



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

October 26, 2009

EA-09-266
NMED Nos. 090691, 090692

Ms. Jacalyn Liebowitz
Vice President, Patient Care Continuum
Allegiance Health
205 N. East Avenue
Jackson, Michigan 49201

**SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03001990/2009-001(DNMS) –
ALLEGIANCE HEALTH**

Dear Ms. Liebowitz:

On September 9, 2009, with continuing in-office review through October 8, 2009, a Nuclear Regulatory Commission Inspector conducted a reactive inspection at the Paul Tejada Center for Radiation Oncology in Jackson, Michigan. The in-office review included assessing your written report dated September 8, 2009. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for two medical events that occurred on April 16, 2009, that the licensee discovered during post-implant dosimetry analysis conducted in August 2009. The enclosed report presents the results of the inspection.

Based on the results of the inspection, one apparent violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Website at (<http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>). The apparent violation concerns the failure to develop adequate written procedures to provide high confidence that each prostate seed implant is in accordance with the written directive as required by Title 10 Code of Federal Regulation (CFR) 35.41. The circumstances surrounding the apparent violation, the significance of the issues, and the need for lasting and effective corrective action were discussed with you and members of your staff at the final exit meeting by telephone on October 13, 2009. As a result, it may not be necessary to conduct a predecisional enforcement conference in order to enable the NRC to make an enforcement decision.

In addition, since your facility has not been the subject of escalated enforcement actions within the last two inspections, and based on our understanding of your corrective action, a civil penalty may not be warranted in accordance with Section VI.C.2 of the Enforcement Policy. The final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter or (2) request a predecisional enforcement conference. If a conference is held, it will be open for public observation. The NRC will also issue a press release to announce the conference. Please contact Tamara Bloomer at (630) 829-9627 within 7 days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to an Apparent Violation in Inspection Report No. 030-01990/2009-001(DNMS); EA-09-266 and should include for each apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in the enclosed NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a predecisional enforcement conference.

In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Website at <http://www.nrc.gov/reading-rm/adams.html>.

J. Liebowitz

-3-

To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

/RA/By Patrick L. Loudon Acting For/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

Docket No. 030-01990
License No. 21-00258-06

Enclosures:

1. Inspection Report 030-01990/2009-01(DNMS)
2. NRC Information Notice 96-28

cc w/encls: Randall Bardwell, Radiation Safety Officer
Karen Yacobucci, Executive Director, Oncology Radiology Services
Deborah Dusseau, Manager, Radiation Oncology
State of Michigan

J. Liebowitz

-3-

To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

/RA/By Patrick L. Loudon Acting For/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

Docket No. 030-01990
License No. 21-00258-06

Enclosures:

1. Inspection Report 030-01990/2009-001(DNMS)
2. NRC Information Notice 96-28

cc w/encls: Randall Bardwell, Radiation Safety Officer
Karen Yacobucci, Executive Director, Oncology Radiology Services
Deborah Dusseau, Manager, Radiation Oncology
State of Michigan

DISTRIBUTION:
See next page

DOCUMENT NAME: Y:\DNMSIII\SEC\Work in progress\ALLEGIANCEHEALTHMEDICALEVENTREPORT.doc

Publicly Available Non-Publicly Available Sensitive Non-Sensitive

To receive a copy of this document, indicate in the concurrence box "C" = Copy without attach/encl "E" = Copy with attach/encl "N" = No copy

OFFICE	RIII-DNMS	RIII-DNMS	RIII-EICS	RIII
NAME	RPHays:jm	TEBloomer:jm	SKOrth	SAREynolds: PLL for
DATE	10/18/09	10/20/09	10/22/09	10/24/09

OFFICIAL RECORD COPY

Letter to Jacalyn Liebowitz from Steven A. Reynolds dated October 26, 2009

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 030-01990/2009-001(DNMS) –
ALLEGIANCE HEALTH

DISTRIBUTION:

