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December 4, 2009

Mrs. Elizabeth Ulrich
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

(52-30841-02)

Mr. Humberto O. Quintana, M.D.
Nuclear Medicine Inc.
P.O. Box 6480
Santa Rosa Unit
Bayamon, Puerto Rico 00960-9005

KARDIO NUCLEAR INC., REQUEST FOR A NEW MATERIAL LICENSE

Please evaluate the following documents for the application for a new material license for the facility Kardio Nuclear located at Hospital San Carlos de Borromeo, 1st Floor, 550 Concepción Vera Ayala Street, Moca, Puerto Rico.

Enclose is the Application for Material License, the Information Check list and the corresponding attachments for each item of this application According to NUREG 1556, VOL.9 Rev 2. Also a copy of the check list information for the Application for Material License items 5 through 11 and Items 7 through 11 on NRC Form 313.

Please contact me for any additional information at phone number (939) 717-1959

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APPLICATION FOR MATERIALS LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
612 E. LAMAR BOULEVARD, SUITE 400
ARLINGTON, TX 76011-4125

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

A. NEW LICENSE

B. AMENDMENT TO LICENSE NUMBER _____

C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Dr. Humberto Quintana
PO Box 6480
Bayamon, Puerto Rico 00960-9005

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Kardio nuclear, Inc.
Hospital San Carlos De Borromeo
1er piso calle Concepcion Vera Ayala 550
Moca, PR 00676

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dr. Humberto O. Quintana, Nuclear
Cardiology and the Radiation Control
Program Director

TELEPHONE NUMBER

(939) 717-1959

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time. **See Attachment 1**

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE. **See Attachment 1**

9. FACILITIES AND EQUIPMENT. **See Attachment**

11. WASTE MANAGEMENT. **See Attachment 1**

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED. **See Attachment 1**

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS. **See Attachment 1**

10. RADIATION SAFETY PROGRAM. **See Attachment 1**

12. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY	7C	AMOUNT ENCLOSED	\$ 1,900.00
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13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Dr. Humberto O. Quintana Irazola RCPD		12/03/2009

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

Information Check list for the Application for Material License items 5 through 11 of NRC Form 313

Attachment 1

ITEM 5 & ITEM 6. Radioactive Material and Purpose:

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
<input checked="" type="checkbox"/>	Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
<input checked="" type="checkbox"/>	Any byproduct material permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
	F-18	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	O-15	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	C-11	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	Any byproduct material permitted by 10 CFR 35.300	Any	_____ millicuries	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300.
	Iodine-131	Any	_____ millicuries	Administration of I-131 sodium iodide.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____) Model No. _____)	_____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____) Model No. _____)	_____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400	Sealed source or device (Manufacturer _____)	_____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.

(Radionuclide _____)	Model No. _____		
Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____) Model No. _____	____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
Strontium-90	Sealed source or device (Manufacturer _____) Model No. _____	____ millicuries	Treatment of superficial eye conditions using an applicator distributed pursuant to 10 CFR 32.74 and permitted by 10 CFR 35.400.
Byproduct material permitted by 10 CFR 35.500 Check all that apply: <input type="checkbox"/> Gd-153; <input type="checkbox"/> I-125; <input type="checkbox"/> Other, describe _____	Sealed source or device (Manufacturer _____) Model No. _____	____ per source and ____ curies total	Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
Iridium-192	Sealed source or device (Manufacturer _____) Model No. _____	____ curies per source and ____ curies total	One source for medical use permitted by 10 CFR 35.600, in a Manufacturer _____ Model No. _____ remote afterloading brachytherapy device. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.
Cobalt-60	Sealed source or device (Manufacturer _____) Model No. _____	____ curies per source and ____ curies total	One source for medical use permitted by 10 CFR 35.600, in a Manufacturer _____ Model No. _____ teletherapy unit. One source in its shipping container as necessary for replacement of the source in the teletherapy unit.
Cobalt-60	Sealed source or device (Manufacturer _____) Model No. _____	____ curies per source and ____ curies total	For medical use permitted by 10 CFR 35.600, in a Manufacturer _____ Model No. _____ stereotactic radiosurgery device. Sources in the shipping container as necessary for replacement of the sources in the stereotactic radiosurgery device.
Any byproduct material under 10 CFR 31.11	Prepackaged kits	____ millicuries	<i>In vitro</i> studies.
Depleted uranium	Metal	____ kilograms	Shielding in a teletherapy unit.
Depleted uranium	Metal	____ kilograms	Shielding in a linear accelerator.

