



Date: November 1, 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: **Report and notification of Medical Event #41133**

Dear Mr. Parker,

As required under 10 CFR 35.3045, this correspondence is provided as written notification within fifteen (15) days after discovery of a Medical Event as defined in 10 CFR 35.3045 (a) (1) (iii) which was discovered on October 18, 2004 and reported to the USNRC Operations Center and Region III on October 19, 2004.

**(i) Licensee name:**



St. Vincent Hospital & Health Care Center  
2001 West 86<sup>th</sup> Street  
Indianapolis, IN 46240-0970

USNRC Materials License Number: 13-00133-02

**(ii) Name of Prescribing Physician:**

Chandrika Patel, M.D.

**(iii) A brief description of the event:**

On 10/11/04 a 49 year old female patient was on treatment at St. Vincent Hospital for what was to be the first of two High Dose Rate (HDR) treatments for endometrial cancer using a remote afterloading unit. The physician planned two fractions of 350 cGy for a total of 700 cGy at 0.5 cm from the GYN cylinder (2.0cm) wall using a 7.031 Ci Ir-192 source. The GYN cylinder is connected to the HDR unit using a 1500 mm transfer tube. A treatment of 189 seconds with an active length of 5 cm was to be

**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

treated with an indexer position of 1500 mm. Due to an error on the part of two medical physicists, an indexer length of 995 was programmed into the treatment unit. The Physician Authorized User (AU) did not identify the error prior to treatment. This resulted in the source not entering the patient. The source remained positioned in the transfer tube for the treatment duration at an estimated distance of 35-50 cm from the patient's skin.

The prescribing physician authorized user (AU) was immediately notified of the Medical Event on October 18, 2004. The Radiation Safety Officer (RSO) was also immediately notified on October 18, 2004. The Radiation Safety Officer notified the USNRC Operations Center by telephone within 24 hours of discovery at 12:05 ET on October 19, 2004, and spoke with Mr. Steve Sandin of the USNRC in Rockville, MD and Mr. Mike LaFranzo of Region III.

Mr. George Parker, Health Physicist, Division of Nuclear Materials Safety completed a special on-site inspection to St. Vincent Hospital, Indianapolis, IN, on October 27 and 28 2004. Mr. Parker met with: Michael Wiemann, M.D., Senior Vice President, Chief Medical Officer, Edward Wroblewski, RSO, Awat Aliyar, Ph.D., Chief Radiation Therapy Physicist, Jeff Hefflefinger MSA, CHE, Executive Director, Oncology, Robert Liebross, M.D., and Susann M. Stephenson, Director, Risk Management all of St. Vincent Hospital. Several other St. Vincent Associates were also interviewed during the announced Special Inspection. The purpose of the visit was to investigate the reported Medical Event of October 11, 2004.

**(iv) Why the event occurred:**

The event occurred as it appears the two medical physicists involved in the treatment planning did not follow the written procedure established for HDR treatments. In particular:

*"(d)....Any member of the team may interrupt the planning and preparation process prior to commencement if they do not understand the directions in their entirety."*

*"(g)....the integrity of the plan will be checked to ensure the correct customization file, step size, source positions, reference distance and prescription points are used."*

On October 22, 2004, a Root Cause Analysis (RCA) was completed with St. Vincent Hospital Associates and Management staff. The RCA revealed the following:

- 1) Two transfer tube lengths are available. A 1500mm transfer tube is used for GYN cylinders while a 995mm transfer tube is used for esophageal or bronchial treatments. The first Medical Physicist reported she was confused when the AU requested semi-orthogonal films which are routinely requested for esophageal or bronchial treatments with the 995 mm transfer tube. The same Medical Physicist did not recognize or compensate in the treatment planning for a GYN cylinder.
- 2) Although the two Medical Physicists read and repeated the written directive, the treatment plan itself was not mentally distinguished from the "typical" HDR Brachytherapy treatment plan for GYN cylinders.

- 3) The second treating Medical Physicist verified an incorrect treatment plan and presented the treatment plan to the Physician AU for signature.
- 4) The Physician AU then signed the treatment plan as presented by the two Medical Physicists and allowed treatment to proceed without identifying the error in the treatment plan.
- 5) There is a "Time-Out" in the written procedure; however, the reference length of the transfer tube was not stated during this "Time-Out" period.

**(v) The effect, if any, on the individual who received the administration:**

This Medical Event resulted in a calculated dose between 1.4 – 4.3 R to the patient's skin. No biological or physical adverse effects are expected as a result of this administration.

