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George Pangburn, Director
Division of Nuclear Materials Safety
Nuclear Regulatory Commission – Region 1
475 Allendale Road
King of Prussia, PA19405-1415

37-01893-01

Docket No. 03003013
CAL No. 1-03-003

Dear Mr. Pangburn:

I am writing in follow-up to the confirmatory action letter (CAL 1-03-003) issued to Robert Packer Hospital on July 28, 2003 (revision letter on July 30, 2003). Specifically, this letter shall serve as the written report of the audit requested on all prostate seed implants performed at Robert Packer Hospital from 2001 to present.

Methodology

The methodology for this review included identification of a master listing of all prostate seed implant cases performed from January 2001 to July 11, 2003. For each case performed, a review of the following occurred:

- A review of the written directives as documented in the medical record
- A determination as to whether post-implant imaging studies were performed
- A determination as to whether dose calculations were performed
- A review of available post-implant implant imaging studies to assess the geometric accuracy of seed placement
- A review of available post-implant dose calculations to assess accuracy of the dose delivered

Additionally, if a post-implant imaging study was either not performed or unavailable for the review, the patient was asked to return to Robert Packer Hospital for a CT scan of the pelvis. Post-implant dose calculations were then performed. It is also pertinent to note that post-implant dose calculations were performed on the entire population of patients reviewed. Last, a root cause analysis was completed on August 18, 2003, whereby participation included former Radiation Oncology staff and caregivers who performed prostate seed implants in 2001. This root cause analysis was conducted under the auspices of the Robert Packer Hospital Patient Safety Committee, as required by Mcare Act 13, and as such, those findings are covered under the confidentiality provisions of this Act. Further, the entire investigation was done within a peer review setting and is therefore protected under the Pennsylvania peer review statute.

Findings

A total of forty-nine patients received prostate seed implants for the review period of January 2001 through July 11, 2003. For each of the forty-nine cases, a written directive was completed prior to the seed implant and could be reviewed for 100% of the cases.

Of the 49 patients, all but four had post-implant imaging studies available for review. The four patients lacking an available study were requested to return to Robert Packer Hospital for a CT of the pelvis, all of which were completed during the month of August 2003. These patients included two from the calendar year 2002 and two from the calendar year 2001.

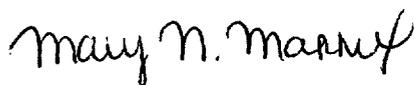
Of the forty-nine patients reviewed, all of the procedures that occurred between October 29, 2002 and July 11, 2003 (a total of nineteen), had post-implant dose calculations completed. Review of post-implant dosimetry was also completed and all patients received a dose to the prostate between 86.4% to 98.1%. It is relevant to note that this grouping of patients were treated by the treatment team under the medical direction of the new chief of Radiation Oncology. Under the direction of the new chief, the protocol and procedures for prostate seed implants were revised to include real time inter-operative treatment planning as opposed to pre-planned treatments. This type of interactive planning allows constant monitoring and visualization of the prostate seed implantation procedure, allowing real time verification and compensation of dose during the implant.

Of the remaining thirty patients, all of whom had procedures performed between January 2001 to January 2002, four (4) appeared to have post-implant calculations performed. Based on our internal review, twenty-one (21) of the thirty patients appeared to meet the NRC definition of a medical event. The findings of this initial internal review are summarized on the attached audit tool excluding all patient or provider identification.

The findings of the root cause analysis remain protected under the confidentiality provisions of Mcare Act 13 and is protected by the Pennsylvania peer review statute. However, we do believe that there is a qualitative difference in the medical direction of the previous seed implant program as compared to the current seed implant program; hence explaining an element of the variation in patient outcomes between the time periods of January 2001 to January 2002 and January 2002 to present. In addition, we believe that qualitative differences exist in the post implant analyses as well.

This letter addresses all components of the audit of all prostate seed implants performed at Robert Packer Hospital from 2001 to present, as requested in point 1 of the confirmatory action letter. Should you have any questions, please do not hesitate to contact me directly at (570) 882-4453.