	<p>Any radionuclide in excess of 30 millicuries for use in calibration, transmission, and reference sources. List radionuclide:</p> <p>Tecnitium 99M</p>	<p>Sealed source or device (Manufacturer _____, Model No. _____)</p> <p>Any</p>	<p>____ millicuries</p> <p>As needed</p>	<p>For use in a Manufacturer _____ Model No. _____ for calibration and checking of licensee's survey instruments.</p> <p>Purpose of use: <u>for calibration and checking of licensee's survey instruments.</u></p>
	<p>Americium-241</p>	<p>Sealed source or device (Manufacturer _____, Model No. _____)</p>	<p>____ millicuries per source and _____ millicuries total</p>	<p>Use as an anatomical marker.</p>
	<p>Plutonium (principal radionuclide Pu-238)</p>	<p>Sealed sources</p>	<p>____ millicuries per source and _____ grams total</p>	<p>As a component of Manufacturer _____ Model No. _____, nuclear-powered cardiac pacemakers for clinical evaluation in accordance with manufacturer's protocol dated _____. This authorization includes: follow-up, explantation, recovery, disposal, and implantation.</p>
<p><input checked="" type="checkbox"/></p>	<p>Other: Cobalt -57</p> <p>Cesium -137</p> <p>Barium-133</p>	<p>Form or Manufacturer: <u>Isotope Products Laboratories</u> Model No. _____</p> <p>Form or Manufacturer: <u>Isotope Products Laboratories</u> Model No. _____</p> <p>Form or Manufacturer: <u>Isotope Products Laboratories</u> Model No. _____</p>	<p>5.00 millicuries</p> <p>0.200 millicuries</p> <p>0.250 millicuries</p>	<p>Purpose of use: <u>for instrument calibration.</u></p> <p>Purpose of use: <u>for instrument calibration.</u></p> <p>Purpose of use: <u>for instrument calibration.</u></p>

Information for the Application for Material Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal <i>(The checklist is included to the application and information is provided separately.)</i>		
Item Number and Title	Suggested Response	Check box to indicate Material included in application
Item 7: Radiation Safety Officer Name: Mr. Jossian J. Pagán Lisboa, RSO on NRC License 52-31166-01 and 52-11810-02	<i>For an individual previously identified as an RSO on an NRC or Agreement State license or permit:</i>	<input checked="" type="checkbox"/>
	Previous license number (if issued by the NRC), or a copy of a license (if issued by an Agreement State), or a copy of a permit (if issued by an NRC master materials licensee) on which the individual was specifically named as the RSO.	
	<i>For an individual qualifying under 10 CFR 35.57(a)(3):</i> Documentation that the individual was: <ul style="list-style-type: none"> • the RSO for only the medical uses of accelerator-produced radioactive material or discrete sources of Ra-226 included in the definition of byproduct material as a result of the EPA Act; • the RSO for the medical uses of these materials before or during the effective period of NRC's waiver of August 31, 2005. 	<input checked="" type="checkbox"/>
	<i>For an individual qualifying under 10 CFR 35.50(a):</i> Copy of certification by a specialty board whose certification process has been recognized by NRC or an Agreement State under 10 CFR 35.50(a). <p style="text-align: center;">AND</p>	<input checked="" type="checkbox"/>
	Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO. <p style="text-align: center;">AND</p>	<input checked="" type="checkbox"/>
	Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed training in and experience required for certification, as well as training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO. <p style="text-align: center;">AND</p>	<input checked="" type="checkbox"/>
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input checked="" type="checkbox"/>
Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities		

& Equipment, Radiation Protection Program, and Waste Disposal <i>(The checklist is included to the application and information is provided separately.)</i>		
Item Number and Title	Suggested Response	Check box to indicate Material included in application
	<p><i>For an individual qualifying under 10 CFR 35.50(b):</i></p> <p>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 the applicant seeks approval of an individual to serve as RSO.</p> <p style="text-align: center;">AND</p>	<input checked="" type="checkbox"/>
	<p>Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.</p> <p style="text-align: center;">AND</p>	<input checked="" type="checkbox"/>
	<p>Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the required training and experience specified in 10 CFR 35.50(b), as well as the training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.</p> <p style="text-align: center;">AND</p>	<input checked="" type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<input checked="" type="checkbox"/>
	<p><i>For an individual qualifying under 10 CFR 35.50(c)(1):</i></p> <p>Copy of the certification(s) as a medical physicist by a board whose certification process has been recognized" by the NRC or an Agreement State under 10 CFR 35.5 1(a) and description of the experience specified in 10 CFR 35.50(c)(1) demonstrating that the proposed RSO is qualified by experience as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.</p> <p style="text-align: center;">AND</p>	<input checked="" type="checkbox"/>
	<p>Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.</p> <p style="text-align: center;">AND</p>	<input checked="" type="checkbox"/>

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(The checklist is included to the application and information is provided separately.)

