October 11, 2007

EA-07-103

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

SUBJECT: NOTICE OF VIOLATION (NRC Investigation Report No. 1-2006-045)
AND CLOSURE OF CONFIRMATORY ACTION LETTER NO. 1-06-004

Dear Mr. Umpierre Maymí:

This refers to an investigation conducted by the NRC Office of Investigations (OI) between July 13, 2006 and March 20, 2007, at the Tomé & Ubiñas Radio Oncology Center (TUROC), in San Juan, Puerto Rico, to determine whether TUROC had willfully violated NRC requirements related to High-Dose-Rate Remote Afterloader Unit (HDR) brachytherapy treatments. The investigation was initiated after you and members of the TUROC staff informed the NRC, during telephone conversations on July 12 and 13, 2006, that on four occasions in late April and early June 2006 TUROC did not meet the physical presence requirements for HDR treatments.

Based on its investigation, OI substantiated that the former Medical Physics Director/Radiation Safety Officer (RSO), a physician Authorized User (AU), and the TUROC licensee willfully conducted HDR oncology treatments in violation of physical presence requirements. As a result, the NRC identified two apparent violations involving failures to: (1) meet the physical presence requirements during the HDR treatments specified in 10 CFR 35.615(f)(2); and, (2) provide the RSO with sufficient authority, freedom and management prerogative to perform his/her duties, as specified in 10 CFR 35.24(g). In a letter dated June 7, 2007, which included a copy of the OI Factual Summary, the NRC described the apparent violations of NRC requirements, and offered you the opportunity to attend a predecisional enforcement conference (PEC).

Previously, on July 17, 2006, the NRC had issued Confirmatory Action Letter (CAL) No. 1-06-004, that documented your agreement to take actions to assure that during the conduct of each HDR treatment, an AU and an Authorized Medical Physicist (AMP) would be physically present (i.e., at or near the console and within normal hearing distance) during the initiation of all patient treatments involving an HDR; and that an AU, or a trained physician under the supervision of an AU, and an AMP would be physically present during continuation of all patient treatments involving HDR. In a letter dated July 21, 2006, you responded to the CAL by informing the NRC that you understood the requirements of 10 CFR 35.615 (f)(2) and that the appropriate measures had been taken to ensure full compliance. On April 18, 2007, NRC Region I conducted an onsite inspection of your HDR program and confirmed: (1) your compliance with the requirements of 10 CFR 35.615(f)(2); and, (2) adherence to the commitments in the CAL, including your July 21, 2006 response.

On September 14, 2007, a PEC was conducted in Carolina, Puerto Rico, with you and members of your staff to discuss the apparent violations, their significance, root causes and your corrective actions. Based on the results of the OI investigation and information provided at the PEC, the NRC has determined that a violation of NRC requirements occurred. The violation, which is described in the enclosed Notice of Violation, involved the willful failure of the AMP and the AU to meet the physical presence requirements during HDR brachytherapy treatments. Specifically, on four separate occasions in 2006, either the AU or the AMP were not physically present during the initiation of all patient treatments involving HDR.

The NRC concluded that the AMP and the AU exhibited careless disregard for compliance with NRC requirements in that they were aware of the physical presence requirements delineated in 10 CFR 35.615(f)(2), yet took no action to prevent the violation from occurring. As such, these actions were considered willful. Since you are responsible for the acts of your employees, contractors and their employees, TUROC is responsible for the willful violation.

In assessing the significance of the violation, the NRC considered that: (1) although there were no health and safety consequences to the patients or the public, not having an AU and an AMP present during HDR brachytherapy treatments could affect patient safety if an emergency medical intervention would have been necessary during the procedure; and, (2) the violation was willful. Therefore, in accordance with Supplement VI of the Enforcement Policy, the NRC has classified this violation at Severity Level (SL) III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $3,250 is considered for a SL III violation. Because this violation was willful, the NRC considered whether credit was warranted for both *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit is warranted for identification because the violation was identified by the TUROC RSO and management staff prior to the NRC becoming aware of the violation. Credit is also warranted for corrective actions because the actions were considered to be prompt and comprehensive. The actions included: (1) meeting all the terms specified in CAL 1-06-004 by July 21, 2006; (2) temporarily stopping the HDR program until an external audit was conducted; and, (3) training physicists on the HDR requirements referenced in 10 CFR 35 Part 600, including physical presence requirements.

Therefore, to encourage prompt identification and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of a SL III violation constitutes escalated enforcement action, that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed in this letter, in your letters dated July 21, 2006 and September 14, 2007, and/or in our June 7, 2007 letter forwarding the OI Factual Summary. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice. To the extent possible, your response should not include any personal privacy,

proprietary, or safeguards information so that it can be made available to the public without redaction.

Alternatively, you may request Alternative Dispute Resolution (ADR) with the NRC in an attempt to resolve the issue. If you request ADR, you will need to contact the Institute on Conflict Resolution (ICR) at 877-733-9415 within 10 days of the date of this letter. 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. Additional information concerning NRC's program is described in the brochure (NUREG/BR-0317) that was provided to you in our June 7, 2007 letter, and can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The ICR at Cornell University has agreed to facilitate the NRC's program as an intake neutral.

In reference to the second apparent violation involving the failure to provide the RSO with sufficient authority, freedom and management prerogative to perform his duties, as specified in 10 CFR 35.24(g), based on information provided at the PEC and submitted in your September 14, 2007 letter, the NRC has concluded that although there was some dysfunction apparent in communications between the RSO/AU and the AMP, you did provide the RSO sufficient authority to perform his duties. Therefore, this apparent violation is not cited in the enclosed Notice.

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 website at http://www.nrc.gov/reading-rm/adams.html. The NRC also includes significant enforcement actions on its website at http://www.nrc.gov.

Sincerely,

/RA/ Original Signed by Marc L. Dapas for

Samuel J. Collins
Regional Administrator

Docket No. 03035220
License No. 52-25487-01

Enclosure:
Notice of Violation

cc:
Commonwealth of Puerto Rico

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NOTICE OF VIOLATION

Tomé & Ubiñas Radio Oncology Center
San Juan, Puerto Rico

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

During an investigation conducted by the NRC Office of Investigations (OI) completed on March 20, 2007, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 35.615(f)(2) requires, in part, that an Authorized User (AU) and an Authorized Medical Physicist (AMP) be physically present during the initiation of all patient treatments involving the high dose rate (HDR) remote afterloader unit, and that an AMP and either an AU or a physician under the supervision of an AU be physically present during continuation of all HDR patient treatments.
>
> Contrary to the above, either an AU or AMP were not physically present during the initiation of all patient treatments involving HDR, nor was either an AMP, and either an AU or a physician under the supervision of an AU, physically present during continuation of all HDR patient treatments. Specifically,
>
> 1. on April 27 and 28, 2006, the licensee initiated and continued HDR treatments without the physical presence of an AMP, and
>
> 2. on June 22 and 23, 2006, the licensee initiated HDR patient treatments without the physical presence of an AU, and continued patient treatments without the AU or a physician under the supervision of an AU physically present.
>
> This is a Severity Level III violation (Supplement VI).

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed in the letter transmitting this Notice, in your letters dated July 21, 2006 and September 14, 2007, and/or in our June 7, 2007 letter forwarding the OI Factual Summary. Therefore, you are not required to respond to this Notice unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, clearly mark your response as a "Reply to a Notice of Violation" and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). To the extent possible, your response should not include any personal privacy, proprietary, classified or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by

10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 11th day of October 2007.