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August 6, 2012

Mr. Anton Vegel, Director
Mr. Anthony Gaines
Mr. Michael Vasquez
Division of Nuclear Materials Safety
US NRC Region IV
1600 East Lamar Blvd
Arlington, TX 76011-4511

Gentlemen:

Re: Response to an Apparent Violation in Inspection Report 030-02404/2012-001; EA 12-107
Benefis Hospitals, Great Falls, MT
License #25-12710-01

This letter is in response to an apparent violation identified in Inspection Report 030-02404/2012-001; EA 12-107 dated July 19, 2012 from a medical event which occurred on January 5, 2012 at the Sletten Cancer Institute at Benefis Hospitals

One apparent violation has been identified:
Licensee's failure to develop and implement procedures to provide high confidence that a high dose-rate (HDR) remote afterloading brachytherapy treatment was in accordance with written directives as required in 10 CFR 35.41 (a) and (b).

1) Reason for the violation
   a. Root cause: The licensee did not have in place any program or process for addressing new or infrequently used modalities to ensure that the appropriate level of planning, practice, communication, and documentation is implemented to prevent undesired outcomes.

2) The corrective steps that have been taken and the results achieved
   a. A policy had been developed in Radiation Oncology that addresses new modalities and the procedure to be followed prior to implementing them. This policy addresses all new modalities in the department and not just new procedures in brachytherapy administrations. The policy is attached to this response.

3) The corrective steps that will be taken to avoid further violations
   a. Continued implementation of new and /or revised policies as needed to encourage a safety first environment at Benefis Hospitals.

b. An additional FTE medical physicist has been added to the staff and will be added to the NRC License as an Authorized Medical Physicist in the near future.

4) The date full compliance was achieved.
   a. July 3, 2012. This is the initial date of the attached "Policy Regarding Implementation of New Radiation Therapy Modalities". There have been minor changes implemented following review of the "Reactive NRC Inspection Report 030-02404/2102-001" dated July 19, 2012.

This response and the NRC Inspection Report have been presented to the members of the Benefis Radiation Safety Committee at the regular quarterly meeting on August 6, 2012.

We sincerely hope that this letter of explanation and the attached policy regarding implementation of new radiation therapy modalities meets with your approval and sufficiently addresses this apparent violation. Please do not hesitate to contact the Benefis Hospitals Radiation Safety Officer listed below at 406-788-7887 if you have any additional questions or concerns.

Sincerely,

Laura L. Goldhahn, MBA, FACHE
President

Kari Cann, MS DABR
Radiation Safety Officer

Benefis Hospitals
Policy/Procedure

TITLE: Implementation of New Radiation Therapy Modalities

Rev. #:
Page(s): 2

AREAS AFFECTED: Radiation Oncology

POLICY: Benefis Hospitals strives to provide a variety of safe and effective radiation therapy treatment modalities to meet the needs of the community cancer population.

PROCEDURE/RESPONSIBILITIES:

I. Planning
- A. Implementation Timeline
  1. Enough time will be given to the careful consideration of the implementation process to ensure safe and accurate implementation of the new modality.
- B. Review of Professional Standards
  1. Prior to implementation, physics personnel will research/review professional standards associated with the new modality.
- C. Assessment of Requirements
  1. A careful assessment of space, staff, and equipment requirements will be performed to ensure requirements are met.
     a. In the case that new equipment must be acquired, it will be installed, accepted, and commissioned per vendor recommendation and per professional standards.

II. Preparation
- A. Clinical Conference for Review of New Modalities
  1. A conference will be held involving all technical and professional personnel who have a part to play in ensuring the quality of the treatment in the new modality. The purpose is to clearly define roles and responsibilities of each job function, and mitigate mistakes arising from incomplete understanding of the clinical processes with the new treatment modality.

III. Practice

A. Training and Simulation

1. Before actually treating any patients, staff will be trained in the new modality treatment procedures.
2. Each new treatment modality will be simulated in detail. Any omissions or problems with the treatment procedures can then be identified and corrected

B. Discussion

1. An open discussion of the simulation will be held with all involved parties to insure all participants understand their roles and responsibilities.

IV. Documentation of Procedures

A. Written Procedures

1. Written procedures describing the technical work instructions associated with the new treatment modality will be in place prior to implementation.
2. Written emergency procedures applicable to any new brachytherapy modality will be in place prior to implementation.

B. Quality Control

1. Physics staff will develop a quality control program to ensure consistent accuracy of the new treatment modality.

C. Monitoring

1. Once the new modality is implemented, the procedures, results, and complications will be presented at both the Benefis Quality Committee and Radiation Safety Committee.

Date of Origin: 7/3/12
Date(s) of Revision: 7/25/12
Date of Last Review:
Effective Date: 7/3/12

References: The JC:

Contact Person: Radiation Oncology Manager