**(vi) Actions that have taken place or are planned to prevent recurrence:**

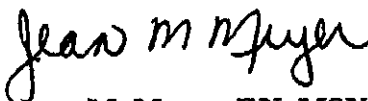
In response to the events of October 11, 2004 concerning the High Dose Rate (HDR) afterloader the following corrective action is provided below to prevent recurrence.

**(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian):**

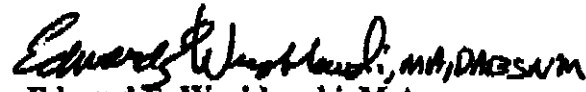
Robert Lieboss, M.D., as radiation oncology physician, has certified he has spoken with the patient and the referring physician and informed both individuals of this medical event.

If you have any questions, please feel free to contact us at 317/338-3911 or 317/338-2381 respectively.

Sincerely,



Jean M. Meyer, RN, MSN  
Senior Vice President  
Chief Nursing Officer  
St. Vincent Hospital



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

Enclosures

cc: Sister Mary Frances Loftin, Chairperson, Board of Directors  
Patricia Maryland, Doctor P.H., President, St. Vincent Hospital  
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)  
Chandrika Patel, M.D. (Indiana Radiation Oncology)  
NRC file

ACTION	DATE	
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 HDR treatment procedures.	10/22/04	
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 months	12/01/04	

# Gary Huang

Home Phone: [REDACTED]

Cell Phone: [REDACTED]

E-Mail: [REDACTED]

Address: [REDACTED]  
[REDACTED]

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## OBJECTIVE

Clinical physicist position where broad range of skills are required and new challenging technologies are applied.

## PROFILE

- ❖ Clinical practice in treatment planning of 3DCRT with ADAC system and IMRT with Radionics system.
- ❖ Professional trained in HDR treatment planning and procedures with Nucletron system.
- ❖ Skilled and experience in Monthly QA and annual calibration of linac and sim/CT.
- ❖ Skilled and experience in IMRT QA.
- ❖ Hands on experience with DICOM RT programming and department computer.
- ❖ Six years of Medical Physicist experience in nuclear medicine in state-of-the-art clinical institute
- ❖ More than ten years of research and development experience in PET and SPECT imaging systems.
- ❖ More than six years of professional Java software R&D experience in telecom/datacom industry.
- ❖ Skilled and experienced in image processing, networking protocols, advanced Java programming, J2SE, Servlet, JSP, RMI, Swing, XML, CGI, ASP, Cold Fusion, Oracle/SQL, C/C++ and Unix/Solaris
- ❖ Strong reasoning, analytical and risk management skills to problem solving.
- ❖ Has demonstrated the ability to work individually as well as in a team environment

## PROFESSIONAL EXPERIENCE

### *Medical Physicist*

2004 – Present

Department of Radiation Oncology  
Newark Beth Israel Medical Center, Newark, NJ

Work in a radiation oncology department with comprehensive procedures. Perform IMRT patient specific QA with phantom. Perform monthly QA and annual calibrations for the treatment units and CT/simulator.

Have extensive trainings and the clinical practice in HDR procedures, such as prostate, lung, henschky and cylinder. Hands on experiences in treatment planning system such as: Radionics XKnife for IMRT with the MMLC unit, Nucletron Plato for HDR treatment and ADAC Pinnacle 3 for three-dimensional conformal treatment system. Participate in a new cancer center planning such as shielding calculation and data network consultation. Implemented a few clinical and QA software tools such as the ROI transfer and independent dose checks.

### *Member of Technical Staff*

1997- 2004

Lucent Technologies, Naperville, IL

As a team leader, successfully designed and implemented the Java Telephony API for the Lucent Softswitch programmability. Implemented the services creation framework based on this API and developed the web based next generation telecom applications by using J2EE.

As an architect and developer, designed and implemented a policy based network management system. This policy enabled system utilized the Policy Definition Language (PDL) to provide the full network management functions to Lucent Softswitch such as alarms/traps, overload control and SNMP interface.

As an organization web master/consultant, responsible for planning, designing and coordinating the department wide web internet/web based development.

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**Medical Physicist****1991 - 1997****Department of Diagnostic Radiology and Nuclear Medicine/Department of Medical Physics  
RUSH PRESBYTERIAN ST. LUKE'S MEDICAL CENTER, Chicago, IL**

Primarily work as a clinical physicist in nuclear medicine department. Successfully setup and support the PET imaging center. Support routine clinical images processing and analysis. Work closely with physicians to define and implement clinical imaging procedures and protocols for routine imaging operation. Designed and implemented in-house clinical and research imaging process software for the PET, SPECT and general nuclear medicine applications such as cardiovascular imaging, stress/rest, GRF, brain SPECT, PET/SPECT attenuation corrections. Evaluate the vendor's trial NM imaging products and procedures.

