

NRC FORM 313
(10-2002)
10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 10/31/2005

APPLICATION FOR MATERIAL LICENSE

Estimated burden per response to comply with this mandatory collection request: 7 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 Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollecta@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:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA PA 19408-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

SAM NUNN ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
81 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-8931

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
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, 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 SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
811 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

LL 31019
03036876
02201
(29-31019-01)

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.

<p>1. THIS IS AN APPLICATION FOR (Check appropriate item)</p> <p><input checked="" type="checkbox"/> A. NEW LICENSE</p> <p><input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____</p> <p><input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)</p> <p>A. Nizar Kahf, M.D., F.A.C.C. 401 Haledon Avenue Haledon, NJ 07508</p>
<p>3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p> <p>401 Haledon Avenue Haledon, NJ 07508 (973) 942 3767</p>	<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>Adel Mustafa, Ph.D., Medical Physics Consulting,</p> <p>TELEPHONE NUMBER</p> <p>(732) 972-3457</p>

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.

<p>5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</p>				
<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.</p>	<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</p>				
<p>9. FACILITIES AND EQUIPMENT.</p>	<p>10. RADIATION SAFETY PROGRAM.</p>				
<p>11. WASTE MANAGEMENT.</p>	<p>12. LICENSE FEES (See 10 CFR 170 and Section 170.31)</p> <table border="1"> <tr> <td>FEE CATEGORY</td> <td>7C</td> <td>AMOUNT ENCLOSED</td> <td>\$ 1,900.00</td> </tr> </table>	FEE CATEGORY	7C	AMOUNT ENCLOSED	\$ 1,900.00
FEE CATEGORY	7C	AMOUNT ENCLOSED	\$ 1,900.00		

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON

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

<p>CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE</p> <p>A. Nizar Kahf, M.D., Director</p>	<p>SIGNATURE</p> 	<p>DATE</p> <p>2/23/05</p>
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FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
		7C	\$		
APPROVED BY				DATE	
					136565

**ATTACHEMNT 5 and 6 on NRC Form 313
RADIOACTIVE MATERIAL AND USE**

Radionuclide	Physical or Manufacturer/ Model Number	Maximum Quantity	Purpose of Use
A. Any byproduct material permitted By 10 CFR 35.200	Any	As needed	Cardiac Imaging and localization study permitted under 10 CFR 35.200
B. Cobalt-57	Sealed sources	2 sources not to exceed 370 Megabecquerels (10mCi) per source	Reference /calibration
C. Cobalt-57	Sealed Disk flood sources	2 sources not to exceed 370 Megabecquerels (10 mCi) per source	Calibration
D. Cesium-137	Sealed sources	18.5 Gigabecquerels (0.5 mCi)	Calibration

(A) To be used for diagnostic imaging and localization studies (human use).

(B),(C),(D) : To be used as reference sources (non-human use) for calibration, testing, quality assurance and radiation safety testing. The request for 2 sources in B & C is to allow for having replacement calibration source and older source in location simultaneously during the replacement process.

APPENDIX C

Table C.2 outlines the detailed responses that may be made to Items 5 and 6 on Form 313 for type of radioactive material requested and purposes for which it will be used. For example, if the applicant is seeking a license for unsealed byproduct material under 10 CFR 35.100 or 35.200, then the applicant should check the “yes” column next to 10 CFR 35.100 and 35.200 in Table C.2. The table then indicates appropriate responses for that type of use. An applicant may copy the checklist and include it in the license application.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material And Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
✓	Any byproduct permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
	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 (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.
	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.

Table C.3 is a checklist that may be used to identify the attached documents that the applicant is supplying for items for which a response is required. For example, an applicant may fill in the name(s) of Radiation Safety Officer in Table C.3 and then check the boxes indicating which documents pertaining to the RSO are being included in the license application. An applicant may copy the checklist and include it in the license application.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 7: Radiation Safety Officer Name: <u>Aiman Hamdan, M.D.</u>	Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.	X <input type="checkbox"/>
	OR	
	Copy of the certification(s) for the board(s) recognized by NRC and as applicable to the types of use for which he or she has RSO responsibilities.	X <input type="checkbox"/>
	OR	
	Description of the training and experience specified in 10 CFR 35.900(b).	<input type="checkbox"/>
	OR	
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.	<input type="checkbox"/>	
AND		
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 licensee 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"/>	

