Community
Health Network

March 18, 2011

US Nuclear Regulatory Commission
Region III
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352

Docket No. 030-01625
License No. 13-06009-01

Dear Sir or Madam:

Response to an Apparent Violation in Inspection Report N0.03001625/2010003(DNMS); EA-11-016

Pursuant to the apparent violation described in the above listed report, Community Hospitals of Indiana, Inc. submits the following response.

1) Reason for the apparent violation
The root cause of the apparent violation was the population of treatment planning parameters with default responses by the software of the treatment planning system (TPS) used for the event cited. The secondary causes were human error and the difference among types of treatments requiring digitization of treatment catheters from either terminal or tip end. Difference in digitization start point is prompted by recommendations and training by vendors of particular transfer devices as well as other considerations prompted by treatment site and patient anatomy.

2) Corrective action taken
At this time it does not appear feasible to require a uniform digitization start point for all treatment plans produced by the TPS. To reduce the likelihood of human error in changing the default, a check box [Tip end selected during catheter reconstruction] has been added to the Treatment Planning Information section of the written directive. The SAVI APBI procedure has been modified to include the verification of catheter reconstruction in the 3D Display. A review of other HDR breast treatments for 2010 yielded no other treatments in

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which an error in planning was made. Treatments delivered since 10/8/2010 has been in accordance with the written directive.

3) Corrective actions that will be taken to avoid further violations
The written directive forms and treatment planning process for all procedures are being reviewed and for those requiring a change to a default response, a check box will be added to remind the AMP and AU of this critical step.

4) Date when full compliance was or will be achieved
The latest revision of the SAVI written directive incorporating the checkbox was completed on 3/3/2011, and the latest revision of the SAVI procedure incorporating the step to verify catheter reconstruction in the 3-D display was completed on 10/27/10.

5) The review of other written directive forms requiring change of default for catheter reconstruction is on-going with all form changes anticipated by 3/31/2011.

Sincerely,

Joseph C. Heckman
Vice President
Cancer Care Services
Community Health Network

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