



Allegiance
H E A L T H

September 8, 2009

U.S. Nuclear Regulatory Commission, Region III

Material Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Licensee's Name: Allegiance
Health

License Number:
21-00258-06

September 4, 2009

Sent via facsimile
301-816-5151
and certified mail

Dear Sirs,

Please find enclosed the written report compiled by Allegiance Health's physicist, Anas Orfali, with regards to event notification # 45294 Medical Event and event notification # 45295 Potential Medical Event. Both events were reported on 8/25/2009 at 14:50 EDT to Mr. Howie Crouch at the NRC Operations Center at (301)951-0550.

If you have any further questions, please do not hesitate to contact me.

Regards,

Karen D. Yacobucci, FACHE, MBA, OTR/L
Executive Director, Oncology Services
Allegiance Health

CC: With annotation to the referring physician, Dr. Nitin Ambani.

Licensee's Name: Allegiance Health
License Number: 21-00258-06

Name of the Prescribing Physicians: Dr. Charlie Pan and Dr. Mary Feng

Case #1: Event Notification #45294, Medical Event:

A brief description of the event:

On 3/17/2009 an ultrasound study for the purpose of pre-planning was done on the patient by Dr. Mary Feng, Authorized User. The pre-plan was produced using VariSeed planning system and reviewed on 3/25/2009 by Dr. Mary Feng, Authorized User. On 4/16/2009 Dr. Charlie Pan, Authorized User, in collaboration with the Urologist, Dr. Nitin Ambani, implanted the patient with a total of 54 sources of I-125 (6711 model) using needles pre-loaded with rapid strand. Each seed had an activity of 0.679U on implant date. The prescribed dose in the written directive was 145 Gy to the prostate. On 4/17/2009 a post-implant CT study was taken of the patient. A post-implant dosimetry analysis was done on 4/22/2009 and reviewed by Dr. Mary Feng, Authorized User. The dose to 90% of the prostate volume (D90) was found to be 60.6% of the prescribed dose. A second CT study was taken of the patient on 5/18/2009. A post-implant dosimetry analysis was done on 6/10/2009 and reviewed by Dr. Charlie Pan. The D90 was found to be 58.7% of the prescribed dose. A local expert in prostate seed implants, Dr. Patrick W McLaughlin, from the University of Michigan and Providence Hospitals was consulted. Upon the expert recommendation, the patient underwent a third CT study on 7/21/2009 and an MRI study on 7/28/2009. A dosimetry analysis was done on 8/13/2009 and reviewed by Dr. Charlie Pan on 8/19/2009. The Authorized User, Dr. Charlie Pan, further consulted with Dr. McLaughlin and finalized the review of the prostate volume and the dosimetry analysis on 8/24/2009, and reached the decision that while there was a slight cold-spot, it was located in the anterior superior portion of the prostate. Therefore, it was recommended that no additional implant be performed, but rather continued and close surveillance.

The final determined D90 was 76.3% of the prescription dose, based upon the MRI delineated volumes, which falls outside of the 20% tolerance for delivered dose.

Why the Event Occurred:

The relative positions of the implanted I-125 seeds did not produce sufficient dose coverage of the prostate volume as specified by the written directive and the pre-plan. A slight cold-spot in the anterior superior portion of the prostate was found.

The effect on the individual who received the administration:

The slight cold-spot in the anterior superior portion of the prostate of less than 2cc, was located in the transitions zone, an area very unlikely to harbor any prostate cancer. Additionally, the patient's known foci of prostate cancer, as determined by his biopsy on 11/4/2008, were in the right mid-lateral region, which was well covered by his implant. Finally, any additional implant, while it would change the D90 to meet the criteria, would not provide any significant clinical benefit but would subject the patient to the additional risks of another prostate implant.

In conclusion, it is unlikely that this event will have any impact on his care, and he will undergo continued close surveillance.

Certification that the licensee notified the individual:

On behalf of the licensee, Dr. Charlie Pan, Authorized User, contacted and informed the patient (through the patient's wife) on 8/24/2009. Dr. Charlie Pan further contacted and informed the referring physician, Dr. Nitin Ambani, within 24 hours on 8/25/2009.

Licensee's Name: Allegiance Health
License Number: 21-00258-06

Name of the Prescribing Physicians: Dr. Charlie Pan and Dr. Mary Feng

Case #2: Potential Medical Event, Event Notification Number 45295

A brief description of the event:

On 3/31/2009 an ultrasound study for the purpose of pre-planning was done on the patient by Dr. Mary Feng, Authorized User. The pre-plan was produced using VariSeed planning system and reviewed on 4/1/2009 by Dr. Mary Feng, Authorized User. On 4/16/2009 Dr. Charlie Pan, Authorized User, in collaboration with the Urologist, Dr. Nitin Ambani, implanted the patient with a total of 56 sources of I-125 (6711 model) using needles pre-loaded with rapid strand. Each seed had an activity of 0.577U on implant date. The prescribed dose in the written directive was 145 Gy to the prostate. On 4/17/2009 a post-implant CT study was taken of the patient. A post-implant dosimetry analysis was done on 4/22/2009 and reviewed by Dr. Mary Feng, Authorized User. The dose to 90% of the prostate volume (D90) was found to be 77.3% of the prescribed dose. A second CT study was taken of the patient on 5/20/2009. A post-implant dosimetry analysis was done on 6/10/2009 and reviewed by Dr. Charlie Pan. The D90 was found to be 53.4% of the prescribed dose. A local expert in prostate seed implant, Dr. Patrick W McLaughlin, from the University of Michigan and Providence Hospitals was consulted. Upon the expert recommendation, the patient underwent a third CT study and an MRI study, both on 8/3/2009. A dosimetry analysis was done on 8/13/2009 and reviewed by Dr. Charlie Pan. The D90 was found to be 46.8%, which falls outside of the 20% tolerance for delivered dose. The Authorized User, Dr. Charlie Pan, further consulted with the local expert, Dr. McLaughlin, and finalized the review of the prostate volume and the dosimetry analysis on 8/24/2009. On that day, the decision was made to proceed with a second corrective implant procedure.

