UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352
December 11, 2014

EN 50603
NMED No. 140733 (closed)

Yuenian (Neal) Zhang, PhD
Chief Physicist, Radiation Oncology
Parkview Health
11141 Parkview Plaza Drive
Fort Wayne, IN 46845

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03001593/2014001(DNMS) – PARKVIEW HEALTH

Dear Dr. Zhang:

On November 17-18, 2014, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your facility in Fort Wayne. The purpose of the inspection was to review the circumstances surrounding an incident you reported to the NRC on November 11, 2014. Mr. Ken Lambert and Mr. Ryan Craffey of my staff conducted a final exit meeting by telephone with you on November 19, 2014, to discuss the inspection findings.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, and interviews with personnel involved in the incident.

Within the scope of this inspection, no violations of NRC requirements were identified. The enclosed inspection report details the results of the 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 made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html.

Please feel free to contact Mr. Lambert or Mr. Craffey of my staff if you have any questions regarding this inspection. Mr. Lambert can be reached at 630-829-9633, and Mr. Craffey can be reached at 630-829-9655.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-01593
License No. 13-01284-02

Enclosure:
IR 03001593/2014001(DNMS)

cc w/encl: State of Indiana

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-01593
License No.	13-01284-02
Report No.	03001593/2014001(DNMS)
EN No./NMED No.	EN 50603 / 140733
Licensee:	Parkview Health
Facility:	11141 Parkview Plaza Drive Fort Wayne, Indiana
Inspection Dates:	November 17-18, 2014
Exit Meeting Date:	November 19, 2014
Inspectors:	Kenneth J. Lambert Senior Health Physicist Ryan J. Craffey, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Parkview Health
NRC Inspection Report 03001593/2014001(DNMS)

This was a reactive inspection of licensed activities to review the circumstances surrounding an event that Parkview Health (the licensee) reported to the U.S. Nuclear Regulatory Commission (NRC) on November 11, 2014.

Following the third fraction of a high dose-rate brachytherapy treatment using iridium-192 (Ir-192), the licensee identified a possible discrepancy in one of the parameters used to describe the treatment site. As a conservative measure, the licensee reported the incident as a potential medical event to the NRC Headquarters Operations Center, because the discrepancy could have resulted in an unintended dose to tissue outside of the intended treatment site. Upon further review, the licensee determined that the discrepancy did not ultimately affect the delivery of the treatment plan, as the discrepancy was limited to a parameter that was not used in the delivery of the treatment. The licensee concluded that all three fractions that had been delivered at the time of the discovery of the potential medical event had been delivered in accordance with the written directive and as intended by the physician authorized user. Based on this, the licensee retracted its report of a potential medical event on November 21, 2014.

The inspectors determined that the three fractions had been delivered in accordance with the treatment plan and written directive. The inspectors agreed with the licensee's assessment that a medical event did not occur. No violations of NRC requirements were identified as a result of this inspection.

REPORT DETAILS

1 Program Overview and Inspection History

Parkview Health was authorized by NRC Materials License No. 21-08317-01 to use byproduct radioactive material for a variety of medical purposes, including diagnostic and therapeutic administrations of radiopharmaceuticals, and radiation oncology using sealed sources of byproduct material, including sources of iridium-192 (Ir-192) for use in high dose-rate remote afterloader brachytherapy (HDR) treatments. The licensee operated a large medical campus in Fort Wayne, Indiana, and several smaller nuclear medicine departments in hospitals and clinics in Northeast Indiana. The licensee's radiation oncology program at its medical campus was staffed by nine authorized users, three authorized medical physicists, and three dosimetrists.

The NRC last performed an inspection of Parkview Health on September 23, 2013, and prior to that on January 10, 2012. No violations were identified as a result of either of these routine inspections.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspector interviewed the Radiation Safety Officer (RSO), an authorized user, and a dosimetrist to obtain the licensee's understanding of the circumstances surrounding a potential medical event involving an HDR treatment.

2.2 Observations and Findings

On October 24, 2014, the licensee completed a written directive for a gynecological HDR treatment using a Nucletron remote afterloading device containing approximately 7.7 curies (Ci) of Ir-192 in sealed form. The authorized user prescribed 2,200 centigray in four identical fractions to 0.5 centimeters (cm) in tissue from the surface of the vaginal cylinder applicator, with a diameter of 3.5 cm and active length (distance between maximally distal and proximal treatment steps) of 6.0 cm. The authorized user approved the treatment plan, his first at Parkview Health for such a procedure, and attended the first two fractions on October 27 and 31, 2014. The licensee delivered both fractions without incident.

Following these two fractions, the authorized user left the country for vacation. On November 11, 2014, a different authorized user and dosimetrist delivered the third fraction. Upon completion of the fraction, the licensee staff noticed that the first dosimetrist had originally indicated an active length of 6.0 cm, but a treatment length of only 5.0 cm for each fraction. According to Parkview's institutional measurement standard (applicator tip to point at which the 100 percent dose line intersects with the applicator surface), the treatment length should have been greater than the active length. The second dosimetrist reviewed the treatment plan and determined according

to Parkview's standard that the treatment length for the third fraction was actually closer to 7.0 cm.