Item Number and Title	Suggested Response	Check box to indicate Material included in application
	<p>Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the required training and experience specified for certification, as well as training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.</p> <p style="text-align: center;">AND</p>	<input checked="" type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<input checked="" type="checkbox"/>
	<p><i>For an individual qualifying under 10 CFR 35.50(c) (2):</i></p>	
	<p>Copy of the licensee's license indicating that the individual is an AU, AMP, or ANP identified on the licensee's license and has experience with radiation safety aspects of similar types of use of byproduct material for which the applicant seeks approval of an individual to serve as RSO.</p> <p style="text-align: center;">AND</p>	<input checked="" type="checkbox"/>
	<p>Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.</p> <p style="text-align: center;">AND</p>	<input checked="" type="checkbox"/>
	<p>Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in 10 CFR 35.50(c)(2), as well as training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.</p> <p style="text-align: center;">AND</p>	<input checked="" type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<input checked="" type="checkbox"/>

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(The checklist is included to the application and information is provided separately.)

Item Number and Title	Suggested Response	Check box to Indicate Material included in application
<p>Item 7: Authorized Users for medical uses:</p> <p>Name(s),(Including license number authorizing practice of medicine, podiatry or dentistry if not provided previously or in attachment); Requested uses for each individual.</p> <p>Humberto O. Quintana, MD on NRC License 52-30841-01.</p> <p>Carlos Jiménez, MD on NRC License 52-31166-01.</p> <p>35.100, 35.200, 35.65</p>	<p><i>For an individual previously identified as an AU on an NRC or Agreement Users for medical State license or permit.</i></p> <hr/> <p>Previous license number (if issued by the NRC), or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the physician, dentist, or podiatrist was specifically named as an AU for the uses requested.</p>	<input checked="" type="checkbox"/>
	<p><i>For an A U requesting authorization for an additional medical use:</i></p> <p>Description of the additional training and experience to demonstrate the AU is also qualified for the new medical uses requested (e.g., training and experience needed to meet the requirements in 10 CFR 35.290 (b), 35.396, 35.390(b)(1)(ii)(G), or 35.690(c)).</p> <p style="text-align: center;">AND</p>	<input checked="" type="checkbox"/>
	<p>A preceptor attestation, if required (e.g., attestation is required to meet the requirements in 10 CFR 35.396, 35.390(b)(1)(ii)(G), or 35.690(c)).</p>	
	<p><i>For an individual qualifying under 10 CFR 35.57(b)(3):</i></p>	
	<p>Documentation that the physician, podiatrist, or dentist:</p> <ul style="list-style-type: none"> • used only accelerator-produced radioactive materials, or discrete sources of Ra- 226, or both, for medical uses before or during the effective period of NRC's waiver of August 31, 2005; and • used these materials for the same medical uses requested. 	<input checked="" type="checkbox"/>
	<p><i>For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is board-certified:</i></p> <p>Copy of the certification(s) by a specialty board(s) whose certification process has been recognized² by the NRC under 10 CFR Part 35, Subpart D, E, F, G, or H, as applicable to the use requested.</p> <p style="text-align: center;">AND</p>	<input checked="" type="checkbox"/>
	<p><i>For an individual with a board certification recognized under 10 CFR 3 5.390, a description of the supervised work experience administering dosages of radioactive drugs required in 10 CFR 35.390(b)(1)(ii)(G) demonstrating that the</i></p>	<input checked="" type="checkbox"/>