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
<p>Item 7: Authorized Users Names and Requested Uses for Each Individual <u>Aiman Hamdan, M.D.</u></p>	<p>Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the physician was specifically named as an AU for the uses requested.</p> <p style="text-align: center;">OR</p> <p>Copy of the certification(s) for the board(s) recognized by NRC under 10 CFR Part 35, Subparts D, E, F, G, H, and as applicable to the use requested.</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience identified in 10 CFR Part 35 Subpart J demonstrating that the proposed AU is qualified by training and experience for the use requested.</p> <p style="text-align: center;">OR</p> <p>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;</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor physician AU, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved.</p> <p style="text-align: center;">AND</p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p style="text-align: center;"><input checked="" type="checkbox"/></p> <p style="text-align: center;"><input checked="" type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p>
<p>Item 7: Authorized Nuclear Pharmacists</p> <p>Names: <u>NA</u></p>	<p>Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named ANP.</p> <p style="text-align: center;">OR</p> <p>Copy of the certification(s) for the radiopharmacy board(s) recognized by NRC under 10 CFR 35.55(a) or 10 CFR 35.980(a).</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience demonstrating that the proposed ANP is qualified by training and experience.</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that a level of competency</p> <ul style="list-style-type: none"> • sufficient to function independently as an ANP has been achieved (10 CFR 35.55), or • sufficient to independently operate a nuclear pharmacy (10 CFR 35.980). <p style="text-align: center;">AND</p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p>

Table C.3 (continued)

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."	X <input type="checkbox"/>
	<p style="text-align: center;">AND/OR</p> 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."	X <input type="checkbox"/>
	<p style="text-align: center;">AND</p> 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.	X <input type="checkbox"/>
	<p style="text-align: center;">AND</p> 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."	X <input 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."	X <input type="checkbox"/>
Item 9: Therapy Unit - Calibration and Use	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 type="checkbox"/>
Item 9: Other Equipment and Facilities	Attached is a description identified as Attachment 9.4, of additional facilities and equipment.	<input type="checkbox"/>
	For manual brachytherapy facilities, we are providing a description of the emergency response equipment.	<input type="checkbox"/>
	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; 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Area radiation monitoring equipment; 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Viewing and intercom systems (except for LDR units); 	<input type="checkbox"/>
<ul style="list-style-type: none"> • 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; 	<input type="checkbox"/>	
<ul style="list-style-type: none"> • Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and 	<input type="checkbox"/>	
	<ul style="list-style-type: none"> • Emergency response equipment. 	<input type="checkbox"/>
Item 10: Safety Procedures and Instructions	Attached procedures required by 10 CFR 35.610.	X <input type="checkbox"/>

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 10: Occupational Dose	<p>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, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees," dated October 2002."</p> <p style="text-align: center;">OR</p> <p>A description of an alternative method for demonstrating compliance with the referenced regulations.</p>	<p style="text-align: center;"><input checked="" type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p>
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 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"/>
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	<p>Name of the proposed employee and types of activities requested:</p> <p style="text-align: center;">AND</p> <p>Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested.</p> <p style="text-align: center;">AND</p> <p>Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.</p>	<p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p>
Item 10: Minimization of Contamination	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 8.14, 8.15, 8.20, 8.24, 8.26, and 8.28, on the topics: Facility and Equipment; Facility Diagram; Radiation Protection Program; Safety Program; and Waste Management.	N/A
Item 11: Waste Management	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 Subpart K to 10 CFR Part 20 and 10 CFR 35.92."	<input checked="" type="checkbox"/>

**ATTACHEMNT 7a Authorized Users and
Authorized Use**

Authorized user for this license is **Aiman M. Hamdan, M.D.**

Dr. Hamdan is currently authorized user on New Jersey State Radioactive materials License number NJSL-70046/01/031 issued to ST Joseph's Regional Medical Center, Paterson, New Jersey. Copy of license is attached (ATTA. 7.1.)

Authorized Use: Imaging procedures permitted under 10 CFR 35.200

NRC License Application

ATTACHEMNT 7b Authorized Radiation Safety Officer

Authorized Radiation Safety Officer for this license is **Aiman M. Hamdan, M.D.**
Dr. Hamdan is Board Certified by the American Board of Nuclear Cardiology.
Copy of Dr. Hamden's Board Certificate is attached as Att. 7.2.

License No.: NJSL-70046/01/031
 Amendment No.: 031
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State of New Jersey

Department of Environmental Protection
 Bureau of Environmental Radiation
 Radioactive Materials Section
 PO Box 415, Trenton, NJ 08625-0415
 Phone (609) 984-5462

*Reference
 Copy*

New Jersey Radioactive Materials License

Pursuant to the New Jersey Radiation Code, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive or use the naturally occurring and/or accelerator produced material(s) (NARM) designated below; and to such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the State Department of Environmental Protection, now or hereafter in effect, and to any conditions specified below.

