U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection Nos.	03020233/2010001 and 03036074/2010001
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License Nos.	47-23066-02 and 47-23066-03
NMED No.	100347
Licensee:	West Virginia University Hospitals, Inc.
Location:	Medical Center
Inspection Dates:	June 8-11, September 8, 2010; February 8, 2011 (exit meeting)
Date Followup Information Received:	July 16, 21; October 12; and December 28, 2010

Inspector: **/RA/** 2-8-11
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EXECUTIVE SUMMARY

West Virginia University Hospitals, Inc.
NRC Inspection Report Nos. 03020233/2010001 and 03036074/2010001

A routine, unannounced inspection was conducted at West Virginia University Hospitals, Inc. (WVUH) in Morgantown, West Virginia on June 8-11 and September 8, 2010. Additional information, contained in correspondence from WVUH on July 16, 21, and October 12, 2010, was also reviewed. The inspection was performed in accordance with NRC Inspection Procedures 87122, 87133, and 87134 and reviewed activities associated with the use of licensed materials within the following departments at WVUH: Nuclear Medicine, Radiation Oncology, Research, and Blood Bank.

The inspectors also reviewed a medical event which involved a microsphere treatment that was conducted on January 20, 2010 at WVUH and reported to the NRC Operations Center on July 7, 2010 (Event No. 46074). The review of the medical event was performed in accordance with NRC Management Directive 8.10.

The inspector conducted interviews with WVUH personnel, observed day-to-day operations, toured WVUH's facilities, and reviewed documents and procedures. In addition, a medical consultant was retained by the NRC to review WVUH's prostate brachytherapy program. The medical consultant completed their review on December 28, 2010.

Based on the results of this inspection, four apparent violations of NRC requirements were identified. Specifically,

- WVUH did not notify the NRC Operations Center no later than the next calendar day after the discovery of a medical event on January 20, 2010, as required by 10 CFR 35.3045(c). After completion of a microsphere treatment on January 20, 2010, WVUH documented that a patient received 71% of the prescribed dose due to a potential equipment malfunction.

- WVUH did not prepare written directives for prostate brachytherapy treatments as required by 10 CFR 35.40. Specifically, written directives were not dated by the authorized user (AU); and a written directive prepared for a treatment on August 3, 2009, did not include the prescribed dose.

- WVUH did not calibrate a dose calibrator at the WVU Heart Institute as required by 10 CFR 35.60(b). Specifically, geometric testing with a 5 cubic centimeter (cc) syringe had not been performed in accordance with the manufacturer's instructions.

- The WVUH Radiation Safety Committee (RSC) authorized an AU for the use of all unsealed sources for therapeutic use under 10 CFR 35.300 without the proper training and experience, as required by Condition 12.B of License No. 47-23066-02. Specifically, the RSC authorized an AU to use iodine-131 and beta emitters with only training and experience for use of iodine-131.

REPORT DETAILS

I. Organization, Scope, and Management Oversight of the Program

a. Inspection Scope

A routine, unannounced inspection was conducted at West Virginia University Hospitals, Inc. (WVUH) in Morgantown, West Virginia on June 8-11 and September 8, 2010. Additional information, contained in correspondence from WVUH on July 16, 21, and October 12, 2010, was also reviewed. The inspection was performed in accordance with NRC Inspection Procedures 87122, 87133, and 87134. The following focus areas were reviewed: (i) security and control of licensed material; (ii) shielding of licensed material; (iii) comprehensive safety measures; (iv) radiation dosimetry program; (v) radiation instrumentation and surveys; (vi) radiation safety training and practices; and (vii) management oversight.

The inspector assessed WVUH's performance associated with the use of licensed materials within the following departments: Nuclear Medicine, Radiation Oncology, Research, and Blood Bank. The inspection also included a review of the licensee's management of the radiation safety program, including oversight of activities by the Radiation Safety Office, the Human Use Committee, the Radiation Safety Committee (RSC), and senior management.

