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Dr. José Meléndez  
Nuclear Medicine  
100 Roseville Drive  
P.O. Box 22  
San Juan, PR 00926

August 3, 2010

U.S. Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406

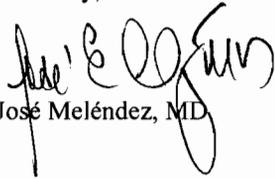
52-31065-01  
03036979

Dear Mr. Sir or Madam:

Please find enclosed a renewal application.

If you need any further information, please contact Dr. José Meléndez at (787) 448-0747 or David Rhoe at (787) 245-7248.

Sincerely,



José Meléndez, MD

2010 AUG -3 11 12:43

RECEIVED

573304  
NMSS/RGN1 MATERIALS-002

Item 1 Address

a) Mailing address  
 Dr. José Meléndez  
 Nuclear Medicine  
 100 Roseville Drive  
 P.O. Box 22  
 San Juan, PR 00926  
 (787) 448-0747  
 Fax (787) 887-3115

b) Main Office address  
 Dr. José Meléndez  
 Nuclear Medicine  
 P.O. Box 1569  
 Rio Grande, PR 00745  
 (787) 887-7055  
 Fax (787) 887-3115

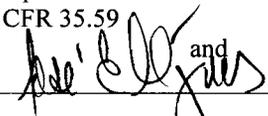
c) Physical location (storage/location of the radiation sources & records)  
*(Nuclear Medicine)*  
 Dr. Denis Ruiz  
 Nuclear Medicine  
 Calle Del Carmen  
 Num. 8 Esquina San Juan  
 Rio Grande, PR 00745  
 (787) 562-2571  
 Fax (787)

<b>X</b>	This license will not be under an ownership of a corporation or legal entity.
	This license will be under an ownership of a corporation or legal entity.  Corporation or legal entity name: _____

The following is based on Medical Use Licenses, NUREG 1556 Vol. 9, October 2002, Appendix C

Item 5 and 6: Materials to be Possessed and Proposed Uses

YES	Radionuclide	Form or Manufacturer	Maximum Quantity	Purpose of Use
<b>X</b>	Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100
<b>X</b>	Any byproduct material permitted by 10 CFR 35.200	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.200
	Any byproduct material permitted by 10 CFR 35.300	Any	600 millicuries	Any uptake, dilution, and excretion study permitted by 10 CFR 35.300
	10 CFR 35.300 - All therapies will be done on an outpatient basis. Inpatients will be referred to a hospital that is approved by the NRC for I-131 therapies.			
	Any byproduct material under 10 CFR 31.11	Prepackaged kits	50 millicuries	In vitro studies

Item No. and Title	Response
<p>7. Radiation Safety Officer.</p> <p>Name: José Meléndez, MD</p>	<p><input checked="" type="checkbox"/> Previously on license number: NRC 52-31065-01. or</p> <p><input type="checkbox"/> Copy of the certification(s) for the board(s) recognized by the NRC and as applicable to the types of use for which he or she has RSO responsibilities. or</p> <p><input type="checkbox"/> Description of the training and experience specified in 10 CFR 35.900(b). or</p> <p><input type="checkbox"/> Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities. and</p> <p><input type="checkbox"/> Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use license has been achieved. and</p> <p><input type="checkbox"/> If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59</p> <p><input checked="" type="checkbox"/> RSO Signature: <u></u> and Date: <u>08/03/2010</u></p>
<p>7. Authorized Users Names and Requested Uses for Each Individual.</p> <p>Name: José Meléndez, MD</p>	<p><input checked="" type="checkbox"/> Previously on license number: NRC 52-31065-01. or</p> <p><input type="checkbox"/> Copy of the certification(s) for the board(s) recognized by the NRC under 10 CFR Part 35, Subparts D, E, F, G, H, and as applicable to the use requested. or</p> <p><input type="checkbox"/> Description of the training and experience specified in 10 CFR 35.900(b). or</p> <p><input type="checkbox"/> Description of the training and experience specified in 10 CFR Part 35 Subpart J demonstrating that the proposed AU is qualified by training and experience for the use requested. or</p> <p><input type="checkbox"/> A description of the training and experience identified in 10 CFR Part 35 Subparts D, E, F, G, and H demonstrating that the proposed AU is qualified by training and experience for the use requested; and</p> <p><input type="checkbox"/> Written certification, signed by a preceptor physician AU, that the above training and experience has been satisfactorily completed and that a level of competency to function independently as an AU for a medical uses authorized has been achieved. and</p> <p><input type="checkbox"/> If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59</p>
<p>9. Facility Diagram.</p>	<p><input checked="" type="checkbox"/> A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. The following information is included:</p> <p><input checked="" type="checkbox"/> Drawing should be to scale, and indicate the scale used.</p> <p><input checked="" type="checkbox"/> Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, as provided above the heading "Discussion";</p> <p><input checked="" type="checkbox"/> Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is restricted or unrestricted area as defined in 10 CFR 20.1003; and</p> <p><input type="checkbox"/> Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent</p>

	<p>verification of the shielding calculations including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.)</p> <p>In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.</p>
<p>9. Radiation Monitoring Instrument.</p> <p>Dose rate meter: Ludlum model 14C Geiger Mueller Range 1-100 mR/hr End window or pan probe</p> <p>Scaler wipe test counter: Capintec Caprac</p>	<p>X A person qualified to perform survey meter calibrations will calibrate radiation monitoring instruments.</p> <p>and/or</p> <p><input type="checkbox"/> We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61.</p> <p>and</p> <p><input type="checkbox"/> A description of the instrument (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multi-channel analyzer, LSC, proportional counter) that will be used to perform required surveys is indicated in the left column.</p> <p>and</p> <p>X We reserve the right to upgrade our survey instrument as necessary as long as they are adequate to measure the type and level of radiation for which they are used.</p>
9. Dose Calibrator and Other Dosage Measuring Equipment.	X Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.
10. Occupational Dose.	<p>X Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide Dosimetry that meets the requirements listed under "Criteria" in NUREG 1556, Vol. 9, "Consolidated Guidance About Materials License: Program-Specific Guidance About Medical Use Licensees," dated October 2002.</p> <p>or</p> <p><input type="checkbox"/> A description of an alternative method for demonstrating compliance with the referenced regulations.</p>
10. Areas Surveys.	X We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.
10. Safe Use of Unsealed Licensed Material.	X We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 1301.
10. Spill Procedures and Minimization of Contamination.	X We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101.
10. Minimization of Contamination	X A response is not required.
11. Waste Management.	X We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR Part 35.92.

This is to acknowledge the receipt of your letter/application dated

8/3/10, and to inform you that the initial processing which includes an administrative review has been performed.

Renew (52-31065-01) There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 573304.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.