



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

June 26, 2006

Docket No. 03037226
Control No. 138956

License No. 52-31166-01

Carlos Jimenez Marchan, M.D.
San Patricio MRI & CT Center
1508 Avenue Roosevelt, Suite 103
San Juan, PR 00920

SUBJECT: SAN PATRICIO MRI & CT CENTER, REQUEST FOR ADDITIONAL
INFORMATION CONCERNING APPLICATION FOR NEW LICENSE,
CONTROL NO. 138956

Dear Dr. Jimenez Marchan:

This is in reference to your application dated June 5, 2006 applying for a Nuclear Regulatory Commission license. The application was filed using the guidance of NUREG -1556, Volume 9, 'Program-Specific guidance About Medical Use Licenses.' However, the application did not request the use of Nuclear Regulatory Commission (NRC) regulated materials for medical use. The appropriate guidance document for the purposes requested is NUREG-1556, Volume 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.' The below requested information is a reflection of the difference in these guidance documents. In order to continue our review, we need the following additional information:

1. F-18, Rd-82, Co-57 produced in a cyclotron is not byproduct material as defined in 10 CFR 30.4 and is not subject to licensing by the NRC. Therefore, you may procure and use it without amendment to your NRC material license. However, you should contact your State regulatory authorities to determine the State licensing or registration requirements for use of this radionuclide.
2. As this will not be a medical license, please specify the maximum amount of technetium - 99 needed to possess. Also please verify that you are requesting technetium-99 or technetium-99m.
3. 10 CFR 30.32(g) requires that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains a sealed source must either identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State; **or** contain the information identified in 10 CFR 32.210(c). The barium 133 source did not list a manufacturer's name or model number. Please provide this information for the sealed source(s) requested in your application.

4. Please state that you will develop an maintain procedures for ensuring material accountability. Also state that "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license."
5. In your application under Item 10, Radiation Safety Program, Occupational Dose heading, you gave statements that you will perform a prospective evaluation or provide dosimetry to personnel. You then stated that you could perform an alternative method. The description of an alternative method for demonstrating compliance must be written and approved prior to use. Either provide a description of an alternative method for demonstrating compliance or state that you do not plan to use an alternative method for demonstrating compliance with occupational dose limits.
6. Per the guidance in Volume 7 of NUREG-1556, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' Section 8.10.7, either state:

"We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG-1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State, to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions."

OR

"We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG-1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State, to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions. As an alternative, we will implement the model leak test program published in Appendix R to NUREG-1556, Vol. 7, "Consolidated Guidance about Materials Licenses: 'Program-Specific Guidance About Academic, Research and Development, and Other Licensees of Limited Scope' dated December 1999."

C. Jimenez Marchan
San Patricio MRI & CT Center

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Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrialc Uses of Nuclear Material**; then **Toolkit Index Page**. 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 8:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 138956. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5366.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Dennis R. Lawyer

Dennis R. Lawyer
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Jossian J. Pagan Lisboa, Radiation Safety Officer

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