The inspectors also reviewed a medical event which involved a microsphere treatment that was conducted on January 20, 2010 at WVUH and reported to the NRC Operations Center on July 7, 2010 (Event No. 46074). The review of the medical event was performed in accordance with NRC Management Directive 8.10.

The inspector conducted interviews with WVUH personnel, observed day-to-day operations and equipment testing, toured the facilities, and reviewed documents and procedures. In addition, a medical consultant was retained by the NRC to review WVUH's prostate brachytherapy program. The medical consultant completed their review on December 28, 2010.

b. Observations and Findings

Licensed Material Program Organization and Scope

WVUH's broad scope medical license (License Number 47-23066-02) authorizes WVUH to conduct medical activities authorized by 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 [high dose-rate (HDR) remote afterloader only], microsphere therapy treatments, medical research, and irradiation of blood products. These activities are performed at the following WVUH facilities: Ruby Memorial Hospital, Health Sciences Center, Jefferson Memorial Hospital, and the WVU Heart Institute. WVUH's medical use of a gamma stereotactic radiosurgery (GSR) device is authorized under a separate limited scope medical license (License Number 47-23066-03).

Nuclear Medicine

Nuclear medicine activities authorized by 10 CFR 35.100, 35.200, and 35.300 are conducted at Ruby Memorial Hospital, Jefferson Memorial Hospital, and the WVU Heart Institute. Five authorized users are involved in the nuclear medicine program. The inspector toured the facilities at Ruby Memorial Hospital and the WVU Heart Institute. Activities at Jefferson Memorial Hospital, which began in 2008, were not inspected during this inspection. The WVU Heart Institute began using technetium-99m and thallium-201 in February 2010 and is staffed by three part-time technologists for the treatment of approximately five patients per day. The facility possesses two dose calibrator sources, one instrument rod source, one camera flood source, and 28 gadolinium-153 sources. A consultant reviews the radiation safety program at the WVU Heart Institute quarterly and supplies the results to the WVUH Radiation Safety Office.

The full range of nuclear medicine activities are conducted at Ruby Memorial Hospital with approximately 12 patients treated per day by four full time and two part time technologists in nuclear medicine. They also treat approximately 15 patients per day in their Positron Emission Tomography (PET) facility which is supported with seven full time technologists. Two of the cameras at Ruby Memorial Hospital contain sealed sources (gadolinium-153 and cobalt-57). WVUH also participates in training nuclear medicine technologists at Ruby Memorial Hospital and currently oversees the training of four students. Radiopharmaceutical therapies are primarily conducted at Ruby Memorial Hospital and usually consist of four hyperthyroid treatments and three carcinoma treatments per month with iodine-131. The inspector noted that most treatments are conducted on an outpatient basis; and WVUH requests information from their patients on whether they will be near children or pregnant women and the destination of the patient after their release (location other than a private residence). Ruby Memorial Hospital also conducts microsphere (Y-90 SirSphere) and zevalin treatments. WVUH primarily uses unit dosages provided by Pharmalogic in all of their nuclear medicine departments. The inspector noted that microspheres are measured in the nuclear medicine department and administered by Radiation Oncology.

The inspector reviewed the dose calibrator testing conducted on the unit installed at the WVU Heart Institute and confirmed that constancy and accuracy tests were completed as required. The inspector noted that the geometry tests on the unit were conducted for the vials and three cc syringes used by the facility. However, geometry testing with five cc syringes had not been completed in accordance with the manufacturer's instructions and 10 CFR 35.60(b). WVUH subsequently performed the required geometric test and provided the results to NRC in a letter dated July 16, 2010.

The inspector toured WVUH's waste storage facility which houses waste generated from the medical broad scope and the academic broad scope licenses and noted that the waste was properly marked to indicate its origin. In addition, during the on-site inspection conducted in June 2010, the inspector noted that when leaving the waste storage room, if the door was not closed with force, the locking mechanism did not always operate correctly to lock the door. While licensed material was found secured, this concern was referred to the licensee; who repaired the unreliable locking mechanism that same day. The inspector confirmed that the lock was operational

immediately after the repair and again during the on-site inspection on September 8, 2010.