In charge of department wide quality assurance and acceptance tests for the PET, SPECT and other nuclear and X-ray imaging devices. The responsibilities included: Perform system calibrations and image quality evaluations. Supervise nuclear medicine technologists to use proper physics and mathematics parameters for routine images processing operations. Supervise and evaluate the daily routine quality control.

Continually consulted and participated in a research project to build a modular detectors brain SPECT system. As a staff in the medical physics department, provided and supported training for the radiology residences and the graduate school students.

**Research Scientist****1989 - 1991****Department of Radiology, UNIVERSITY OF IOWA, IA**

Participate in a NIH founded research project to build a modular detectors brain SPECT system. Successfully designed and implemented a completed data acquisition system to achieve the real time position sensitive detector and energy correction requirements. The system utilized the DSP and associated logic to achieve the high throughput two-dimensional photons detection and data collection task.

**Research Scientist****1983 - 1989****Institute of High Energy Physics, CHINESE ACADEMY OF SCIENCE, Beijing, China**

As one of three primary researchers, designed and fully implemented first prototyping PET scanner in China. The responsibilities in this project included: designed and experimented BGO detectors system. Designed and implemented the system coincidences detection and completed data acquisition system by using ECL logic and DSP. Developed an image reconstruction algorithm with filtered back projections. This project was awarded by the Chinese Academy of Science in 1986 and was published in one of the international medical imaging symposium in 1988.

**EDUCATION****Computer Science, DePaul University, MS, 6/99****Biomedical Engineering, University of Iowa, MS program 1/90 -1/92****Nuclear Physics, Graduate School, Chinese Academy of Science, MS, 9/88****Electrical Engineering, Beijing Posts and Telecom. University, BS, 7/83****REFERENCES**

Available upon request.

## Resume

Benwen Ni, Ph. D., ABMP certification

Address: [REDACTED]  
phone: [REDACTED] pager: [REDACTED]  
email: [REDACTED]

### Professional Experience:

- *Medical Physicist:* Department of Radiation Oncology, Loyola University Medical Center, Maywood, IL, April 2002-present
- *Member of Technical Staff:* Lucent Technology, 1997-2002
- *Physicist II,* Department of Radiation Oncology, Rush-Presbyterian-St. Luke's Medical Center, Chicago, IL, 1993-1997

### Certification :

Therapeutic Radiology Physics by American Board of Medical Physics.

### Education:

Ph.D. in physics, Yale University (1989)

### Clinical Experience:

Proficient in all the following:

#### External Beam:

- Linear Accelerator (with dynamic MLCs and wedges) acceptance testing, commissioning (Wellhofer 3D phantom), and QA (CMS Dynascan System for both water phantom and film scan, and Profiler from Sun Nuclear Corporation)
- TG-51 and TG-21 calibration, TLD inter-institution calibration
- Treatment Planning Computer commissioning (CMS Focus XiO) for both photon and electron beams.
- 3-D treatment planning (Focus XiO along with Focal Sim and PICKER Voxel Q virtual simulation)
- IMRT treatment planning (both CMS Focus XiO and Nomos MIMic and Corvus)
- Stereotactic Radiosurgery and fractionated Radiotherapy (Radionics X-knife RT)
- Total Body Irradiation (commissioning and MU calculation)
- QA of Cobalt teletherapy machine (Theratron 1000 )
- Photon and electron beam MU calculation and verification
- RadCalc (a MU calculation program) commissioning.
- Patient chart verification
- IMPAC Record and Verify System
- Digital Portal Imaging (Varian PortalVision 6.1)



**Brachytherapy:**

- Remote afterloading LDR: Selectron, planning with Focus XiO
- Remote afterloading HDR: Gamma Med Plus with planning
- Ir-192 ribbon interstitial brachytherapy both with and without template, planning with Focus XiO.
- Iodine-125 prostate implant
- Intravascular Brachytherapy with Ir-192 source
- Radiation source (seed and ribbon) calibration with well chambers.
- Radiation source inventory

**Computer Skills:**

Languages: C, Quick BASIC, FORTRAN, Assembler.

Hardware: SUN Sparc 20, DEC Alpha, HP 9000 workstations, VAX 8600, PC, Macintosh.

Systems: UNIX, MS-DOS, Windows 95/98/2000/XP

Software: Microsoft Word, Excel, Powerpoint, Access

Algorithms: Monte Carlo simulations, fast Fourier transform, cubic spline fitting, least square parameter estimation, digital image processing, multivariate mathematical modeling.

**Personal:**

U.S. Citizen.