



Date: November 22, 2004

**Mr. George Parker
Health Physicist
Nuclear Materials License Branch
United States Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352**

P.O. Box 40970
Indianapolis, IN 46240-0970
317-338-CARE

www.stvincent.org

Re: *Medical Event #41133 (Amended Corrective Action)*

Dear Mr. Parker,

In re-evaluating the Corrective Action submitted to the United State Nuclear Regulatory Commission (USNRC) of November 1, 2004, it has come to light the second item stated may be contrary to St. Vincent Hospital's ability to provide comprehensive radiation oncologic care. The second item in the corrective action stated the following:

Single catheter delivery length (1500mm) will be used for all HDR treatment procedures. 10/22/04



The Corrective Action should have stated:

Single catheter delivery length (1500mm) will be used for all GYN, Bronchogenic & Esophageal HDR treatment procedures (excluding Mammosite). The transfer tube manufactured by Nucletron and catheter manufactured by Proxima will be used for Mammosite HDR procedures. 10/22/04

I have attached the entire "amended" corrective action for your review as part of this correspondence as we discussed in our telephone conversation this morning.

St. Vincent Core Values
We are called to
Service of the Poor
Generosity of spirit for persons most in need.
Reverence
Respect and compassion for the dignity and diversity of life.
Integrity
Inspiring trust through personal leadership.
Wisdom
Integrating excellence and stewardship.
Creativity
Courageous innovation.
Dedication
Affirming the hope and joy of our ministry.


Multidisciplinary team meeting to review USNRC visit on Oct. 27-28, 2004, and begin drafting response.	10/28/04	
Single catheter delivery length (1500mm) will be used for all GYN, Bronchogenic & Esophageal HDR treatment procedures (excluding Mammosite). The transfer tube manufactured by Nucletron and catheter manufactured by Proxima will be used for Mammosite HDR procedures.	10/22/04	Amended Corrective Action 11/22/04.
A formal "time-out" will be conducted before HDR treatment is implemented and will include active participation of the prescribing physician and the physicist to verify the procedure being performed.	11/01/04	
The physicists currently working with Novalis procedures will independently and extensively review and improve the written procedure for preparing and verifying HDR treatment plans.	11/29/04	
The Chief Physicist involved in this medical event is no longer participating in USNRC licensed activities at St. Vincent Hospital and is no longer in this position. Medical Physicist duties will be assumed by other radiation therapy physicists in the radiation oncology department.	11/12/04	
The medical physicist involved with the medical event in April and October 2004 is terminated from employment at St. Vincent Hospital	11/12/04	
The 2 Novalis physicists are qualified and experienced with HDR and will assume responsibility for oversight of all HDR procedures. (Curriculum vitae and certificates of training attached.)	11/1/04- 11/19/04	
Contractual obligations with other St. Vincent Health radiation therapy facilities will be terminated and the physicist that services those facilities will return to full time support of the St. Vincent Indianapolis location.	As soon contractual obligations can be met without imposition of legal consequences.	
The second physicist who currently travels to other locations will work only at the St. Vincent Indianapolis Hospital.	11/01/04	
Radiation Oncology Physician Authorized Users will be provided additional training by a qualified Medical Physicist for additional oversight of written directives and treatment plan verification.	11/01/04- 11/30/04	
Any Medical Physicist involved in HDR activities using the Nucletron Selectron will undergo manufacturer's recommended training if not previously trained. New physicists to our staff will undergo recommended training as training courses become available. New Physicists will be accompanied by a Medical Physicist who has received formalized training by Nucletron.	As necessary	
One of the Novalis therapy physicists will conduct monthly quality assurance chart audits.	11/30/04	
The Radiation Safety Officer will add a Therapy Plan audit to quarterly safety audits.	12/01/04	
An independent radiation therapy physicist consultant will be sought to conduct on-site quality assurance reviews of the radiation oncology department once a month for twelve	12/01/04	

St. Vincent Hospital (continued)
November 22, 2004

Page 3

If you have any questions, please feel free to contact me at 317/338-2381.

Sincerely,


Edward E. Wroblewski, M.A.
Diplomate, ABSNM
Radiation Safety Officer
St. Vincent Hospital

Enclosures

cc: Patricia Maryland, Doctor P.H., President, St. Vincent Hospital
Jean Meyer, M.S.N., Senior Vice President, Chief Nursing Officer
Jeff Hefflefinger, M.S.A., C.H.E., Executive Director, Oncology
Susann M. Stephenson, R.N., J.D., Risk Management
Frank Peyton, M.D. (Indiana Radiation Oncology)
NRC file