Radiation Oncology

Radiation Oncology generally has five authorized users (AU) and two authorized medical physicists involved with the program to conduct GSR, HDR, prostate brachytherapy, and Y-90 SirSphere treatments. WVUH conducts approximately two gynecologic treatments per week and four breast treatments per year with a HDR. They perform approximately one treatment per month with the GSR and a few Y-90 SirSphere treatments per year. The inspector noted that a contract authorized medical physicist was employed in May 2010 by WVUH until a full-time replacement could be found for a retiring physicist. The licensee appropriately oversaw the activities conducted by the contract employee. WVUH personnel responsible for HDR and GSR operations demonstrated appropriate spot check procedures for the inspector.

WVUH installed a new Perfexion GSR device in September 2010 and began clinical use the last week of October 2010. The five year maintenance on the old GSR device was performed on October 17, 2007, as required, and did not identify any concerns.

The inspector reviewed various records associated with receipt, calibration, and maintenance on the HDR unit. The inspector noted that WVUH appropriately reported issues and concerns in a timely manner to the HDR manufacturer for resolution and correction. The inspector also noted that in September 2008, an HDR source was delivered to an unauthorized location (i.e., admissions desk) by the mail carrier service. WVUH conducted an investigation into this incident. Based on a review of the investigation report and discussions with WVUH personnel, the inspector concluded that WVUH appropriately responded to this incident and took appropriate corrective actions. WVUH maintained adequate control of the material at all times and exposures to the public were within regulatory limits.

The inspectors noted that the iridium-192 brachytherapy sources listed on the license were properly stored and have not been used since the last inspection. Manual brachytherapy is limited to iodine-125 prostate brachytherapy implants, with six treatments conducted since the last inspection. The prostate brachytherapy program is currently considered inactive by WVUH. The inspector reviewed the written directives and treatment planning records for the six treatments which were conducted since the last inspection and noted that the AU did not date when the written directive was created and the prescribed dose was not included in a written directive that was prepared for a treatment that occurred on August 3, 2009. During the exit meeting, WVUH stated that they had revised their written directive forms used in prostate brachytherapy implants to better ensure all required information was included. A copy of the revised form was provided on February 8, 2011. WVUH also stated that all physicists and AUs would be trained immediately on the revisions.

Due to the large dose difference (20-40%) documented in written directives, as compared to treatment planning dosimetry calculations, a medical consultant was retained by the NRC to review WVUH's prostate brachytherapy program. Specifically,

the medical consultant reviewed treatments that were performed on October 14, 2008 and August 3, 2009. The medical consultant completed his review on December 28, 2010 and concluded that both treatments were acceptable and the AU included additional seeds during the implant to achieve a better seed distribution. The medical consultant noted that the discrepancy between the prescribed dose in the written directive and the D90 dose (minimum dose received by 90% of the prostate volume) in the treatment plans was attributed to the AU defining the prescribed dose to include the prostate plus margins while the D90 dose calculated by the medical physicist only included the prostate. In both cases, the medical consultant also concluded that "the patient's disease was under control with no adverse effects noted" but that the documentation of the revision of the written directive was "poor and ambiguous" and suggested that the licensee draft a form to better document revisions to written directives.