Why the Event Occurred:

The relative positions of the implanted I-125 seeds did not produce sufficient dose coverage of the prostate volume as specified by the written directive and the pre-plan. A cold spot in the superior/base portion of the prostate was found.

The effect on the individual who received the administration:

Due to the insufficient dose coverage of the prostate, a second corrective implant procedure will be performed. Presuming that this corrective procedure results in adequate coverage, there should be no adverse affect on this patient's clinical care. This patient will be subjected to the risks of another implant procedure, but these risks, as well as the need for a secondary procedure, were discussed with the patient prior to the initial implant.

Planned corrective actions:

The Authorized User, Dr. Charlie Pan, in cooperation with the referring physician, Dr. Nitin Ambani has scheduled a second corrective implant procedure for this patient in order to improve the dose coverage to the superior/base portion of the prostate. The scheduled date of the corrective implant procedure is 9/28/2009.

Certification that the licensee notified the individual:

On behalf of the licensee, Dr. Charlie Pan, Authorized User contacted and informed the patient on 8/24/2009. Dr. Charlie Pan further contacted and informed the referring physician, Dr. Nitin Ambani, within 24 hours on 8/25/2009.

What actions have been taken or are planned to prevent recurrence, Case#1 and Case#2:

The licensee intends to take the following actions:

1. The ultrasound study done for the purpose of pre-planning should be done within three weeks of the implant date, in order to minimize the potential changes to the prostate volume.
2. The authorized user performing the implant should have either:
 - a. Documented experience in successfully performing prostate seed implants in the past 18 months.Or
 - b. Documented training in the performance of prostate seed implants in the past 18 months.
3. During the implant procedure, as various needles are placed in the patient, the authorized user is to use appropriate imaging modalities (including bi-planar ultrasound and/or fluoroscopy) to ensure the following:
 - a. The patient's prostate is still localized correctly.
 - b. The radioactive seeds are placed in the intended positions in the patient.

Extremely Urgent

This envelope is for use with the following services:

**UPS Next Day Air®
UPS Worldwide Express™
UPS 2nd Day Air®**

Call 1-800-PICK-UPS® (1-800-742-5877) or visit UPS.com®.

- For UPS Next Day Air services, there is no weight limit for envelopes containing correspondence, urgent documents, and electronic media. When a UPS Next Day Air service is selected, UPS Express Envelopes containing items other than those listed above are subject to the corresponding rates for the applicable weight.

- For UPS Worldwide Express, the UPS be used only for documents of no cor is no limit on the weight or number o

- Do not use UPS 2nd Day Air services over 13 ounces in this envelope. For l UPS Express Envelopes weighing one to the corresponding rates for the apj

- Do not send cash or cash equivalent.

0407-1012
 P: YELLOW S: 4BB
 I: 411
 2443 WARRENVILLE RD
 LISLE IL 60632-3873

Apply shipping documents on this side.

Do not use this envelope for:

**UPS Ground
UPS Standard
UPS 3 Day Select™
HDC Worldwide Expedited™**

23005
 092014 P1
 61235819
 3 of 100

**UPS Next Day Air
UPS Worldwide Express™**
Shipping Document

WEIGHT	DIMENSIONAL WEIGHT	LARGE PACKAGE	SHIPPER RELEASE
LTR		<input type="checkbox"/>	<input type="checkbox"/>

- EXPRESS (INT'L)
- DOCUMENTS ONLY

The shipper certifies that the contents of this envelope are not hazardous materials, technology or software items exported from the United States in accordance with the Export Administration Regulations. (Penalty: Contrary to U.S. law is prohibited.)

SATURDAY DELIVERY

J216 075 703 3

 J216 075 703 3

SHIPMENT FROM
 UPS ACCOUNT NO. [REDACTED]

REFERENCE NUMBER
 1410 - UNC SERVICES
 TELEPHONE
 KAREN YARBURU 317-741-6406
 ALLEGIANCE HEALTH
 505 N EAST AVE
 JACKSON, MI 49201

UPS Next Day Air

DELIVERY TO
 TELEPHONE
 301-951-0550

US Nuclear Regulatory Commission
 Region III
 2443 Warrenville Rd. Ste 210
 Lisle, IL 60532-4352

J216 075 703 3

 J216 075 703 3

DATE OF SHIPMENT
 9,8,09

010191120 1/07 S United Parcel Service, Louisville, KY



International Shipping Notice — Carriage hereunder may be subject to the rules relating to liability and other terms and/or conditions established by the Convention for the Unification of Certain Rules Relating to International Carriage by Air (the "Warsaw Convention") and/or the Convention on the Contract for the International Carriage of Goods by Road (the "CMR Convention"). These commodities, technology or software were exported from the U.S. in accordance with the Export Administration Regulations. Diversion contrary to U.S. law prohibited.

010195101 11/03 BL United Parcel Service, Louisville, KY