Docket File
ADAMS (PARS)
RidsSecyMailCenter
OCA Distribution
R. Borchardt, EDO
M. Virgilio, DEDMRT
C. Carpenter, OE
B. Sosa, OE
K. Day, OE
M. Satorius, RIII
C. Pederson, RIII
C. Marco, OGC
M. Itzkowitz, OGC
C. Miller, FSME
R. Lewis, FSME
M. Burgess, FSME
G. Villamar, FSME
D. White, FSME
E. Brenner, OPA
H. Bell, OIG
G. Caputo, OI
M. Williams, OCFO
D. Holody, RI
C. Evans, RII
W. Jones, RIV
P. Louden, RIII
V. Mitlyng, RIII
P. Chandrathil, RIII
J. Heck, RIII
A. Barker, RIII
J. Lynch, RIII
P. Loughheed, RIII
P. Pelke, RIII
M. Gryglak, RIII
OEMAIL

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.: 030-01990

License No.: 21-00258-06

Report No.: 03001990/2009-001(DNMS)

Licensee: Allegiance Health

Location: 205 N. East Avenue
Jackson, Michigan

Date of Inspection: September 9, 2009, with continued
in-office review through October 8, 2009

Preliminary Exit Meeting September 9, 2009

Final Exit Meeting October 13, 2009

Inspector: Robert P. Hays, Health Physicist

Reviewed By: Tamara Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

**Allegiance Health
Jackson, Michigan
Inspection Report No. 03001990/2009-001(DNMS)**

This was a reactive inspection to review the circumstances, root and contributing causes, and corrective actions associated with two reported medical events that occurred at Allegiance Health, Jackson, Michigan, on April 16, 2009. The medical events involved two different patients undergoing permanent seed implant therapy for treatment of prostate cancer. Each patient was prescribed a treatment dose of 145 Gy to the prostate. In the first medical event, the dose to 90% of the patient's prostate volume (D90) was determined to be 76.3% of the prescribed dose. For the second medical event, the D90 dose to the patient was determined to be 46.8% of the prescribed dose. Each case is a medical event because the prostate received a dose that differed from the prescribed dose by more than 0.50 Gy and the total dose delivered differed from the prescribed dose by more than 20 percent. The licensee identified the medical events during post-implant dosimetry analysis of the permanent seed treatments. The root cause of the medical events was due to the relative positions of the implanted seeds not producing sufficient dose coverage of the prostate volume. A contributing factor for the medical events was patient pre-treatment plans were developed more than three weeks ahead of the scheduled implant procedure, which allowed time for the patient's prostate volume to change. For both medical events, the licensee determined that all seeds were inside of the treatment site.

The licensee did not expect either patient to have any adverse medical effects as a result of the medical events. For the first medical event, no additional treatment is planned for that patient because the patient's known foci for prostate cancer was well covered by the seed implants. The patient involved in the second medical event will receive a second implant procedure to improve dose coverage for specific portions of the prostate.

The inspector identified an apparent violation of NRC requirements involving a failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive for I-125 seed prostate implants, as required by 10 CFR 35.41(a) and (b)(2). To reduce the likelihood of recurrence of a similar event, the licensee initiated several immediate and long-term corrective actions. The corrective actions included: (1) temporarily suspending patient implant procedures until a full evaluation of the medical events could be completed; (2) scheduling the operating room for the implant procedure first, then schedule the CT study for the pre-treatment plan within three weeks of the implant date to minimize the potential changes to the prostate volume; (3) during each implant procedure the authorized user (AU) will use appropriate imaging modalities (including bi-planar ultrasound and/or fluoroscopy) to ensure that the patient's prostate is still localized correctly and the seeds are placed in the intended positions in the prostate; and (4) implementing a hospital policy requiring any AU performing seed implants to have documented experience in successfully performing prostate seed implants within the past 18 months, or have documented training in the performance of prostate seed implants within the past 18 months.

Report Details

1 Program Scope and Inspection History

The hospital was authorized by NRC License No. 21-00258-06 to use a variety of byproduct materials for diagnostic and therapeutic nuclear medicine, including iodine-131. The license was amended on February 28, 2008, to use iodine-125 (I-125) permitted by 10 CFR 35.400 for any manual brachytherapy procedure. The licensee uses I-125 as seeds for implants in the treatment of prostate cancer and has treated five patients using seed therapy since the license was amended.