	proposed AU is qualified for the types of administrations for which authorization is sought;	
AND		
Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal <i>(The checklist is included to the application and information is provided separately.)</i>		
Item Number and Title	Suggested Response	Check box to indicate Material Included in application
	For an individual with a board certification recognized under 10 CFR 35.390 for medical uses described in 10 CFR 35.200, a description of the supervised work experience eluting generator systems required in 10 CFR 35.290(c)(1)(ii)(G) demonstrating the proposed AU is also qualified for imaging and localization medical uses;	<input checked="" type="checkbox"/>
	AND	
	For an individual with a board certification recognized under 10 CFR 35.490 or 35.690 seeking authorization under 10 CFR 35.396(d), a description of the classroom and laboratory training and supervised work experience required to demonstrate qualifications for administering parenteral administrations of unsealed byproduct material requiring a written directive;	<input checked="" type="checkbox"/>
	AND	
	For an individual seeking authorization under 10 CFR Part 35, Subpart H, description of the training specified in 10 CFR 35.690(c) demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought;	<input checked="" type="checkbox"/>
	AND	
	Written attestation, signed by a preceptor physician AU, that the training and experience specified for certification, as well as the clinical casework, or training and experience required by 10 CFR 35.396(d); or training for 10 CFR 35.600 types of use, if appropriate, have been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved;	<input checked="" type="checkbox"/>
	AND	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input checked="" type="checkbox"/>
	<i>For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is not board-certified:</i>	
	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(s) requested.	<input checked="" type="checkbox"/>
	AND	
	For an individual seeking authorization under 10 CFR Part 35, Subpart H, description of the training specified in 10 CFR 35.690 (c) demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought.	<input checked="" type="checkbox"/>
	AND	
	Written attestation, signed by a preceptor physician AU, that the above training and experience have been satisfactorily completed and that a level of	<input checked="" type="checkbox"/>

	competency sufficient to function independently as an AU for the medical uses authorized has been achieved.	
AND		
Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal <i>(The checklist is included to the application and information is provided separately.)</i>		
Item Number and Title	Suggested Response	Check box to indicate Material included in application
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>
Item 7: Authorized Nuclear Pharmacists Name(s) and license to practice pharmacy:	<i>For an individual previously identified as an ANP on an NRC or Agreement State license or permit:</i>	<input type="checkbox"/>
	Previous license number (if issued by the NRC), or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named ANP.	
	<i>For an individual qualifying under 10 CFR 35.57(a)(3):</i>	<input type="checkbox"/>
	Documentation that the nuclear pharmacist: . used only accelerator-produced radioactive materials or discrete sources of Ra-226, or both, in the practice of nuclear pharmacy before or during the effective period of NRC's waiver of August 31, 2005; and . used these materials for the same uses requested.	
	<i>For an individual qualifying under 10 CFR 35.55(a):</i>	<input type="checkbox"/>
	Copy of the certification(s) of the specialty board whose certification process has been recognized under 10 CFR 35.55(a).	
AND		
	Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved.	<input type="checkbox"/>
AND		
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>
	<i>For an individual qualifying under 10 CFR 35.55(b).</i>	<input type="checkbox"/>
	Description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience.	
AND		
	Written attestation, signed by a preceptor ANP, that the above training and experience have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved.	<input type="checkbox"/>

	AND	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input checked="" type="checkbox"/>
Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal <i>(The checklist is included to the application and information is provided separately.)</i>		
Item Number and Title	Suggested Response	Check box to indicate Material included in application
Item 7: Authorized Medical Physicists Name(s):	<i>For an individual previously identified as an AMP on an NRC or Agreement State license or permit:</i>	<input checked="" type="checkbox"/>
	Previous license number (if issued by the NRC), or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named an AMP for the uses requested.	
	<i>For an individual qualifying under 10 CFR 35.57(a)(3):</i>	<input checked="" type="checkbox"/>
	Documentation that the medical physicist: <ul style="list-style-type: none"> • used only accelerator-produced radioactive material, discrete sources of Ra-226, or both, for medical uses before or during the effective period of NRC's waiver of August 31, 2005; and • used these materials for the same medical uses requested. 	
	<i>For an individual qualifying under 10 CFR 35.51(a).</i>	<input checked="" type="checkbox"/>
	Copy of the certification(s) of the specialty board(s) whose certification process has been recognized ¹⁴ under 10 CFR 35.51(a).	
	AND	<input checked="" type="checkbox"/>
	Description of the training and experience specified in 10 CFR 35.51 (c) demonstrating that the proposed AMP is qualified by training in the types of use for which he or she is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system.	
	AND	<input checked="" type="checkbox"/>
	Written attestation, signed by a preceptor AMP, that the required training and experience required for certification, as well as the training and experience specified in 10 CFR 35.51(c) have been satisfactorily completed, and that a level of competency sufficient to function independently as an AMP has been achieved.	
	AND	<input checked="" type="checkbox"/>
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	
	<i>For an individual qualifying under 10 CFR 35.51(b):</i>	

	Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.51 (b)(1) for the uses requested.	<input checked="" type="checkbox"/>
AND Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal <i>(The checklist is included to the application and information is provided separately.)</i>		
Item Number and Title	Suggested Response	Check box to indicate Material included in application
	Description of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which he or she is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system.	<input checked="" type="checkbox"/>
AND		
	Written attestation, signed by a preceptor AMP, that the required training and experience have been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved.	<input checked="" type="checkbox"/>
AND		
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input checked="" type="checkbox"/>
Item 7: Authorized User for non Medical uses Name(s): Requested types, quantities, and non medical uses for each individual	Note: For purposes of this section of the table, the term "authorized user" is used to mean individuals authorized for the non medical uses described. See Sections 8.11 and 8.12. For an individual previously authorized for non medical use on an NRC or Agreement State license or permit: Previous license number (if issued by the NRC), or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named an AU for the types, quantities, and uses requested.	<input checked="" type="checkbox"/>
	For individuals qualifying under 10 CFR 30.33(a)(3): Documentation of the individual's training and experience demonstrating that the individual is qualified to use the types and quantities of licensed materials for the requested uses.	<input checked="" type="checkbox"/>
Item 9: Facility Diagram	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:	<input checked="" type="checkbox"/>
	<ul style="list-style-type: none"> • Guidance in Section 5.2 was reviewed and security-related sensitive information provided is marked accordingly. • Drawings should be to scale, and indicate the scale used. • Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, location of direct transfer delivery tubes from a PET radionuclide/radioactive drug production facility or production area of PET radioactive drugs under 10 CFR 30.320), and areas where higher energy gamma-emitting radionuclides (e.g., PET radionuclides) are used; • 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, indicating whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and • Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of 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). 	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>

	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.	<input checked="" type="checkbox"/>
Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal <i>(The checklist is included to the application and information is provided separately.)</i>		
Item Number and Title	Suggested Response	Check box to indicate Material included in application
Item 9: Radiation Monitoring Instruments	A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations." AND/OR	<input checked="" type="checkbox"/>
	A statement that: "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." AND	<input checked="" type="checkbox"/>
	A description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys. AND	<input checked="" type="checkbox"/>
	A statement that: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."	<input checked="" type="checkbox"/>
Item 9: Dose Calibrator and Other Dosage Measuring Equipment	A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."	<input checked="" type="checkbox"/>
	When administering dosages of alpha-emitting unsealed byproduct material in other than unit dosages made by a manufacturer or preparer licensed under 10 CFR 32.72 or 10 CFR 30.32(j), <ul style="list-style-type: none"> • A statement that: "Dosages will be determined by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation." OR	<input checked="" type="checkbox"/>
	We are providing a description of the dosage measurement equipment, the nationally recognized calibration standard (or manufacturer's calibration instructions), and dosage measurement procedures.	<input checked="" type="checkbox"/>
Item 9: Therapy Unit - Calibration and Use N/A	We are providing the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.	<input checked="" type="checkbox"/>
Item 9: Other Equipment and Facilities	Guidance in Section 5.2 was reviewed and security-related information and provided is marked accordingly.	<input checked="" type="checkbox"/>
	Attached is a description identified as Attachment 9.4, of additional facilities and equipment.	<input checked="" type="checkbox"/>
N/A	For manual brachytherapy facilities, we are providing a description of the	<input checked="" type="checkbox"/>

	emergency response equipment.	
	For PET radionuclide use, PET radioactive drug production, and radiopharmaceutical therapy programs, we are providing a description of the additional facilities and equipment for these uses.	<input checked="" type="checkbox"/>

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(The checklist is included to the application and information is provided separately.)

Item Number and Title	Suggested Response	Check box to Indicate Material included in Application
<u>N/A</u>	For teletherapy, GSR, and remote afterloader facilities, we are providing a description of the following: <ul style="list-style-type: none"> ▪ Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room; ▪ Area radiation monitoring equipment; ▪ Viewing and intercom systems (except for LDR units); ▪ Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room; ▪ Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and ▪ Emergency response equipment. 	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
Item 10. Safety Procedures and Instructions <u>N/A</u>	Attached procedures required by 10 CFR 35.610	<input checked="" type="checkbox"/>
	Guidance in Section 5.2 was reviewed and security-related sensitive information provided is marked accordingly.	<input checked="" type="checkbox"/>
Item 10: Occupational Dose	A statement that: "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, Rev. 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.'" OR	<input checked="" type="checkbox"/>
	A description of an alternative method for demonstrating compliance with the referenced regulations.	<input checked="" type="checkbox"/>
Item 10: Area Surveys	A statement that: "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."	<input checked="" type="checkbox"/>
Item 10: Safe Use of Unsealed Licensed Material	A statement that: "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 20.1301."	<input checked="" type="checkbox"/>
Item 10: Spill/Contamination Procedures	A statement that: "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."	<input checked="" type="checkbox"/>

