Gaines, Anthony

From: Cann,Kari [KariCann@benefis.org]
Sent: Monday, February 06, 2012 4:21 PM
To: Gaines, Anthony
Cc: Poston-Brown, Martha; Andreassen,Andrew; Stephenson, Jeffrey; Nelson,Vickie L - RadOnc; Cann,Kari
Subject: RE: Interview
Attachments: addendum Final report Medical Event 1_5_2012.doc; Contact people for NRC.doc; HDR patient.pdf

Hello Tony,

We had a successful Radiation Safety Committee meeting today and I believe we have answered all of the outstanding questions. I have attached the amended report, graphic of the dose distribution to be used in assessing the dose to the patient and a list of the contact information. Please note that HIPPA requires a signed document before we can release patient information and for that you will need to go through Dr Stephenson or Vickie Nelson.

Dr Stephenson will be the medical point of contact for Dr Nag.
Please feel free to contact us with any further questions,

Kari

Kari Cann, MS DABR
Medical Physicist/ RSO
Benefis Hospitals
Great Falls MT
406-788-7887

From: Gaines, Anthony [mailto:Anthony.Gaines@nrc.gov]
Sent: Mon 2/6/2012 8:38 AM
To: Cann,Kari
Cc: Poston-Brown, Martha
Subject: RE: Interview

Kari,

When we last talked, I had asked for contact information (telephone number and email address) for some people (yourself, Andrew, Vickie, and Dr. Stephenson). I forgot to ask for the same information for the patient and the referring physician. Please provide that information too. Also, if you would like to name someone as the primary point of contact for our medical consultant, provide me with that information. We have not sent the agreement letter out to the medical consultant yet (I need the information above before I can send it out), but here is the information for the medical consultant:

Subir Nag, MD, FACR, FACRO
Director of Brachytherapy Services
Kaiser Permanente Radiation Oncology
3800 Homestead Road
Santa Clara, CA 95051

Clinical Professor (Affiliated),
Department of Radiation Oncology,
Stanford School of Medicine, Stanford, CA

(408) 851-8085 Direct Line
(408) 851-8001 Front Office
(408) 820-0088 Beeper
(408) 851-8010 Fax
e-mail: subir.nag@kp.org

Tony

Radiation Safety Officer Report of Medical Event
which occurred on January 5, 2012 at 1523 hrs
Sletten Cancer Institute, Benefis Hospitals, Great Falls, Montana

NRC License number 25-12710001

Summary of Events:
On January 5, 2012, patient JM was treated with the HDR unit. The target was the distal esophagus approximately 29 cm from the incisors. The prescription dose was 700cGy to 1 cm depth. At the end of the procedure, the nasogastric tube and intraluminal brachytherapy catheter were removed as a unit and it was discovered that the brachytherapy catheter was not advanced to the end of the nasogastric tube by approximately 4cm. The clinical result was that the targeted area was not completely treated and a non target portion of the esophagus was treated. This qualifies as a Medical Event per the Nuclear Regulatory Commission (NRC) regulations 10 CFR Part 35.3045 section "(3) A dose to the skin or an organ or tissue other than the treatment site that exceed by 0.5Sv (50 rem) to and organ or tissue..."

At the time of the event, the physician did not feel that a Medical Event had occurred as there was potential for disease in the area that was treated. The RSO was notified by the Medical Physicist about the treatment after hours on January 6, 2012. The RSO, Department Manager and Medical Physicist (via telephone) met on January 9 to investigate the occurrence. At that time it was decided that this could be a Medical Event and the RSO called and reported it to the NRC operations Center at 2pm MST on January 9. The RSO also conferred with representatives of the NRC Region IV office (Jackie Cook) and confirmed that this incident satisfies the conditions of a Medical Event.

Licensee Name: Benefis Hospitals

Name of Prescribing Physician: Dr Jeffrey Stephenson, MD

Brief Description of the event: Please see above

Why the event occurred:
1) Misidentification of the distal end of the brachytherapy catheter due to radio-opaque markers in the nasogastric catheter.
2) Lack of familiarity with the nasogastric catheter and its radio opaque markers.

The effect, if any, on the individual who received the administration:
None. The physician does not feel that there will be adverse effects to the patient

What actions, if any, have been taken or are planned to prevent recurrence:
1) Future esophageal treatment will be done so that the brachytherapy catheter and the nasogastric tube are introduced to the patient as a unit and appropriate catheter length measurements will be done prior to the procedure
2) We are searching for a nasogastric catheter that does not have radio opaque markers

Certification that the licensee notified the individual:
Dr. Stephenson spoke to the patient and his family and this is documented in the Radiation Oncology Procedure note dated 01/05/12

Kari Cann, MS DABR
Medical Physicist and RSO
Benefis Hospitals
406-788-7887

Update to this report February 6, 2012

On January 17, the Medical Physicist at Benefis conducted phantom testing and determined that the dose was delivered to a location 29 cm proximal to the end of the catheter. I have attached the dosimetry that was done to determine if any structures deemed by the Radiation Oncologist to be "Critical Structures" were over dosed. It does not appear that this is the case. The patient has since returned for additional treatment and follow up and is not experiencing any side effects of the Medical Event.

An addendum to the "Actions to prevent recurrence" of the event:

1. We have been unable to locate a nasogastric tube that does not have a radio opaque marker.
2. We have implemented a policy that the entire length of the catheter will be visible in the CT scan. This includes the entrance of the catheter in the patient down through the end of the catheter. This policy is in force for all HDR .procedures.

This incident was discussed at the regular Radiation Safety committee meeting held today at Benefis.

No further reporting of this incident is anticipated

Kari Cann, MS DABR
Medical Physicist and RSO
Benefis Hospitals
406-788-7887