

March 13, 1997

Dr. Luis A. Vázquez Outpatient
Surgery Clinic
ATTN: Lcdo. Roberto Ruiz Asencio, MHSA
Administrator
Box 3748 - MA. Station
Mayagüez, PR 00681

SUBJECT: QUALIFICATIONS OF OPHTHAMOLOGISTS TO USE STRONTIUM-90 EYE APPLICATORS

Dear Mr. Ruiz:

This refers to our March 4-7, 1997 inspection, and the March 10, 1997 telephone conversation between you and Mr. H. Bermúdez of my staff, regarding the credentials of four physicians who administered radiation doses with a strontium-90 eye applicator at your facility between August 23, 1993 and January 14, 1994.

Specifically, the conversation addressed whether the training and experience of Drs. Pérez, Maestre, Townsend and Izquierdo, at the time of the administrations, 1) met the requirements specified in 10 CFR 35.941, enclosed, or 2) whether they were listed as authorized users for ophthalmic radiotherapy in any license issued by the NRC or an Agreement State, or 3) whether they were authorized to perform ophthalmic radiotherapy under a license of broad scope such as the University of Puerto Rico Medical Sciences Campus.

You indicated not being familiar with 10 CFR 35.941 nor the credentials of the referenced physicians, but that you would inquire. Shortly after the conversation Mr. Bermúdez faxed you a copy of 10 CFR 35.941.

In order for us to continue our review of this case, please respond within ten days of the date of this letter addressing the needed information. If you have any questions regarding this letter or if you need additional time please contact me at (404) 331-5571 or Mr. H. Bermúdez at (404) 331-7880, respectively.

We appreciate your cooperation on this matter.

Sincerely,

(original signed by
J. Potter)

John P. Potter, Chief
Materials Licensing/Inspection
Branch 2
Division of Nuclear Materials Safety

Docket No.: 030-32477
License No.: 52-16660-03 (Terminated)

Enclosure: As Stated

cc: Commonwealth of Puerto Rico

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
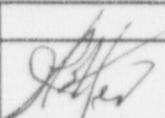
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PART 35 • MEDICAL USE OF BYPRODUCT MATERIAL

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

- (i) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;
- (ii) Selecting the proper brachytherapy sources and dose and method of administration;
- (iii) Calculating the dose; and
- (iv) Post-administration followup and review of case histories in collaboration with the authorized user.

§ 35.941 Training for ophthalmic use of strontium-90.

Except as provided in § 35.970, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:

- (a) 24 hours of classroom and laboratory training that includes:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity; and
 - (4) Radiation biology;
- (b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes:
 - (1) Examination of each individual to be treated;
 - (2) Calculation of the dose to be administered;
 - (3) Administration of the dose; and
 - (4) Followup and review of each individual's case history.

§ 35.950 Training for use of sealed sources for diagnosis.

Except as provided in § 35.970, the licensee shall require the authorized user of a sealed source in a device listed in § 35.500 to be a physician, dentist, or podiatrist who:

- (a) Is certified in:

- (1) Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;
- (2) Nuclear medicine by the American Board of Nuclear Medicine;

- (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

- (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

- (b) Has had 8 hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes:

- (1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;
- (2) Radiation biology;
- (3) Radiation protection; and
- (4) Training in the use of the device for the uses requested.

§ 35.960 Training for teletherapy.

Except as provided in § 35.970, the licensee shall require the authorized user of a sealed source listed in § 35.600 in a teletherapy unit to be a physician who:

- (a) Is certified in:

- (1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

- (2) Radiation oncology by the American Osteopathic Board of Radiology;

- (3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

- (4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

- (b) Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and supervised clinical experience as follows:

- (1) 200 hours of classroom and laboratory training that includes:

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity; and
- (iv) Radiation biology;
- (2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

- (i) Review of the full calibration measurements and periodic spot checks;
- (ii) Preparing treatment plans and calculating treatment times;
- (iii) Using administrative controls to prevent misadministrations;
- (iv) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and
- (v) Checking and using survey meters; and

- (3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology