



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

DCS  
PDR

October 21, 1996

EA 96-154

Dr. José L. Fernández  
160 Ponce de León Avenue  
Puerta de Tierra  
San Juan, Puerto Rico 00901

SUBJECT: ORDER MODIFYING NRC MATERIALS LICENSE  
NO. 52-25114-01 (EFFECTIVE IMMEDIATELY)

Dear Dr. Fernández:

The enclosed immediately effective Order Modifying License (Order) is being issued to you as the result of your failure to identify medical misadministrations and to notify the affected patients. Since February 9, 1996, the Nuclear Regulatory Commission (NRC) has requested that you identify all medical misadministrations which have occurred under your NRC license and that you complete the required notifications to the involved patients and the NRC. NRC regulations in Title 10 of the Code of Federal Regulations Part 35.21 (10 CFR 35.21) and 10 CFR 35.33, require that you identify and investigate misadministrations and notify the affected patients. You have repeatedly failed to adequately comply with those requirements and provide NRC with reliable and complete information.

The enclosed Order requires you, among other things, to: (1) within 30 days of the Order, submit for NRC approval the credentials of an independent Health Physicist/Radiation Physicist Consultant with expertise in therapy dosimetry calculations who is prepared to assist you in responding to this Order; (2) following the NRC's approval, ensure that the consultant reviews all patient radiation dose administrations to identify any medical misadministrations and assess the completeness and accuracy of your misadministration records; (3) submit an updated, final report to the NRC of all misadministrations; (4) notify individuals who received misadministrations; (5) maintain the strontium-90 sources in locked, safe storage until the sources are transferred to an authorized recipient; and (6) transfer the sources to an authorized recipient within 90 days of this Order.

Pursuant to Section 223 of the Atomic Energy Act of 1954, as amended, any person who willfully violates, attempts to violate, or conspires to violate, any provision of this Order, once effective, shall be subject to criminal prosecution as set forth in that section. Violation of this Order may also subject the licensee to a civil monetary penalty of up to \$100,000. In addition, issuance of this Order does not preclude the NRC from taking further enforcement action for the violations described in this Order. You should be aware that, in determining whether to take enforcement action for the violations described in this Order, the NRC will consider, among other things, your compliance with the provisions of the Order.

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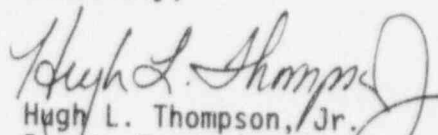
In your letter of August 20, 1996, you requested NRC's assistance in obtaining a list of consultants located in Puerto Rico. NRC employees are generally prohibited from providing advice or recommendations to licensees; however, given your stated continued inability to obtain a consultant, the need to expedite the identification of misadministrations, and the absence of professional organizations in Puerto Rico that could assist you in locating a consultant, Region II representatives provided you a list for information purposes of individuals and institutions who might be able to provide the services and/or information required by the Order during a meeting with you on September 27, 1996. At your request, another copy of the list was provided to you by facsimile on October 3, 1996. No representations or recommendations are made or offered concerning the completeness of the list which is also enclosed with the Order or the individuals and institutions identified on the list, nor has any assessment been made concerning each individual's qualifications or ability to provide assistance. You remain under an obligation to assure yourself and the NRC that any consultant you hire meets the provisions of this Order.

Finally, following your completion of the requirements of this Order, the NRC will address the termination of your license as you requested in your August 20, 1996 letter, and whether further escalated enforcement is appropriate.

Questions concerning this Order should be addressed to Mr. James Lieberman, Director, Office of Enforcement, who may be reached at (301) 415-2741.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

Sincerely,



Hugh L. Thompson, Jr.  
Deputy Executive Director for  
Nuclear Materials Safety, Safeguards  
and Operations Support

Docket No. 030-31873  
License No. 52-25114-01

Enclosures:

1. Consultants/Institutions List
2. Order Modifying License

cc w/encl 2 only:  
Commonwealth of Puerto Rico  
Tribunal Examinador de Médicos de Puerto Rico  
[Puerto Rico Board of Medical Examiners]  
ATTN: Dr. Humberto Vázquez  
President  
P.O. Box 13969  
San Juan, Puerto Rico 00908

Potential Consultants in Puerto Rico

Encl. 1

Alison De Hoyos	(787) 265-5130, (787) 265-4160
Santiago Gómez	(787) 751-0042
Ricardo González	(787) 759-1255 u-2181812, (787) 754-3831 (787) 767-0382
Pedro J. Montes García	(787) 763-4149, (787) 754-0315
Samuel Muñoz	(787) 754-0315
Heidi Pabón Pérez	(787) 758-7575 x-3255
María M. Palacios de Lozano	(787) 758-7575 x-5413
José D. Pacheco	(787) 764-4215
Carmelo Pérez	(787) 802-2472 x-7074
José V. Pérez Bobonis	(787) 766-3062
Cecilia Ramírez	(787) 765-2212
Miria Roque Palacios	(787) 754-0315
Shakil Shafique	(787) 767-2251
Roberto J. Torres	(787) 265-5833
Heriberto Torres	(787) 758-2525 x-1450, x-1439
Daniel Torres Ortiz	(787) 834-8686 x-2770

No representations or recommendations are made or offered concerning the completeness of this list, the individuals and/or institutions identified on this list, nor has any assessment been made concerning their qualification or ability to provide assistance.

Additional Sources of Information

American Academy of Health Physics, Secretariat  
8000 West Park Drive  
McLean, Virginia 22102  
Telephone: 703-790-1745

American Association of Physicists in Medicine  
1 Physics Ellipse  
College Park, Maryland  
Telephone: 301-209-3100

Society of Nuclear Medicine/American College of Nuclear  
Physicians  
Government Relations  
1101 Connecticut Avenue, NW  
Washington, DC 20036  
Telephone: 202-429-5120

American College of Medical Physicists  
1891 Preston White Drive  
Reston, Virginia 22091  
Telephone: 703-648-8966

No representations or recommendations are made or offered concerning the completeness of this list, the individuals and/or institutions identified on this list, nor has any assessment been made concerning their qualification or ability to provide assistance.

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OE:EA File (Also by E-Mail)

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JPiccone, NMSS

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JPotter, RII (IFS Update Required)

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RTrojanowski, RII

ABoland, RII

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