachment

cc: Chair, National Radiation Safety Committee
Network Director, VISN 11 (1011)

RADIATION SAFETY PROGRAM INSPECTION
Inspection Report Number 583-10-101
Richard L. Roudebush VA Medical Center, Indianapolis, Indiana
January 6 through April 9, 2010

1. Introduction

a. Paul L. Yurko, M.S., VHA National Health Physics Program (NHPP), performed an announced reactive inspection of the Richard L. Roudebush VA Medical Center, Indianapolis, Indiana, on January 6, 2010, with continuing review until April 9, 2010.

(1) The inspection was initiated in response to a reported medical event resulting from a patient treatment involving Yttrium-90 (Y-90) microspheres. The treatment was performed on December 30, 2009.

(2) Medical center staff discovered the medical event on December 30, 2009, and reported the event, that same day, to NHPP. NHPP reported the event to the NRC Operations Center on December 31, 2009 (Event Number 45602). A 15-day report was sent to NRC on January 12, 2010.

(3) The inspector presented his preliminary findings at a meeting with key medical center staff on January 6, 2010.

b. The inspection focused on the medical event circumstances and the Y-90 microsphere therapy program and did not serve as a routine NHPP inspection.

(1) NRC regulations in 10 CFR 35.3045 define a medical event. The inspector used this definition as a basis to evaluate the medical event. The medical center determined a medical event had occurred based on the fact that the total activity delivered to the treatment site was less than 80% of the total activity documented in the written directive.

(2) The inspector conducted an exit meeting on January 6, 2010, and left the inspection open pending a review by medical center staff and representatives from MDS Nordion of the activity remaining in the vial and the microcatheter. That review was conducted on February 18, 2010, and the results were documented in a report titled "Root-Cause Analysis and Follow-up Investigation of Delivery Apparatus," dated February 26, 2010. The report was attached to a letter dated March 4, 2010, from the medical center director to NHPP. The inspection was closed during a telephone call to the medical center Radiation Safety Officer (RSO) on April 9, 2010.

c. NHPP staff reviewed information (including pre- and post-therapy measurement data) associated with the December 30, 2009, patient treatment and agreed with the medical center that a medical event had occurred. The inspector reviewed information on other Y-90 microsphere treatments during the inspection, and no additional medical events were discovered. The identification of a medical event under 10 CFR 35.3045 is not, by itself, a violation of NRC regulations. In addition, the December 30, 2009, Y-90 microsphere treatment was deemed by the facility's medical staff to be clinically successful and the patient involved was not harmed. Although a lower than prescribed activity was administered, the authorized user (AU) estimated

the absorbed dose to the liver was 109 gray and the therapeutic target range for the procedure was 100 to 150 gray.

2. Scope of inspection

The inspection was risk-informed and performance-based. All items on the inspection plan were completed including, but not limited to, the following:

a. Interviews with medical center and contract staff,

b. Review of records related to the event and radiation safety program,

c. Tour of facilities and review of equipment involved,

d. Review of the medical center's initial actions regarding the event, including a review of the effectiveness and comprehensiveness of the initial actions to prevent a recurrence,

e. Review of compliance with other regulatory requirements under 10 CFR 35 for the Y-90 microsphere therapy program,

f. Evaluation of root or basic causes for the event, and

g. Review of corrective actions to prevent future occurrence.

3. Findings and impressions (background information)

a. The most recent NRC inspection at the medical center, on June 30, 2003, cited no violations. NHPP inspected the medical center on September 17-23, 2008, and cited one Severity Level IV violation under 10 CFR 35.40(a) for failure to complete a signed and dated written directive prior to performing a "Quadramet" therapy utilizing Sm-153. This therapy is not related to the Y-90 microsphere therapy program.

b. The medical center has not previously reported any medical events involving the Y-90 microsphere therapy program.

c. The inspector gathered information about the Y-90 microsphere therapy program at the medical center and the workload.

(1) The program was first approved by the medical center Radiation Safety Committee (RSC) at its December 9, 2006, meeting. The first infusion was performed January 26, 2007, and to date the facility has performed a total of 36 procedures. In 2009, the facility performed 14 infusions.

(2) The physician AU, who is also an AU at the affiliate university, was approved on March 25, 2009, by the medical center RSC for the Y-90 therapy procedures.

(3) The medical center written directive procedures require preparation of a written directive form before each procedure. This information includes the radionuclide, treatment site, planned activity in millicuries, and dose in grays. Title 10 CFR 35.40 specifies that the part of the written directive completed before the therapy procedure must state the treatment site, radionuclide, and dose. The medical center's written directive procedures and form appeared to conform to 10 CFR 35.40 requirements.

(4) A unit dose is ordered from the vendor MDS Nordion.

(5) The vendor ships a package containing the Y-90 microspheres to the medical center. The package is delivered to the Nuclear Medicine Service. A member of the radiation safety or nuclear medicine staff takes the package and completes the receipt survey.