No violations or NRC regulatory requirements were identified during the two previous NRC inspections of the licensee's activities, which were conducted on June 7, 2004 and August 16, 2007.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspector reviewed the sequence of events that resulted in the medical events and the licensee's investigation report. In addition, the inspector toured the facility, interviewed selected staff, and reviewed patient treatment records and procedures.

2.2 Observations and Findings

a. Medical Event #1

On March 17, 2009, the patient had an ultrasound study as part of the licensee's pre-treatment planning for the implant procedure. Based upon the results of the ultrasound study, the licensee developed an implant dose and seed distribution configuration for the patient. The treatment plan called for implanting 54 seeds to deliver a prescribed dose of 145 Gy to the prostate. The treatment plan was reviewed and approved by an authorized user (AU) on March 25, 2009, and reviewed again on April 8, 2009, by the medical physicist. On April 16, 2009, a written directive was developed and signed by the administering AU to implant 54 seeds for a total dose of 145 Gy. The implant procedure was performed on April 16, 2009, using needles preloaded with rapid strand seeds. The procedure was completed with all seeds implanted as prescribed by the written directive. On April 17, 2009, a post-implant CT study was taken on the patient. A post implant dosimetry analysis performed by a different AU on April 22, 2009, determined that the dose to 90% of the prostate volume (D90) was 60.6 % of the prescribed dose. Subsequent additional CT studies and dosimetry analysis were performed to verify the D90 dose. A local expert medical physicist (EMP) was consulted to review the case. The EMP recommended the patient have another CT study and a MRI study. Another dosimetry analysis was performed and reviewed by the administering AU and EMP on August 24, 2009. The dosimetry analysis determined that the D90 dose to the prostate volume was 76.3% of the prescribed dose.

b. Medical Event # 2

On March 31, 2009, the patient had an ultrasound study as part of the licensee's pre-treatment planning for the implant procedure. Based upon the results of the ultrasound study, the licensee developed an implant dose and seed distribution configuration for the patient. The treatment plan called for implanting 56 seeds to deliver a prescribed dose of 145 Gy to the prostate. The treatment plan was reviewed and approved by an AU on April 1, 2009, and reviewed again on April 8, 2009, by the medical physicist. On April 16, 2009, a written directive was developed and signed by the administering AU to implant 56 seeds for a total dose of 145 Gy. The implant procedure was performed on April 16, 2009, using needles preloaded with rapid strand seeds. The procedure was completed by the AU with all seeds implanted as prescribed by the written directive. On April 17, 2009, a post-implant CT study was taken on the patient. A post implant dosimetry analysis performed by a different AU on April 22, 2009, determined that the (D90) was 77.3% of the prescribed dose. Subsequent additional CT studies and dosimetry analysis were performed to verify the D90 dose. The EMP was consulted to review this case, as with the first case. The EMP recommended the patient have another CT study and a MRI study. Another dosimetry analysis was performed and reviewed by the administering AU and EMP on August 24, 2009. The dosimetry analysis determined that the D90 dose to the prostate volume was 46.8% of the prescribed dose.

Title 10 CFR 35.41(a) states in part, that for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b). Title 10 CFR 35.41(b)(2), requires, in part, that the procedures required by 10 CFR 35.41(a) must address methods for verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive. For these medical events, the licensee's procedures did not contain any steps to ensure that no changes had occurred in the patient's prostate volume between the time the treatment plan was prepared and the administration of the treatment, and no other method was provided to ensure that the administration was in accordance with the written directive. The failure to have written procedures to provide high confidence that each administration is in accordance with the written directive, is an apparent violation of 10 CFR 35.41(a) and 10 CFR 35.41(b)(2).

The licensee determined that a medical event had occurred for each patient implant because the prostate received a dose that differed from the prescribed dose by more than 0.5 Sv (50 rem) and the total dose delivered differed from the prescribed dose by more than 20%. Once the licensee had identified the medical events, the licensee immediately initiated an investigation and determined that the root cause of the medical events was that the relative positions of the implanted seeds did not produce sufficient dose coverage of the prostate volume. A contributing factor for the medical events was patient pre-treatment plans were developed more than three weeks ahead of the scheduled implant procedure which allowed time for the patient's prostate volume to change prior to the implant procedure. The inspector also reviewed the other seed implant cases performed by the licensee and did not identify any issues that would have constituted a medical event.