The inspector reviewed the records of Y-90 Sir-Sphere treatments performed by WVUH. The inspector noted during a January 20, 2010 treatment, that 71% of the activity prescribed was administered to the right lobe of a patient's liver; a value greater than 20% different than the dosage intended. After the treatment, the interventional radiology (IR) physician documented in the patient's record that "a planned dose of 30 mCi resulted in actual dose of 22 mCi due to leaking within the canister." The difference was documented on the written directive and the post-procedure dose verification form was updated to state that the "delivered dose differs from the prescribed dose by: 29%." radiation safety staff assisting with the treatment documented that the patient went into stasis, a condition that prohibits continued infusion of the radioisotope. During interviews of WVUH personnel familiar with this treatment, the IR physician confirmed that stasis did not occur and that their dictated note was correct. Based on the above the inspector determined that radiation safety staff assisting with the treatment incorrectly concluded and documented that the patient went into stasis. The patient returned for treatment to the left lobe of the liver on February 17, 2010, using a new delivery device and during the treatment the IR physician dictated into the patient's record that "a planned dose of 10 mCi was reduced to a dose of 5.3 mCi due to stasis." Additionally, the written directive was correctly revised to document that the "delivered dose differs from the prescribed dose by: 46%" and the reason for the change was due to stasis.

From January 20 until April 5, 2010, WVUH held the delivery device used in the above event for decay, prior to sending it back to the manufacturer. On June 21, 2010, the manufacturer's report confirmed leakage around the v-vial stopper; however the manufacturer could not conclude whether the leakage was from a manufacturer defect or from the physician applying too much pressure on the delivery device during the procedure. Based on this inconclusive evidence, WVUH requested that the manufacturer repeat the proctor evaluation of both physicians (i.e., IR physician and AU) involved in the treatment and subsequently concluded that both the IR physician and AU were "qualified to implant SIR-Spheres microspheres."

Research

There is currently no medical research activity being conducted by WVUH. All non-

medical research is conducted under a separate academic broad scope license (License Number 47-23035-01). The inspector reviewed medical research records from WVUH's Institutional Review Board and Radioactive Drug Research Committee and noted that currently all medical research is being performed with FDA approved radiopharmaceuticals and that no radioactive research drugs are currently being tested.

The inspector identified that an americium-241 source that is listed on WVUH's medical broad scope license was not listed on their sealed source inventory records. WVUH personnel stated that the source was properly disposed of in the 1990's with a large waste disposal shipment, but inadvertently left off of the shipping manifest. Thus far, WVUH has contacted the previous RSO and the prior waste brokers, Ecology Services and US Ecology, in an attempt to locate the records. WVUH committed to continuing their efforts to obtain the disposal documentation to support removal of the source during the upcoming renewal of their license.

Blood Bank

The inspector verified that the sealed sources used in the blood bank are appropriately leak tested and inventoried; and maintenance on the device is conducted, in accordance with WVUH's license commitments. Additionally, all blood bank staff interviewed by the inspector appeared knowledgeable on the operating and emergency procedures.

Management Oversight

The radiation safety office is comprised of a RSO and four staff responsible for implementation of the radiation safety program. The RSO reports directly to the Vice President for Ancillary and Support Services. In addition, WVUH utilizes a contractor that reports to the RSO, who is responsible for conducting audits of WVUH's nuclear medicine departments. The RSC meets quarterly to review any events, dosimetry reports, audit results, and approve new uses, facilities, or users.

The inspector reviewed RSC meeting minutes and a sampling of AUs' and authorized medical physicists' training and experience documentation. During the review, the inspector noted that the RSC approved an AU for uses of all of 10 CFR 35.300 licensed material, which includes iodine-131 and beta emitters. However, a review of the training and experience submitted by the proposed AU indicated that the AU only had experience with iodine-131. The RSO immediately confirmed that the AU had only been involved with iodine-131 treatments and notified the RSC members of the issue; and drafted a revised authorization memo for the AU indicating the correct authorization for iodine-131 only as permitted by 10 CFR 35.300. A copy of the memo approved by the RSC on June 11, 2010, was provided to the NRC in a letter dated July 16, 2010.