<p align="center">Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal <i>(The checklist is included to the application and information is provided separately.)</i></p>		
Item Number and Title	Suggested Response	Check box to indicate Material included in application
<p>ITEM 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources</p>	<p>Name of the proposed employee and types of activities requested:</p> <p align="center">_____</p> <p align="center">AND</p>	<input checked="" type="checkbox"/>
	<p>Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested.</p> <p align="center">AND</p>	<input checked="" type="checkbox"/>
	<p>Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.</p>	<input checked="" type="checkbox"/>
	<p>A response is not required under the following condition: the NRC will consider that the above criteria have been met if the information provided in applicant's responses satisfy the criteria in Sections 8.15, 8.16, 8.21, 8.25, 8.27, and 8.29, on the topics: facilities and equipment, facility diagram, Radiation Protection Program, safety program, and waste management.</p>	N/A
<p>Item 10: Minimization of Contamination</p> <p align="center"><u>N/A</u></p>		
<p>Item 11: Waste Management</p>	<p>A statement that: "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 10 CFR Part 20, Subpart K, and of 10 CFR 35.92."</p>	<input checked="" type="checkbox"/>
	<p>Attached is a description of the radioactive waste incinerator facility and related portions of the Radiation Safety Program (10 CFR 20.2004).</p>	<input checked="" type="checkbox"/>
	<p>Attached is a request to receive potentially contaminated radiation transport shields from consortium members receiving PET radioactive drugs non commercially transferred under 10 CFR 30.32(j) authorization.</p>	<input checked="" type="checkbox"/>

Attachment 1

Information for the Application for Material License items 5 - 11 of NRC Form 313

ITEM 5: RADIOACTIVE MATERIAL

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any byproduct material permitted by 10 CFR 35.100	Any	As needed
Any byproduct material permitted by 10 CFR 35.200	Any	As needed
Any sealed sources permitted by 10 CFR 35.65	Any	As needed
Technetium-99m	Any	As needed

ITEM 5: SEALED SOURCES AND DEVICES

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any sealed sources permitted by 10 CFR 35.65	Any	As needed
Technetium-99m	Any	As needed
Cobalt -57	Form or Manufacturer: <u>Isotope Products</u> <u>Laboratories</u> Model No. _____	5.00 millicuries
Cesium -137	Form or Manufacturer: <u>Isotope Products</u> <u>Laboratories</u> Model No. _____	0.200 millicuries
Barium-133	Form or Manufacturer: <u>Isotope Products</u> <u>Laboratories</u> Model No. _____	0.250 millicuries

ITEM 6: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

LICENSED MATERIAL	PURPOSE(S)
10 CFR 35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required
10 CFR 35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required
10 CFR 35.65	Use of sealed reference sources authorized by 10 CFR 35.65

ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAMS AND THEIR TRAINING AND EXPERIENCE**Sec. 8.11 RADIATION SAFETY OFFICER (RSO)**

- **Information Provided:**
 - Name of the proposed RSO: **Jossian J. Pagán Lisboa.**
 - **An individual previously identified as an RSO on an NRC or Agreement State license or permit:**
 - Previous license number: NRC License **52-31166-01** and **52-11810-02**

Sec. 8.12 AUTHORIZED USERS (AUs) for Medical Uses

- **Information provided:**
 - Name of the proposed AU: **Humberto O. Quintana, MD**
(35.100, 35.200, 35.65)
 - **Medical license number and issuing entity:**
 - License **7273** from **Commonwealth of Puerto Rico, Department of Health of Puerto Rico Board of Medical Examiners**
 - **An individual previously identified as an AU on an NRC or Agreement State license or permit:**
 - Previous license number: NRC License **52-30841-01.**
 - Name of the proposed AU: **Carlos Jiménez Marchan, MD**
(35.100, 35.200, 35.65)
 - **Medical license number and issuing entity:**
 - License **11046** from **Commonwealth of Puerto Rico, Department of Health of Puerto Rico Board of Medical Examiners**
 - **An individual previously identified as an AU on an NRC or Agreement State license or permit:**
 - Previous license number: NRC License **52-31166-01.**
 - **AU for Medical Uses:**
 - Radiation safety commensurate with use of byproduct material
 - Administration of a radiation dose or dosage and how it is prescribed
 - Direction of individuals under the AU's supervision in the preparation of byproduct material for medical use and in the medical use of byproduct material
 - Preparation of written directives (WD), if required.

ITEM 9: FACILITIES AND EQUIPMENT

Sec. 8.16 FACILITY DIAGRAM

A facility diagram is enclosed and describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. The following information is included:

- Drawings of Kardio Nuclear at Hospital San Carlos de Borromeo in Moca, Puerto Rico facility is included.
- Location of each room or area where radioactive material will be used or stored (Camera Room, Control Room, Hall Ways, Hot Room, Injection Site, Rest Room, Stress Room etc.)

