



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

July 17, 2006

Docket No. 03035220
CAL No. 1-06-004

License No. 52-25487-01

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

SUBJECT: CONFIRMATORY ACTION LETTER NO. 1-06-004

Dear Mr. Umpierre:

License Number 52-25487-01 for Tomé & Ubiñas Radio Oncology Center, located in San Juan, PR, authorizes the use of Iridium-192 in a High Dose Remote Afterloader (HDR) for medical use permitted by 10 CFR 35.600. On July 12 and 13, 2006, during telephone conversations with you and members of your staff, Pamela Henderson and other members of NRC staff requested information concerning your facility and the physical presence requirements for use of HDR as provided in 10 CFR 35.615(f)(2). During the course of these conversations, you provided information to Ms. Henderson that on five occasions in late April and early June, you did not meet the physical presence requirements for HDR treatments. Specifically, (1) your Authorized Medical Physicist (AMP) was not present at your facility on April 27 and 28, 2006, when four HDR treatments were conducted; and (2) on June 22, 2006, while an HDR treatment was being conducted, an Authorized User (AU) left the HDR console to provide emergency care for a patient on another floor of your facility. 10 CFR 35.615(f)(2) requires that an AU and an AMP be physically present 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 be physically present during continuation of all patient treatments involving an HDR.

Pursuant to a telephone conversation between you and Ms. Henderson of this office on July 13, 2006, it is our understanding that you have taken or will take the following actions immediately:

For HDR treatments, an AU and an AMP will 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 will be physically present during continuation of all patient treatments involving an HDR.

Pursuant to Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, you are required to:

- 1) Notify me immediately if your understanding differs from that set forth above;

- 2) Notify me if for any reason you cannot complete the actions within the specified schedule and advise me in writing of your modified schedule in advance of the change; and
- 3) Notify me in writing when you have completed the actions addressed in this Confirmatory Action Letter.

Issuance of this Confirmatory Action Letter does not preclude issuance of an order formalizing the above commitments or requiring other actions on the part of the licensee, nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this letter. In addition, failure to take the actions addressed in this Confirmatory Action Letter may result in enforcement action.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material**; then **toolkit index page**. The current NRC Enforcement Policy is included on the NRC's website at www.nrc.gov; select **What We Do, Enforcement**, then **Enforcement Policy**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter 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>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. 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 withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (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.

Sincerely,

Original signed by George Pangburn

George Pangburn, Director
Division of Nuclear Materials Safety

cc:

Luis A. Rivera, M.M.Sc., Radiation Safety Officer
Commonwealth of Puerto Rico

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