Sincerely,



Mary N. Mannix, FACHE
Chief Operating Officer

cc: William F. Vanaskie
Ralph D. Zehr, MD
Gary Proulx, MD
Sandra Gabriel

Robert Packer Hospital
Patient Safety Committee
Radiation Therapy - NRC Reporting

AUDIT 1 2001-2003

B#	Date of Implant	Review of Written Directives	Post-Implant Imaging	Post-Implant Dose Calculation	Review of Imaging (CT)	Review of V100	Non Target V-50	Treatment Team (Oncology, Urology, Phys.)	Referring Physician Notified	Patient Informed
2002										
929984	1/3/02	Y	10/22/02	No	8/1/03	76.3%				
968834	1/7/02	Y	8/22/03	No	9/4/03	98.0%				
882208	1/10/02	Y	8/12/03	No	8/14/03	54.0%				Y
2001										
717059	1/22/01	Y	2/7/01	Yes	8/14/03	72.9%				Y
278805	2/8/01	Y	2/22/01	No	7/28/03	18.8%	98.9%			Y
468957	2/8/01	Y	2/23/01	No	8/14/03	67.8%				Y
584964	2/12/01	Y	2/27/01	No	8/4/03	29.0%				Y
37003	2/22/01	Y	3/9/01	Yes	8/14/03	52.5%	79.9%			Y
756460	2/22/01	Y	3/9/01	No	7/28/03	30.7%	93.8%			Y
551595	3/15/01	Y	3/20/01	No	8/14/03	58.6%	86.5%			Y
190760	3/21/01	Y	8/11/03	No	8/14/03	39.3%	88.2%			Y
41678	4/4/01	Y	4/19/01	No	7/29/03	36.9%	95.8%			Y
584044	4/9/01	Y	4/24/01	No	8/14/03	82.7%				Y
332613	4/24/01	Y	5/9/01	No	7/29/03	45.4%	100.0%			Y
245500	5/23/01	Y	6/12/01	No	8/14/03	62.2%	57.6%			N (dec)
93952	5/24/01	Y	6/8/01	No	6/18/03	0.0%	93.2%			Y
319381	5/31/01	Y	6/19/01	Yes	8/14/03	67.7%				Y
976182	6/21/01	Y	8/13/03	No	8/14/03	73.3%				Y
68409	7/5/01	Y	7/23/01	No	8/14/03	49.2%				Y
307099	7/11/01	Y	7/26/01	No	8/14/03	80.5%				Y
270315	7/31/01	Y	8/14/01	No	7/18/03	23.6%	80.2%			Y
665986	9/5/01	Y	9/18/01	No	8/14/03	59.5%				Y
970433	10/1/01	Y	10/16/01	No	8/14/03	90.7%				Y
258590	10/18/01	Y	11/6/01	No	8/14/03	87.2%				Y
205103	11/12/01	Y	11/19/01	No	8/14/03	96.4%				Y
438183	12/13/01	Y	12/27/01	No	8/14/03	69.9%	98.9%			Y
45100	6/21/01	Y	7/10/01	No	8/14/03	96.2%				Y
220785	8/22/01	Y	9/6/01	No	8/28/03	88.7%				Y
127970	10/3/01	Y	10/23/01	No	9/3/03	72.5%				Y
050004	10/4/01	Y	10/18/01	No	9/3/03	66.7%				Y

B#	Date of Implant	Review of Written Directives	Post-Implant Imaging	Post-Implant Dose Calculation	Review of Imaging (CT)	Review of Dosimetry Prostate V100	Non Target V-50	Treatment Team (Oncology, Urology, Phys.)	Referring Physician Notified	Patient Informed
2002										
51645	10/29/02	Y	11/26/02	Yes	11/26/02	89.4%				
37675	11/10/02	Y	12/19/02	Yes	12/19/02	90.5%				
72215	11/26/02	Y	12/19/02	Yes	12/19/02	86.6%				
2003										
1003071	1/6/03	Y	2/5/03	Yes	2/5/03	86.4%				
32679	1/17/03	Y	2/18/03	Yes	2/18/03	93.3%				
394951	1/17/03	Y	2/18/03	Yes	2/18/03	96.0%				
959091	1/20/03	Y	2/20/03	Yes	2/20/03	88.5%				
532221	1/24/03	Y	2/26/03	Yes	2/26/03	92.1%				
784626	1/24/03	Y	3/4/03	Yes	3/4/03	90.1%				
1011694	1/27/03	Y	2/27/03	Yes	2/27/03	93.0%				
241173	2/17/03	Y	3/25/03	Yes	3/25/03	94.9%				
631968	3/10/03	Y	4/11/03	Yes	4/11/03	90.3%				
601493	3/21/03	Y	4/23/03	Yes	4/23/03	98.1%				
475006	3/21/03	Y	4/24/03	Yes	4/24/03	88.7%				
288437	5/16/03	Y	6/18/03	Yes	6/18/03	94.1%				
391843	5/23/03	Y	6/25/03	Yes	6/25/03	93.2%				
990929	6/16/03	Y	7/25/03	Yes	7/25/03	90.8%				
786783	6/20/03	Y	7/18/03	Yes	7/18/03	89.2%				
959216	7/11/03	Y	8/22/03	Yes	8/26/03	92.7%				