(6) Activity of the Y-90 microspheres is measured in the facility dose calibrator and the activity is recorded on the written directive.

(7) The dose vial is then delivered to the interventional radiology suite, where the patient is prepared and the microspheres are infused by the treatment team.

(8) Standard operating procedures require the shielded dose vial be agitated vigorously to bring the microspheres into full suspension, the initial reference exposure rate is recorded and should be approximately 2.0 mR/hr at the prescribed distance of 60 cm.

(9) After infusion of the microspheres, the RSO surveys the patient as well as the surrounding area with a thin window GM survey meter to locate any contamination. The RSO routinely surveys the container (vial), lines (catheters), gloves, tongs, tape, and any other waste from the procedure.

4. Findings and impressions (regulatory compliance)

a. The inspector reviewed and evaluated information about the medical event that had been reported and overall implementation of the Y-90 microsphere therapy program.

b. The inspector concluded that, even though there had been a medical event, no violations could be identified.

5. Findings and impressions (medical event)

a. The inspector collected information regarding the Y-90 treatment that resulted in the December 30, 2009, medical event.

(1) A written directive was completed prior to the procedure by the AU and was in accordance with 10 CFR 35.40.

(2) The circumstances associated with the treatment were as follows:

(a) Prescribed dose: 63.24 mCi; 100 – 150 Gy

(b) Drawn dose from dose calibrator: 62.7 mCi

(c) Calculated activity delivered to liver: 45.9 mCi

(d) Calculated activity outside of liver from shunting: 1.08 mCi

(e) Total activity delivered: 47 mCi

(f) Activity remaining in vial and microcatheter: 15.7 mCi

(3) The treatment resulted in an underdose to the treatment site (liver) of 25.04% in terms of activity. Because this deviation exceeds 20%, a medical event is considered to have occurred in accordance with 10 CFR 35.3045(a)(1). Although a lower than prescribed activity was administered, the AU estimates the absorbed dose to the liver was 109 gray and was within the therapeutic target range for the procedure, 100 to 150 gray.

b. The AU stated that during delivery of the activity to the treatment site the dose rate monitor usually has a consistent reading of 4 to 6 mR/hr, but during this treatment a spike in the dose rate meter was observed at about 14.8 mR/hr. The AU did flush the microcatheter three times per the standard operating procedure and did not notice any resistance on the syringe during the flushes.

c. A follow-up review of the activity remaining in the vial and the microcatheter was completed by the permittee, in conjunction with the vendor, on February 18, 2010.

(1) The follow-up review reported that a high concentration of microspheres was found in the connection hub of the "Lexan ®" coupler.

(2) A possible cause of the high concentration involved the infusion of iodinated contrast media in the catheter. Contrast media is infused under fluoroscopy immediately before infusion of the radioactive microspheres as part of the standard operating procedures. The contrast media has a higher viscosity than the saline solution microspheres; so residual contrast media might impede or "trap" an aggregation of microspheres along the microcatheter.

(3) To avoid this possibility in the future, a recommendation from the review was to flush the catheter with plain saline solution to remove any residual contrast media remnants before the microspheres are infused.

6. Causes of Medical Event

a. The inspector performed a causal analysis using the TapRooT® root cause categories. The inspector determined the root cause to be "Procedures, wrong, situation not covered," in that introduction of a higher density solution into the catheter prior to introducing the microspheres might have impeded the microsphere infusion.

b. As a corrective action, based on the follow-up review to preclude the possibility that microsphere infusion might be impeded in future treatments, the permittee revised its standard operating procedures on March 23, 2010, to include a step to flush the catheter with plain saline solution to remove any residual contrast media before the microspheres are infused.

c. Evaluation of the effectiveness of this corrective action should be performed by the RSO for future infusion procedures.

d. Based on the following impressions, the inspector concludes that the medical center's procedures for Y-90 microsphere therapy, both in existence at the time of the medical event and currently, provide high confidence that each administration is in accordance with the written directive.

(1) A significant density effect appears to occur at an extremely low probability since there has not been previously observed circumstances in numerous treatments at the medical center. The medical center has performed 36 treatments since January 2007, and this was the first treatment to demonstrate this effect.

(2) Only in follow-up to this medical event did the vendor identify this circumstance as a possibility in its delivery protocol.

(3) The medical center has been following the delivery protocol recommended by the vendor and has not previously had any issues.

7. Notice of Violation

The inspector did not identify any violations.

8. Persons contacted

Thomas Mattice, FACHE, Medical Center Director
Jeffrey Ramkaransingh, M.D., Authorized User
George W. Harris, Medical Imaging Supervisor
Mary Ann Spilker, Nuclear Medicine Supervisor
Thomas Schumacher, Radiation Safety Officer
Michael Pappas, Clinical Associate, MDS Nordion