2.3 Conclusions

The inspector identified an apparent violation of 10 CFR 35.41(a) and 10 CFR 35.41(b)(2) concerning the licensee's failure to develop adequate procedures to provide high confidence that prostate seed implants are performed in accordance with the written directive. The inspector concurred with the licensee's root cause determination. The licensee did not expect any adverse medical effects for either patient because of the medical events.

3 Licensee Corrective Actions

3.1 Inspection Scope

The inspector reviewed the licensee's proposed corrective actions to preclude similar events. The review included the licensee's September 8, 2009, written report regarding the medical event, interviews of selected licensee personnel, and the licensee's revised policies and procedures.

3.2 Observations and Findings

The inspector determined that the licensee initiated several immediate and long-term corrective actions to prevent recurrence of a similar medical event. The corrective actions included:

- (1) Temporarily suspending patient implant procedures until a full evaluation of the medical events could be completed;
- (2) Scheduling the operating room for the implant procedure first, then schedule the CT study for the pre-treatment plan within three weeks of the implant date to minimize the potential changes to the prostate volume;
- (3) During each implant procedure the authorized user (AU) will use appropriate imaging modalities (including bi-planar ultrasound and/or fluoroscopy) to ensure that the patient's prostate is still localized correctly and the seeds are placed in the intended positions in the prostate; and
- (4) Implementing a hospital policy requiring any AU performing seed implants to have documented experience in successfully performing prostate seed implants within the past 18 months, or have documented training in the performance of prostate seed implants within the past 18 months.

3.3 Conclusions

The inspector determined that the licensee developed corrective actions to address the violation and prevent similar medical events.

4 Notifications and Reports

4.1 Inspection Scope

The inspector interviewed selected licensee staff and reviewed the licensee's notification to the NRC Operations Center and the associated 15-day written report to ensure compliance with NRC reporting requirements.

4.2 Observations and Findings

On August 24, 2009, the licensee determined that the administered dose to a prostate cancer patient was 76.3% of the prescribed dose for an implant procedure. In another implant procedure, the licensee determined that the administered dose to the patient was 46.8% of the prescribed dose. Each case is considered a medical event because the prostate received a dose that differed from the prescribed dose by more than 0.50 Sv and the total dose delivered differed from the prescribed dose by more than 20%. Title 10 CFR 35.3045(a)(ii) requires a licensee to report any medical event where the dose received differs from the prescribed dose by more than .5 Sv (50 rem) to an organ and the total dosage delivered differs from the prescribed dosage by 20% or more. Title 10 CFR 35.3045(c) requires a licensee to notify the NRC Operations Center no later than the next calendar day after discovery of the medical event. The licensee's medical physicist notified the NRC Operations Center of the event at 14:50 EDT on August 25, 2009. Each patient or the patient's spouse and the referring physician for both medical events were notified on August 24, 2009, by the administering AU in accordance with 10 CFR 35.3045(e). The licensee's 15-day report, dated August 8, 2009, contained the information required by 10 CFR 35.3047(d).

4.3 Conclusions

The licensee made all of the notifications and submitted the reports required by 10 CFR 35.3045 within the specified time period. The inspector determined that the licensee included all of the required information.

5 Exit Meeting

On September 9, 2009, at the completion of the onsite inspection, the inspector discussed the findings in this report with licensee management. The inspector held a final exit meeting by telephone on October 13, 2009, where the inspector discussed the sequence of events that led to the medical event, the root and contributing causes of the event, and the licensee's corrective actions. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

PARTIAL LIST OF PERSONS CONTACTED

- * Karen Yacobucci, Executive Director, Oncology Services
- * Deborah Dusseau, Manager Radiation Oncology
- * Mary Feng, M.D., Authorized User
- * Anas Orfali, Medical Physicist

- * Attended the October 13, 2009, final telephonic exit meeting