1. License No.: NJSL-70046/01/031	2. Expiration Date: 01/31/2007
3. Licensee: ST. JOSEPH'S REGIONAL MEDICAL CTR.	4. Address: 703 Main Street Paterson NJ 07503-0000
Radiation Safety Officer: Mark M. Belanich, M.S.	County: Passaic Telephone: (973) 754-2681
Administrator: Patrick R. Wardell	5. Reference No.: 2400

RADIOACTIVE MATERIALS DATA (A)

6. Material	7. Limit (mCi)	8. Form
A. Any NARM included under Group I, Section 4.7 of NJAC 7:28-4.	50.0000	Any radiopharmaceutical included under Group I, Section 4.7 of NJAC 7:28-4.
B. Any NARM included under Group II, Section 4.7 of NJAC 7:28-4.	500.0000	Any radiopharmaceutical included under Group II, Section 4.7 of NJAC 7:28-4.
C. Any NARM included under Group III, Section 4.7 of NJAC 7:28-4.	100.0000	Any radiopharmaceutical included under Group III, Section 4.7 of NJAC 7:28-4.
D. CO-57	120.0000	Scaled Source
E. PD-103	700.0000	Scaled Source
F. Ge-68	30.0000	Scaled Source

RADIOACTIVE MATERIALS DATA (B)

9. Authorized Use
- A. Any diagnostic procedure under Group I of NJAC 7:28-4, Section 4.7
 - B. Any diagnostic procedure under Group II of NJAC 7:28-4, Section 4.7
 - C. Preparation and use of radiopharmaceuticals for any diagnostic procedure under Group III of NJAC 7:28-4, Section 4.7
 - D. Reference and/or calibration source
 - E. Therapeutic procedure under Group VI of NJAC 7:28-4, Section 4.7.
 - F. Reference and/or calibration source.

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Amendment No.: 031
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New Jersey Radioactive Materials License

10. Radioactive material shall only be used at 703 Main Street, Paterson, New Jersey.
11. The authorized use of Group I & II radiopharmaceuticals in item 9A and 9B will include Positron Emission Tomography procedures.
12. Radioactive materials shall be used as follows:
 - A. Radioactive material listed in items 6A - 6D shall be used by or under the supervision of the following: Fred Cushmore, M.D., Vidor Berstein, M.D., Frank Yuppa, M.D., George Baumgardner, M.D., Joung Yoon Lee, M.D., Jeffrey Plutchok, M.D., Rajendra Achaibar, M.D., Mahendra R. Modi, M.D. and Robin Frank-Gerszberg, M.D.
 - B. Radioactive materials specified in subitem 6B used for cardiac imaging and diagnosis of cardiac function and 6D may be used by: Mahesh Bikkina, M.D., Donna Konlan, M.D., Ijaz R. Vehra, M.D., David E. Cohen, M.D., Steven Grossman, M.D. and Aimam M. Hamdan, M.D.
 - C. Radioactive materials specified in subitem 6E may be used by Thomas M. Herskovic, M.D. and Michael J. Percirra, M.D.
13. Compliance with other U.S. Agencies having jurisdiction and regulations for radiopharmaceuticals must be maintained.
14. The licensee shall retain records of misadministrations in the use of the licensed radioactive materials. Misadministrations being defined as a radiopharmaceutical or radiation from a sealed source which is improperly used as follows:
 - A. Administration of the wrong radiopharmaceutical or sealed source.
 - B. Administration to the wrong patient.
 - C. Administration by a route other than that intended by the prescribing physician.
 - D. Administered diagnostic dose differing by more than 50 percent of the prescribed dose.
 - E. Administered therapeutic dose differing by more than 10 percent of the prescribed dose.Records of misadministrations are to include the following information: name of the referring physician, description of the event, the effect on the patient and the action taken to prevent recurrence.
15. The licensee shall not open sealed sources containing radioactive material.
16. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months.
 - A. The test shall be capable of detecting the presence of 0.005 microcuries of removable radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surface of the device in which the sealed source is permanently mounted or stored.
 - B. If the test reveals the presence of 0.005 microcuries of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with the Department regulations. Within five days after obtaining results of the test, a report shall be filed with the Department describing the circumstances, the test results and the corrective action taken.
 - C. The sealed sources shall be tested for leakage and/or contamination by appropriately trained personnel.