Medical Event Reporting and Follow-up

WVUH reported the January 20, 2010 medical event to the NRC Operations Center on July 7, 2010 (Event # 46074) and noted in the report that "the patient was notified of the dose received." On July 21, 2010, WVUH submitted the required 15-day report, and documented that the patient was not informed that a medical event had occurred;

however, as noted above, the patient was made aware of the dose difference. In addition, the referring physician was the IR physician, who was aware of the patient not receiving the full prescribed dose. WVUH concluded that the medical event occurred due to leakage of the delivery device.

On July 28, 2010, the WVUH RSC discussed the medical event during a quarterly meeting. The minutes from the meeting stated that WVUH "did not know that there was a medical event until readings came back incorrect…The issue happened in January, but not discovered until inspection, this is when it was sent to NRC, upon discovery." In a letter dated October 12, 2010, WVUH further stated that the delay in reporting from receipt of the manufacturer's report on June 21, 2010, until the report was made on July 7, 2010 was to allow time for the IR and the AU to review the manufacture's report before a final determination was made concerning the need to report a medical event.

The following corrective actions were taken by WVUH to address the medical event:

- Refresher training was provided by the manufacturer on the administration of Y-90 SirSpheres to the IR physician and the AU.

- Dose preparation form was revised to require the signatures and documentation from the of the AU and IR physician if the difference in the dose delivered is less than 80% of the prescribed dose due to stasis or from a medical event.

- RSO met with the physicians and radiation safety staff to discuss the medical event and the reporting requirements in 10 CFR 35.3045. The revised dose preparation form was also reviewed during these meetings.

c. Conclusions

The inspector concluded that the evaluation performed by WVUH was adequate and identified the likely causes of the medical event. The corrective actions developed and implemented by WVUH appear reasonable. However, the inspector determined that on January 20, 2010, WVUH personnel had information readily available in the patient's record to determine that a medical event had occurred. Therefore, WVUH should have notified the NRC Operations Center by January 21, 2010 that a medical event had occurred.

The inspector identified four apparent violations of NRC requirements. Specifically:

- WVUH did not notify the NRC Operations Center no later than the next calendar day after the discovery of a medical event on January 20, 2010, as required by 10 CFR 35.3045(c). After completion of a microsphere treatment on January 20, 2010, WVUH documented that a patient received 71% of the prescribed dose due to a potential equipment malfunction.

- WVUH did not prepare written directives for prostate brachytherapy treatments as required by 10 CFR 35.40. Specifically, written directives were not dated by the AU; and a written directive prepared for a treatment on August 3, 2009, did not include

the prescribed dose.

- WVUH did not calibrate a dose calibrator at the WVU Heart Institute as required by 10 CFR 35.60(b). Specifically, geometric testing with a 5 cc syringe had not been performed in accordance with the manufacturer's instructions.

- The WVUH RSC authorized an AU for the use of all unsealed sources for therapeutic use under 10 CFR 35.300 without the proper training and experience, as required by Condition 12.B of License No. 47-23066-02. Specifically, the RSC authorized an AU to use iodine-131 and beta emitters with only training and experience for use of iodine-131.

II. Exit Meeting

At the conclusion of the on-site inspection on June 11 and September 8, 2010, the preliminary inspection findings were discussed with WVUH's senior management. WVUH acknowledged the inspector's findings and immediately initiated corrective actions. An exit meeting was held by telephone on February 8, 2011 with Mr. Stephen Tancin, Vice President for Ancillary and Support Services, and other members of his staff, to discuss the results of the inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

*Darlene Headley, Director, Radiology and Radiation Oncology
+Stephen Tancin, Vice President
*Dr. Fred Butcher, Vice President
*Beverly D. Kerr, Deputy General Counsel
*+Stephen I. Root, Radiation Safety
*+Dr. Nasser Razmianfar, Radiation Safety Officer
*Dr. Gary Marano, Chair Human Use Committee
Various technologists, authorized users, authorized medical physicists, radiation safety, and support staff

*Attended briefing conducted on June 11 or September 8, 2010
+Attended telephonic exit meeting conducted on February 8, 2011