



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

October 20, 2005

Docket No. 03037043
Control No. 137776

License No. 52-31094-01

Maria Margarita Palacios
Radiation Safety Officer
Centro Medico San Pablo
Edificio Arturo Cadilla (AIRC)
Primer Piso
Bayamon, PR 00961

SUBJECT: PET IMAGING CORPORATION, REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 137776

Dear Ms. Palacios:

This is in reference to your application dated September 27, 2005 applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. The application was written per the guidance in NUREG-1556, Volume 9, "Program-Specific Guidance About Medical Use Licenses." However, the NRC regulated materials are not used on humans, the appropriate guide is NUREG-1556, Volume 7, Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope. Because of this difference, some areas need additional information. On Item 5 of your application, you requested for any byproduct material authorized under 10 CFR 35.65. Since this will not be a medical license, 10 CFR 30.32(g)(1) requires, in part, that your application must either identify a sealed source or device by manufacturer and model number as registered with the Commission under 10 CFR 32.210 or with an Agreement State, or contain the information identified in 10 CFR 32.210. Your license will be written in a format which authorizes only those sealed sources identified in your application, which requires modification of some possession limits and forms. In your response to this letter, please provide limits commensurate with your program and sealed source identification in the format shown below. For sealed sources, please list all manufacturers and model numbers that you currently possess or may use in the future. When setting the limits for the materials below, please consider the maximum activity you will have on site at any one time including activity in waste or in storage until transfer. For sealed sources in devices, you may wish to request a possession limit adequate to allow for the possession of a spare source during replacement of the source in the device.

<u>Radionuclide:</u>	<u>Form or Manufacturer/Model No.</u>	<u>Possession limit:</u>
Cesium-137	Sealed Sources (Manufacturer _____, Model No. _____; Manufacturer _____, Model No. _____; Manufacturer _____, Model No. _____; Manufacturer _____, Model No. _____; Manufacturer _____, Model No. _____)	____ millicuries
Cobalt-60	Sealed Sources (Manufacturer _____, Model No. _____; Manufacturer _____, Model No. _____; Manufacturer _____, Model No. _____; Manufacturer _____, Model No. _____; Manufacturer _____, Model No. _____)	____ millicuries
List Other Radionuclides	Sealed Sources (Manufacturer _____, Model No. _____; Manufacturer _____, Model No. _____; Manufacturer _____, Model No. _____; Manufacturer _____, Model No. _____; Manufacturer _____, Model No. _____)	____ millicuries

2. Cobalt-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.
3. On your application you listed the purpose for licensed material as approved under 10 CFR 35.65. As this will not be a medical license, this purpose for materials is not authorized as written. Please list the specific use or purpose of each radioisotope.
4. In your application, you did not describe a training program for radiation workers and ancillary personnel (maintenance, security, etc.). The training given to each group should be commensurate with the duties and responsibilities of the group. The training program must assure that personnel are instructed before assuming duties with, or in the vicinity of, licensed materials and specify a frequency for periodic refresher training. Appendix J of NUREG-1556, Volume 7 addresses radiation safety training topics and may be helpful in developing your response. Page 8-18 of NUREG-1556, Volume 7 describes the guidance and response from applicants concerning training.
5. Your application did not specifically discuss ensuring material accountability. Per NUREG-1556, Volume 7, Page 8-30, it states that an applicant needs to state that they developed a procedure for ensuring material accountability and state, "Physical inventories will be conducted at intervals not to exceed six months to account for all sealed source and devices received and possessed under a license," or give a description of the procedures for ensuring that no sealed sources have been lost, stolen, or misplaced. Please make these statements.

6. Your application did not address a survey program. Please read section 8.10.7 in NUREG-1556, Volume 7. Please respond per the guidance as outlined in that section on page 8-46.
7. Your application appears to indicate that your location of use may be controlled by an entity other than yourself. If so, please provide documentation of a clear contractual agreement concerning access to your location of use for the purpose of decontamination or removal of licensed material from the location of use in the event of disharmony between you and the owner entity. This documentation should consist of signed certification from both parties.
8. The application has requested that Maria M. Palacios, M.S., be named Radiation Safety Officer (RSO) on your license. It appears that this individual may be an outside consultant\contractor. If this is so, in support of this request, please address the following:
 - a. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.
 - b. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of on-site time (hours per week).
 - c. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.
 - d. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.

Current NRC regulations and guidance 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**. 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).

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. 137776. If you have any technical questions regarding this deficiency letter, please call Dennis Lawyer at (610) 337-5303 or me at (610) 337-5303.

M. Palacios

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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 Thomas K. Thompson

Thomas K. Thompson
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:

Juan V. Bernal, Executive Director

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SISP Review Complete: DRL 1

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