New Jersey Radioactive Materials License

17. Repair, initial leak tests and disposal of sealed sources containing radioactive material shall be performed only by the manufacturer or by other persons specifically licensed by New Jersey or the Federal Government to perform this service.
18. Radioactive material with a physical half live of less than 300 days may be disposed of as non-radioactive waste provided that (a) the radioactive waste is stored behind adequate shielding to meet the requirements of New Jersey Radiation Code 28-6, (b) the radioactive waste is held for ten half-lives of the longest lived radioisotope to be disposed of, (c) the radioactive waste is monitored with a GM meter prior to disposal to insure background levels, (d) all radiation labels are removed or obliterated and (e) a log shall be maintained to include the results of the radiation survey and date of disposal.
19. The following surveys shall be performed and documented during Palladium-103 implant procedures.
 - A. Survey of the patient and administration area immediately after implanting sources in a patient to confirm that no sources have been misplaced.
20. The licensee shall make a record of Palladium-103 use which must include:
 - A. The number and activity of sources removed from storage, the patients name and room number, the time and date they were removed from storage, the number and activity of sources in storage after return.
 - B. The number and activity of sources returned to storage, the patients name and room number, the time and date they were removed from storage, the number and activity of sources in storage after return.
 - C. The number and activity of sources administered, the patients name and room number, the time and date the sources were implanted and the initials of the individual administering the sources.
21. A survey of the administration area used for stress thallium studies shall be performed and documented on the day the test is done.
22. In laboratory areas where small quantities of radioactive materials are used (i.e. less than 200 microcuries):
 - A. Monthly surveys of areas are to be performed and the results documented.
 - B. Monthly wipe test of areas are to be performed and the results documented.
 - C. Protective gloves are to be worn by individuals handling radioactive material.
 - D. Decayed radioactive waste will be surveyed prior to disposal to ensure background levels.
 - E. Radioactive material symbols shall be removed and/or obliterated from all containers no longer containing material prior to disposal.
23. The licensee shall make the following items available to their staff:
 - A. Copy of the New Jersey Radiation Protection Code.
 - B. Copy of the New Jersey State Radioactive Material License.
24. The licensee shall post the following items in an area frequented by employees engaged in the use of licensed materials:
 - A. Notice to employees - RPP-14.
 - B. Emergency procedures involving major, minor spills including the names and phone numbers of people to contact.

New Jersey Radioactive Materials License

C. Appropriate signs and labels in areas and/or containers and equipment in which radiation and/or radioactive material are contained. These postings are to conform to Subchapter 10 of the Code.

25. The following tests shall be performed as a minimum:

A. Surveys of:

1. All radioactive materials received.
2. All radioactive waste decayed to background levels prior to release.
3. Uncontrolled areas, where sealed and unsealed sources are routinely used to be surveyed on days they are used.
4. Controlled area, where sealed and unsealed sources are used on days they are used.
5. Personnel at the end of the day.

B. Wipe tests of:

1. Controlled and uncontrolled area where unsealed sources of radioactive material are routinely used, weekly.

26. The following records shall be maintained:

- A. Radioactive materials received including but not necessarily limited to date of receipt, radionuclide, activity, mass or volume of material, results of package survey, instrument used for surveys and surveyor's initials.
- B. Radioactive materials administered to patients including but not necessarily limited to date of administration, radionuclide, calibrated activity administered, quantity, patient name, administrator's signature.
- C. Radioactive material disposals including but not necessarily limited to:
 1. Disposal to Vendor: nuclide, activity, vendor name, quantity, date of disposal.
 2. Disposal by Decay: Results of survey of the waste, date of survey, date of waste disposal, instrument used, and surveyor's initials.
 3. Disposal to Sanitary Sewer: nuclide, activity, volume of dilution waste per day, date of disposal.
- D. Survey instrument calibration performed annually and after instrument repair.
- E. Sealed source leak tests at intervals not to exceed six months. Results are to be reported in microcuries.
- F. Surveys performed in controlled and uncontrolled areas including but not necessarily limited to: test results in mR/hr, date performed, instrument used and surveyor's initials.
- G. Wipe tests performed in controlled and uncontrolled areas including but not necessarily limited to: test results in dpm, date performed instrument used and surveyor's initials.
- H. Personnel dosimetry records including but not necessarily limited to: name, social security number, and prior employment exposure history.
- I. Daily personnel monitoring results including but not necessarily limited to instrument used, date performed and initials.