The second dosimetrist notified the attending medical physicist (the RSO) of the discrepancy. Because the first authorized user was out of the country until the end of the week and could not be consulted until his return, the RSO conservatively reported the incident to the NRC Headquarters Operations Center as a potential medical event for an unintended dose to tissue outside of the treatment site. The RSO also directed the second authorized user to notify the patient of the potential medical event the following morning.

On November 14, the first authorized user returned to the facility to review the treatment fraction delivered in his absence. The authorized user indicated that contrary to the apparent discrepancy, the fraction had actually been performed as intended. He indicated that his measurement standard for treatment length was slightly different (applicator tip to point at which the 100 percent dose line intersects the prescribed treatment depth, which is effectively shorter) than the licensee's, and therefore he had not been concerned that the treatment length was noted as shorter than the active length.

The licensee further determined that there had also been a minor error in the calculation of the treatment length noted on the plan; the true value, by the authorized user's standard, was approximately 6.3 cm. However, the licensee concluded that the erroneous treatment length was not used by the staff in performing the treatment. Instead, the treatment was developed using the active length, a parameter which was well understood by all involved, and was consistent and correct throughout all steps of the treatment. The licensee concluded that the treatment had in fact been in accordance with the written directive and that no medical event had actually occurred.

Because of the misunderstanding between parties and the potential consequences, the licensee took a number of proactive steps to improve its process for performing HDR treatments. The licensee discussed the measurement standards with staff to develop a common focus on active length, modified its HDR Brachytherapy Quality Management Form and developed a treatment plan checklist to improve the quality assurance process for these procedures.

2.3 Conclusions

The inspectors reviewed the licensee's conduct before and after the discovery of the potential medical event. The inspectors determined that the licensee's assessment of the incident was adequate and agreed with the licensee's conclusion that no medical event occurred. The inspectors had no findings in this area.

3 NRC Assessment of Event

3.1 Inspection Scope

The inspectors interviewed the Radiation Safety Officer as well as the attending authorized user and dosimetrist to evaluate the treatment in question. The inspectors also reviewed documentation for this and other similar treatments, as well as the licensee's procedure for the conduct of HDR brachytherapy.

3.2 Observations and Findings

The inspectors reviewed the written directive, treatment plan, and treatment records for the first three fractions of the treatment. The inspectors verified that the written directive contained the required information, and that each fraction had been performed in accordance with the written directive. The inspectors discussed the treatment length discrepancy with the authorized user and the RSO, and verified that the authorized user's measurement standard for treatment length was slightly different than the licensee's. The inspectors also verified that the treatment length was not used in determining the treatment and that the active length, which was used for determining the treatment, was correct and in accordance with the written directive. The inspectors reviewed the licensee's procedure for administration of HDR treatments and a selection of previous HDR treatment documentation to verify that the licensee's procedures provided high confidence that these administrations were in accordance with the written directive. The inspectors also reviewed the additional quality assurance measures that the licensee had implemented as a result of this incident.

3.3 Conclusions

The inspectors determined that each fraction was delivered in accordance with the written directive and treatment plan, and the licensee followed its procedures for administration of the HDR procedure. The inspectors had no findings in this area.

4 Reporting the Event

4.1 Inspection Scope

The inspectors interviewed the RSO and evaluated the licensee's initial notification to evaluate compliance with regulatory reporting requirements.

4.2 Observations and Findings

The treatment fraction in question occurred on November 11, 2014. The licensee discovered the potential medical event shortly following the completion of the fraction, and the RSO reported the potential medical event to the NRC Headquarters Operations Center at 4:25 pm that day. The incident was logged as EN 50603.

The licensee retracted the event at 9:30 am on November 21, 2014, following the onsite inspection, after the licensee made a determination that the potential medical event did not meet any of the NRC's medical event reporting criteria.

4.3 Conclusions

The inspectors reviewed the licensee's reporting of the November 11, 2014, incident. The inspectors had no findings in this area.

5 Exit Meeting Summary

The inspectors presented preliminary inspection findings immediately following the onsite inspection on November 18, 2014. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary, and acknowledged the findings presented. The inspectors conducted a final exit meeting with the RSO by telephone on November 19, 2014.

LIST OF PERSONNEL CONTACTED

Shelly Hire – Dosimetrist
Wesley Russell, MD – Authorized User
#^ Yuenain (Neal) Zhang, PhD – Radiation Safety Officer

Attended preliminary exit meeting on November 18, 2014
^ Attended final exit meeting by telephone on November 19, 2014

INSPECTION PROCEDURES USED

87103 – Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing
87132 – Brachytherapy Programs