



Nuclear Regulatory Commission (NRC)  
Medical Branch  
NRC Region I  
Attn: Sandra Gabriel, Ph.D.  
Senior Health Physicist

Bayonne Medical Center  
29th St. & Avenue E., Bayonne, NJ 07002  
Bayonne, New Jersey

September 18, 2007

***Re: Plan for Ongoing Quality Assurance for Brachytherapy Services, including Seed Implants and High Dose Rate (HDR) Procedures***

Dear Dr. Gabriel:

As you requested at our last meeting, Bayonne Medical Center (BMC), is proposing the following plan for ongoing quality assurance. This plan we hope will avoid future deficiencies with BMC's Brachytherapy Program. Bayonne Medical Center, Bayonne Radiology Associates (BROA) and mpowermed, inc. (see attachment A) have jointly agreed to the following steps for improvement to ensure compliance with the NRC guidelines:

1. Dr. Castillo will remain the RSO for Bayonne Medical Center (BMC)
2. Quarterly Audits of the brachytherapy program at Bayonne Medical Center will be performed by mpowermed, on behalf of BMC by a qualified RSO who meets the NRC training requirements [ 35.50, 35.57, 35.59- See NRC Form 313A (RSO)]
3. An annual, independent, external audit will be performed to include BMC's Brachytherapy Seed Program as outlined in the NUREG Manual 1556, Vol 9, Rev. 1, Appendix L, "Model Medical Licensee Audit." This will be performed by year end 2007 and annually thereafter. Items #2 and #3 will be continued when BROA takes over this portion of BMC's license.
4. BMC will submit letter relinquishing license for HDR and Sr90.
5. BROA will submit NRC Form 313, "Application for Material License" for HDR and Sr90.
6. The Radioactive License will be amended to remove Dr.'s Desai, Varsos, Eanelli and Greenblatt. Items #4, #5 and #6 will be submitted on or before October 19, 2007 in the same packet.
7. mpowermed's physics staff, on behalf of BROA and BMC, will ensure that all Written Directives are signed off by the ordering BROA physician prior to each

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brachytherapy seed procedure performed at BMC as a quality assurance measure. The physics staff will counter sign each directive as confirmation that the physician signed the Written Directive.

8. Completed HDR Safety Training for physics staff and the authorized user physician, Saul Arber, MD. (This was completed and will performed annually).
9. All required calibrations on the HDR unit have been performed, submitted and approved.
10. Assign a qualified RSO to BROA who meets the NRC training requirements [35.50,35.57, 35.59- See NRC Form 313A (RSO)]. Mark Belanich will be named the initial RSO for the new BROA license until which time Tian Chen, MS,DABR will be named RSO after the initial license is issued.

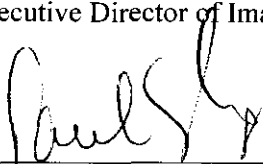
Both Bayonne Medical Center, BROA and mpowermed, inc. thank you and the NRC for your patience and guiding us through this process. We take these deficiencies seriously and will do whatever it takes to make the necessary changes to adhere to the recommended NRC regulations, and provide the safest environment for our patients.

A representative from Bayonne Medical Center, Bayonne Radiation Oncology Associates and mpowermed, inc. are all in agreement with the outlined aforementioned plan. If you should have any questions, please feel free to contact me at (201) 858-5394.

Sincerely,



Vito Comes  
Executive Director of Imaging and Vascular Services



Saul Arber, MD  
Medical Director  
Bayonne Radiology Oncology Associates, LLC

Date: 9.18.07



Mark Belanich  
VP of Medical Physics Services  
mpowermed, inc.

Date: 9-18-07

cc:

**Bayonne Medical Center:**

Sabina Fallon, RN, EdD - Assistant Vice President - Administration

**mpowermed, inc.:**

Thomas Maher- President/CEO

Donna Neil-Exec. VP/COO

### **Attachment A**

Bayonne Radiation Oncology Associates, LLC was jointly formed by BMC Radiation Oncology Services, LLC (25% ownership-hospital) and Advanced Radiation Oncology Services of Bayonne, LLC (75% ownership- physician's group).

mpowermed, inc. is a medical practice management company who was hired by both Bayonne Medical Center and BROA to perform medical physics services, and provides ongoing practice management services to BROA.