

LaFranzo, Michael

From: Potters, Dr. Louis [LPotters@NSHS.edu]
Sent: Wednesday, April 20, 2011 9:22 AM
To: LaFranzo, Michael
Cc: Bloomer, Tamara
Subject: Re: Liberty Hospital - Additional Information
Attachments: NRC_Liberty.docx

Please see attached document. Let me know if there are additional questions.

Louis Potters, MD
Prof & Chair, Dept. of Radiation Medicine
North Shore-LIJ Health System

On 4/9/11 1:24 PM, "LaFranzo, Michael" <Michael.LaFranzo@nrc.gov> wrote:

Dear Dr. Potters,

On March 23, 2011, NRC acknowledged your input that additional information had not been received by you from Liberty Hospital (licensee) so that your review of the medical event could be complete. NRC requested the additional information and in a letter dated April 1, 2011, the licensee forwarded the requested information to NRC. Attached is the information that the licensee provided. You may note that several area's had been blocked out; the blocked out information was related to patient identification. If you require that or similar information, please contact me and it can be forwarded to you.

NRC believes that the additional information does address all areas that you had discussed with NRC as deficient. However, NRC has not made a determination on whether the information is sufficiently complete in each area to your satisfaction regarding your review of the medical event. If you require additional information, please contact me and NRC will attempt to gain the information requested.

The NRC looks forward to your final report and if you have any questions, please feel free to contact me.
Thank you

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April 20, 2011

To: Michael LaFranzo, Tamara Bloomer

From: Louis Potters, MD

Re: Liberty Hospital Seed Implant Investigation: Supplemental Report

Additional reports were reviewed: Introductory letter from Christopher Moore, Clinical summary from Dr. Scott Cozad, Brachytherapy Policy document, Attachment #1 (Planning system acceptance test), Attachment #2 (CT QA report), Attachment #3 (copy of written directive), attachment #4 (room survey document).

Comments:

The patient developed proctitis. This is not described in detail but is an accepted complication from prostate brachytherapy. It is impossible to tell based on this or past submitted information whether the proctitis is a result of the misadministration of radioactive activity. This appears, as is typical to be a limited clinical problem.

The patient's PSA response is suboptimal. His PSA in late 2010 was 7.45 ng/ml following the implant on 10/6/10. His next PSA in 2/11 was 5.62ng/ml. It is expected that a PSA response would be more brisk and given the misadministration of radioactive brachytherapy procedure, the patient should have been started on supplemental external beam radiation therapy. The note from Dr. Cozad remains ambivalent regarding supplemental external beam radiation therapy. That said, the patient has physical limitations that likely precluded his receiving supplemental radiation during the winter.

Dr. Cozard's statement suggests that changes have been made to the implant process at Liberty Hospital. Nonetheless, the Prostate Brachy Therapy Policy/Procedure QA Program document does not reflect those changes. Nor is this documented dated or signed to indicate its acceptance in the department.

The policy document is not dated and not signed, It has language that is confusing. Such as (on the top of page 2) 'This can also be...' Use of the word 'can' implies they do NOT perform fluoroscopic imaging, although it 'can' be done. Further, they state that they review a D90-minimum dose V100 and R100, but do not define what values are acceptable.

Personal comments:

The Liberty Hospital prostate program may be in compliance with NRC regulations, based on documentation submitted. That said, it is not clear that a 'lesson learned' from this misadministration has provided additional impetus toward improvement and modernization of their program. The QA policy document is very weak and allows plenty of wiggle room for a future event.

The patient's clinical management remains lax. Given that this is a supplemental statement, and not actual chart copies of notes, and that the statement is spurious about the clinical condition of the patient presents a serious disregard this event. Taken in total, this program may be compliant, but certainly one that I would not refer to and one that should be watched very carefully.

ELECTRONICALLY SIGNED: Louis Potters, MD 4/20/2011 0900