Sec. 8.17 RADIATION MONITORING INSTRUMENTS:

- "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."
- A description of the instrumentation that will be used to perform required surveys is as follows:
 - **Survey Meter:** The external pancake probe is used to check hands, clothing, floors, furniture, equipment, and package surfaces for contamination. Survey Meter with Pancake GM Probe (Model 14C), monitors alpha, beta and gamma rays. It has five counting scales (x0.1, x1, x10, x100, x1000).
- "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."

Sec. 8.18 DOSE CALIBRATOR AND OTHER EQUIPMENT USED TO MEASURE DOSAGES OF UNSEALED BYPRODUCT MATERIAL

- For the administration of gamma- and beta-emitting unsealed byproduct materials, provide the following:
 - "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."
- When administering dosages of alpha-emitting unsealed byproduct material in other than unit dosages made by a manufacturer or preparer licensed under 10 CFR 32.72 or 10 CFR 30.32(j),
 - "Dosages will be determined by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation."

Attachment 9.4

Sec. 8.20 OTHER EQUIPMENT AND FACILITIES

A brief description of other equipment and facilities available to safely receive, use, store, and dispose of radioactive material listed in Item 5 of this application.

- **HOT LAB (ROOM):** Is a restricted area and a Radioactive Material Sign will be posted on the door. Here is where the radioactive material (unit doses) will be stored when received from the radiopharmacy Lantheus Medical Imaging. The doses will be stored for daily use in their respectively lead shields. This area is prepared for the safety use, management , storage and measurement of radioactive material:
 - **Dose Calibrator:** This instrument will be used to measure and to confirm the activity received by the Radiopharmacy before patient's administration. The Dose Calibrator will have response time, extended measurement range and computer compatibility provide state-of-the-art performance for PET pharmacies, chemistry laboratories or clinics. It will provide fast, accurate radionuclide activity measurements that easily surpass the most stringent regulatory requirements. There a few isotope selection keys, and are pre-programmed for the most commonly used and constancy radionuclides. Any key can be reprogrammed by the user for a desired isotope. Activity is displayed on a LED readout in either Curie or Becquerel units. Background correction and zero adjustment will be performed at the touch of a button. Range selection is automatic.
 - **Wipe Counter:** Will be used to measure surface contamination levels in areas where radiopharaceuticals are used.
 - **L-Block Shield:** Used for receiving and preparing unit doses of high-energy radionuclides. It contains a 1.5 inch thick lead shielding in front, and 1 inch thick lead in the base. A lead brick cave is added to provide lateral shielding around the full perimeter of the L-block's base. it is to protect the Nuclear Medicine Technologist from radioactive exposure while measuring the unit doses for each patient and while performing the calibration procedure for the dose calibrator.
 - **Lead nest:** Sealed vial reference sources are stored.
 - **Sharps Container Shield:** It is use for disposal of syringes that have been contaminated with high energy radionuclides. The shield is constructed of steel and lined with 1" thick (2.5cm) lead.
 - **Decay storage area:** radioactive waste will be stored for decay and then treated as regular trash.
- **INJECTION SITE:** It is a restricted area and it is use for the administration of radioisotope to the patient's.
- **OPENING PACKAGES:**
 - We will use the model Appendix P contains model procedures that represent one method for safely opening packages containing radioactive materials.

▪ **MATERIAL RECEIPT AND ACCOUNTABILITY**

- To maintain accountability of licensed material we will do the following:
 - Secure licensed material
 - Maintain records of receipt, transfer, and disposal of licensed material
 - Conduct physical inventories at required frequencies to account for licensed material

▪ **ORDERING AND RECEIVING**

- Authorize, through a designee, each order of radioactive materials, and ensure that the requested materials and quantities are authorized by the license for use by the requesting AU and that possession limits are not exceeded.
- Establish and maintain a system for ordering and receiving radioactive material that include the following information:
 - Records that identify the AU or department, radionuclide, physical and/or chemical form, activity, and supplier;
 - Confirmation, through the above records, that material received was ordered through proper channels.
 - For deliveries during normal working hours, carriers will deliver radioactive packages directly to a specified area (Hot Room).
 - For deliveries during off-duty hours, security personnel or other designated persons will accept delivery of radioactive packages that arrives outside normal working hours. Packages will be taken immediately to the Nuclear Medicine Division, Hot Room, unlock the door, place the package on the designated area, and relock the door. If the package appears to be damaged, immediately contact one of the following individuals: Radiation Safety Officer, Director of Nuclear Medicine, Nuclear Medicine Technologist Supervisor, Nuclear Medicine Technologist, or the Nuclear Medicine Physician. The carrier will be instructed to remain at the facility until it can be determined that neither the driver nor the delivery vehicle is contaminated.

