UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 7, 2007

Docket No. 03035220 License No. 52-25487-01
EA-07-103

Guido Umpierre Maymí
Chief Executive Officer
Tomé & Ubiñas Radio Oncology Center
P.O. Box 70321
San Juan, PR 00936-7921

SUBJECT: NRC OFFICE OF INVESTIGATIONS REPORT NO. 1-2006-045

Dear Mr. Umpierre Maymí:

On July 13, 2006, the NRC Office of Investigations (OI), Region I Field Office, initiated an investigation at the Tomé & Ubiñas Radio Oncology Center (TUROC), in San Juan, Puerto Rico. This investigation was conducted under the above referenced license to determine whether the licensee had willfully violated NRC requirements related to High-Dose-Rate (HDR) brachytherapy treatments. Based on the evidence developed during the investigation, OI substantiated that the former Medical Physics Director/Radiation Safety Officer, a physician authorized user (AU), and the TUROC organization willfully conducted HDR oncology treatments in violation of the physical presence requirements specified in 10 CFR 35.615(f)(2).

As a result of this OI investigation, the NRC identified two apparent violations. The apparent violations are being considered for escalated enforcement in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included in the NRC's Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The results of the OI investigation are included in the enclosed Factual Summary.

The first apparent violation involves TUROC's failure to meet the physical presence requirements. 10 CFR 35.615(f)(2) requires the physical presence of an AU and authorized medical physicist (AMP) during the initiation of all HDR patient treatments, and that an AMP and AU (or a physician under the supervision of an AU) be physically present during the continuation of all HDR patient treatments. OI determined that on April 27 and 28, 2006, the licensee treated a patient with an HDR unit without the physical presence of an AMP. Additionally, on June 22 and 23, 2006, after initiating a treatment, the licensee continued treating a patient with its HDR unit without the physical presence of an AU (or a physician under the supervision of an AU).

The second apparent violation involved 10 CFR 35.24(g) which requires, in part, that the licensee provide the Radiation Safety Officer (RSO) sufficient authority, freedom and management prerogative to: (1) identify radiation safety problems; (2) initiate, recommend, or provide corrective actions; and (3) stop unsafe operations. On June 23, 2006, a licensee AU left the HDR treatment area during a treatment disregarding notice from the RSO that an AU must be present during HDR treatments.

Before an enforcement decision is made, the NRC would like to discuss these apparent violations with you at a Predecisional Enforcement Conference (PEC) at the Region I office. The conference will be closed and transcribed. The decision to hold a PEC does not mean that the NRC has determined that violations have occurred or that enforcement action will be taken. This conference will be held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. The conference would provide you an opportunity to present your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your corrective actions will be considered in assessing any civil penalty of the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Related to Development and Implementation of Corrective Actions," may be helpful.

Instead of a PEC, TUROC may request Alternative Dispute Resolution (ADR) with the NRC. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The technique that the NRC has decided to employ is mediation. In mediation, a neutral mediator with no decision-making authority helps parties clarify issues, explore settlement options, and evaluate how best to advance their respective interests. The mediator's responsibility is to assist the parties in reaching an agreement. However, the mediator has no authority to impose a resolution upon the parties. Mediation is a confidential and voluntary process. If the parties to the ADR process (NRC and TUROC) agree to use ADR, they select a mutually-agreeable neutral mediator and share equally the cost of the mediator's services. Additional information concerning the NRC's ADR program can be obtained in the NRC website at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute of Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as an intake neutral. Intake neutrals perform several functions, including: assisting the parties in determining ADR potential for their case, advising parties regarding the ADR process, aiding the parties in selecting an appropriate mediator, examining the extent of confidentiality, and providing any other logistic assistance as necessary. Please contact ICR at (607) 255-1124 within ten days of the date of this letter if you are interested in pursuing resolution to this issue through ADR. Guidance on the post-investigation ADR Program is also enclosed.

Please contact Ms. Pamela Henderson at (610) 337-6952 within ten days of the date of this letter to notify the NRC of your decision to either participate in a PEC or ADR.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC web site at http://www.nrc.gov/reading-rm/adams.html.

Thank you for your cooperation.

Sincerely,

Original signed by Mark Thaggard

Brian E. Holian, Director
Division of Nuclear Materials Safety

Enclosures:
1. Factual Summary of OI Investigation Report No. 1-2006-045
2. Excerpts from NRC Information Notice 96-28, “Suggested Guidance Related to Development and Implementation of Corrective Action”
3. NUREG/BR-0317, “Post-Investigation ADR Program”

cc:
David M. Rhoe, Radiation Safety Officer
Commonwealth of Puerto Rico

Thank you for your cooperation.

Sincerely,

Original signed by Mark Thaggard

Brian E. Holian, Director
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David M. Rhoe, Radiation Safety Officer
Commonwealth of Puerto Rico

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FACTUAL SUMMARY OF OI INVESTIGATION REPORT NO. 1-2006-045

On July 13, 2006, the U. S. Nuclear Regulatory Commission's (NRC) Office of Investigations (OI), Region I (RI) Field Office, initiated an investigation to determine if individuals at the Tomé & Ubiñas Radio Oncology Center in Puerto Rico conducted high dose rate (HDR) oncology treatments in violation of NRC requirements. OI issued the subject investigation report on March 20, 2007.

OI substantiated that (1) the Medical Physics Director/Radiation Safety Officer (who was the licensee's only authorized medical physicist (AMP) at the time), (2) a physician (an authorized user (AU)), and (3) the licensee, were responsible for the willful conduct of HDR treatments at the facility in violation of NRC requirements. An AMP and an AU (or physician under the supervision of the AU) must be physically present for the treatments to proceed in accordance with the NRC requirements.

OI found that on certain occasions on April 27 and 28, 2006, HDR treatments were conducted by the physician/AU without the AMP being present at the facility (in fact, OI found that the AMP was in Florida while the treatments were occurring in Puerto Rico). During the OI investigation, the AMP admitted that he knew HDR treatments were scheduled to occur while he was going to be in Florida, even though at that time he was the only AMP for the facility. Therefore, OI concludes that the AMP exhibited careless disregard for the NRC requirements, knowing that a violation would likely occur during treatments on April 27 and 28, when he was not present at the facility.

In addition, OI found that on June 22 and 23, 2006, HDR treatments were conducted while the AU was not always present within audible range of the treatment area. OI also concluded that the AU exhibited careless disregard for compliance with NRC requirements in having authorized and performed HDR treatments in April and June 2006, while admitting no understanding of the relevant regulations pertaining to the requirements for physical presence, including the need for the AU to be within audible range of the treatment area during treatments.

Finally, OI concluded that there was a dysfunctional working relationship between the AU and the AMP, and that this poor relationship was at the center of many of the occurrences. OI noted that other Tomé & Ubiñas Radio Oncology Center officials were aware of the difficulties in the working relationship between the AMP and the AU and chose not to intercede despite their official authority. Their inaction, coupled with the careless disregard by the AMP and the AU, indicated a careless disregard of NRC regulations on the part of the licensee organization. As a result, OI concluded that the AMP, the AU, and the Tomé & Ubiñas Radio Oncology Center licensee willfully conducted HDR oncology treatments in violation of regulations.