

February 22, 2006

Michael Wiemann, M.D.
Senior Vice President/Chief Medical Officer
St. Vincent Hospital & Medical Center
2001 West 86th Street
Indianapolis, IN 46240

SUBJECT: LETTER DATED FEBRUARY 2, 2006

Dear Dr. Wiemann:

This acknowledges receipt of your letter dated February 2, 2006, with attachment. Based on our review of your letter and a conversation between Robert Gattone of my staff and Edward Wroblewski of your staff on February 16, 2006, it is our understanding that:

1. Rather than having a second medical physicist verify that High Dose Rate (HDR) brachytherapy treatment parameters are correct prior to treatment at your Anderson, Indiana facility, you will have a qualified medical dosimetrist independently verify that the treatment parameters are correct prior to treatment.
2. You will take the action described in Item 1 above because you recently obtained an HDR unit at your authorized location in Anderson, Indiana, and you determined that the workload does not justify a second medical physicist at that location.
3. You will continue to provide two authorized medical physicists during HDR brachytherapy treatments at your Indianapolis, Indiana facility.
4. The authorized medical physicist who reviewed all of the HDR treatments as part of your corrective action taken in response to medical events will continue to be an integral part of your ongoing monthly peer process that will include records of HDR treatments that are conducted at your Anderson, Indiana facility.
5. An authorized medical physicist will manually calculate the treatment dose and compare it to the dose developed in the HDR treatment plan and the written directive prior to treatment.

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M. Wiemann

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If our understanding is incorrect, please contact this office immediately.

Sincerely,

/RA/

John R. Madera, Chief
Materials Inspection Branch

License No.: 13-00133-02

Docket No.: 03001579

cc: E. Wroblewski

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