▪ **SEALED SOURCE INVENTORY**

- A sealed source physical inventory will be conducted semi-annually basis.

▪ **RECORDS OF DOSAGES**

- Records will be maintained of each dosage and administration prior to medical use. The records will include the following information:
 - Radiopharmaceutical
 - Patient's name or identification number
 - Prescribed dosage and administered dose
 - Date and time of dosage determination
 - Name of the individual who determined the dosage

▪ **RECORDKEEPING**

- We will maintain certain records to comply with NRC regulations and will refer to the table of recordkeeping requirements that appears in Appendix X (Regulatory Guide NUREG - 1556 Vol 9 Rev 2).

▪ **LEAK TESTS**

- To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- A well counter system with a single or multi channel analyzer will be used to analyze samples obtained from gamma-emitting sources.
- Instrumentation used to analyze leak test samples will be capable of detecting 185 Bq (0.005 μ Ci) of radioactivity.

▪ **WASTE**

Model Waste Management Procedures General Guidelines

- A reference source used for equipment calibration will be returned the radiopharmacy and they will be shipped back to the manufacture company for proper disposal procedures when ever a new one is purchase.
- All radioactivity labels must be defaced or removed from containers and packages prior to disposal in in-house waste.
- Remind employees that non-radioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.
- Occasionally all procedures monitor to ensure that radioactive waste is not created unnecessarily. All new procedures will be reviewed to ensure that waste is handled in a manner consistent with established procedures.
- Housekeeping staff will receive adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or to radiation.

Procedure for disposal by Decay-In-Storage (DIS):

- The syringe used after the administration of radioactive material to a patient is stored in the lead pig and returned back to the radopharmacy inside the ammo box for proper disposal procedures. The ammo box will remain inside the Hot Lab until next day. The syringes can also be kept in the radioactive storage area for decay and disposed as regular biohazard trash.
- Short-lived waste will be segregated from long-lived waste (half-life greater than 120 days).
- Waste will be stored in suitable well-marked containers, and the containers will have adequate shielding.
- When the container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.
- The identification label should include the date when the container was sealed, the name of the longest lived radioisotope in the container, date when ten half-lives of the longest-lived radioisotope will have transpired or it comes down to background levels, the radiation level in mr/hr and the initials of the individual who sealed the container. The container should be transferred to the DIS area for decay.
- The contents of the container should be allowed to decay for at least 10 half-lives or it comes down to background levels.

Prior to disposal as ordinary trash, each container should be monitored as follows:

- Check the radiation detection survey meter for proper operation.
- Survey the contents of each container in a low background area (less than 0.05 millirems per hour).
- Remove any shielding from around the container.
- Monitor all surfaces of the container.
- Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity, (surface readings are indistinguishable from background).
- If the surveys indicate residual radioactivity, return the container to DIS area and contact the RSO for further instructions.
- If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (used or unused material, gloves, etc.), survey instrument used, background levels, readings of radioactivity in mr/hr and the initials of the individual performing surveys and disposing of the waste. This information will be documented in a Waste Disposal Log Book.

Attachment 2

ITEM 10: RADIATION PROTECTION PROGRAM

Licensee will abide by all applicable regulations, develop, implement, and maintain procedures when required, and/or provide requested information about the proposed Radiation Protection Program during the licensing process to protect health or to minimize danger to life and property.

Sec. 8.23 OCCUPATIONAL DOSE

"Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 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, Volume 9, Revision 2, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.' "

Sec. 8.24 AREA SURVEYS

"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."

Sec. 8.25 SAFE USE OF UNSEALED LICENSED MATERIAL

"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 20.1301."

Sec. 8.26 SPILL/CONTAMINATION PROCEDURES

"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."

ITEM 11: WASTE MANAGEMENT

Sec. 8.29 WASTE MANAGEMENT

"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 of 10 CFR 35.92."

ITEM 12. LICENSE FEES:

Sec. 8.29 LICENSE FEES:

- A. Fee Category: 7C
- B. Amount Enclosed: \$1,900.00

This is to acknowledge the receipt of your letter/application dated 12/4/09 ^{received} and to inform you that the initial processing which includes an administrative review has been performed.

(New License Application) (03038197)
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

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** 144323.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.