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New Jersey Radioactive Materials License

- 27. Protective equipment and clothing including but not necessarily limited to syringe shields, remote handling equipment, adequate shielding, laboratory coats, and disposable gloves shall be used by personnel while utilizing radioactive material.
- 28. Eating, drinking, smoking and applying cosmetics shall not be permitted in controlled areas.
- 29. Except as specifically provided by this license, the licensee may possess and use radioactive material described in this license in accordance with statements, representations and procedures contained in New Jersey Radioactive Material License Application dated December 27, 2001 signed by Patrick R. Wardell.

New Jersey Department of Environmental Protection Signature

Date: January 8, 2002

By: John Terry
For the NJ Department of Environmental Protection

THE CERTIFICATION BOARD OF NUCLEAR CARDIOLOGY

Incorporated 1996

CERTIFIES THAT

Aïman M. Hamdan, MD

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD FOR PHYSICIANS RESIDING
IN THE UNITED STATES AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,
IS HEREBY DESIGNATED

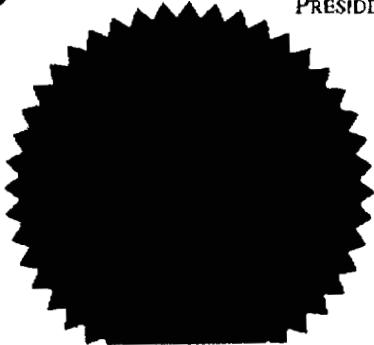
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

NUCLEAR CARDIOLOGY

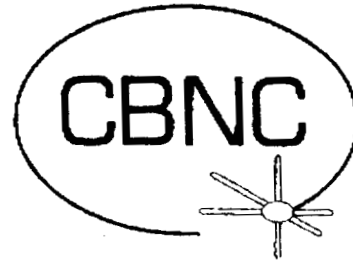
FOR THE PERIOD 2002 THROUGH 2012

Mamadou Couguera
PRESIDENT

[Signature]
SECRETARY



CERTIFICATE # 2383

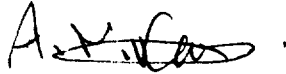


OCTOBER 20, 2002

Dr. Kahf's Nuclear Cardiology Office
401 Haledon avenue, Haledon, NJ 07508

To: All Employees and users of radioactive materials

From: **Nizar Kahf, M.D.**
Director



Subject: Delegation of Authority

Aiman Hamdan, M.D. has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program,; verifying implementation of corrective action; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet with those responsibilities.

Item 8 : TRAINING PROGRAM

We will establish and implement the model training program for individuals involved in the usage of byproduct materials included in Appendix J of NRC NUREG-1556-volume 9. The following identifies the groups of workers who will receive training and the method and frequency. Records of training will include lists of attendees, dates and topics. These records will be retained for three years.

<u>INDIVIDUALS</u>	<u>FREQUENCY</u>	<u>METHOD</u>
Chief Nuclear Medicine Technologist	Per the model program	Reviewed by the RSO, authorized user and/or as provided by our visiting consultants.
Nuclear Medicine Technologist.	Per the model program	Reviewed by the RSO, authorized user, Nuclear medicine technologist and/or as provided by our visiting consultants.
Other staff as appropriate.	At orientation and Annually thereafter	Reviewed by RSO, authorized user, Nuclear Medicine Technologist and/or participation in health physics audits or review of the audit reports as provided by our visiting consultants.

ITEM 9: Facilities and Equipment

9.1. Annotated drawing is attached for

9.2. Instrumentation:

9.2.1. Radiation Monitoring Equipment

9.2.1.1 Survey Meter : GM type Ludlum 14 C, with Pancake Probe

Range : x 0.1 - x 1000

Range 0.01 – 2000 mR/hr

Calibration: We will establish 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

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.

9.2.1.2 Wipe test counter: 6 channel, Auto DPM calculation, sensitivity 22 dpm/cm² or Equivalent

9.2.2 Dose Calibrator with remote chamber, J 086-250. Type Capentic CRC-15R or equivalent

Calibration: Equipment used to measure dosage will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

9.2.3 Gamma Camera: Dual head Camera from Philips.

Calibration: Equipment used for imaging will be tested in accordance with nationally recognized standards or the manufacturer's instructions.

9.3. Other equipment and protection

- L-Block shield, syringe shield, Forceps, lead lined waste container, sharps container, decontamination kit, caution signs
- 20" Deep stainless steel countertop with cabinet underneath
- Shielded carry case for transport of syringes
- **TLD** badges for personnel monitoring

ITEM 10 : RADIATION SAFETY PROGRAM

Item 10.1. Occupational dose

We will provide dosimeter that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," Dated October 2002.

ITEM 10.2. 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

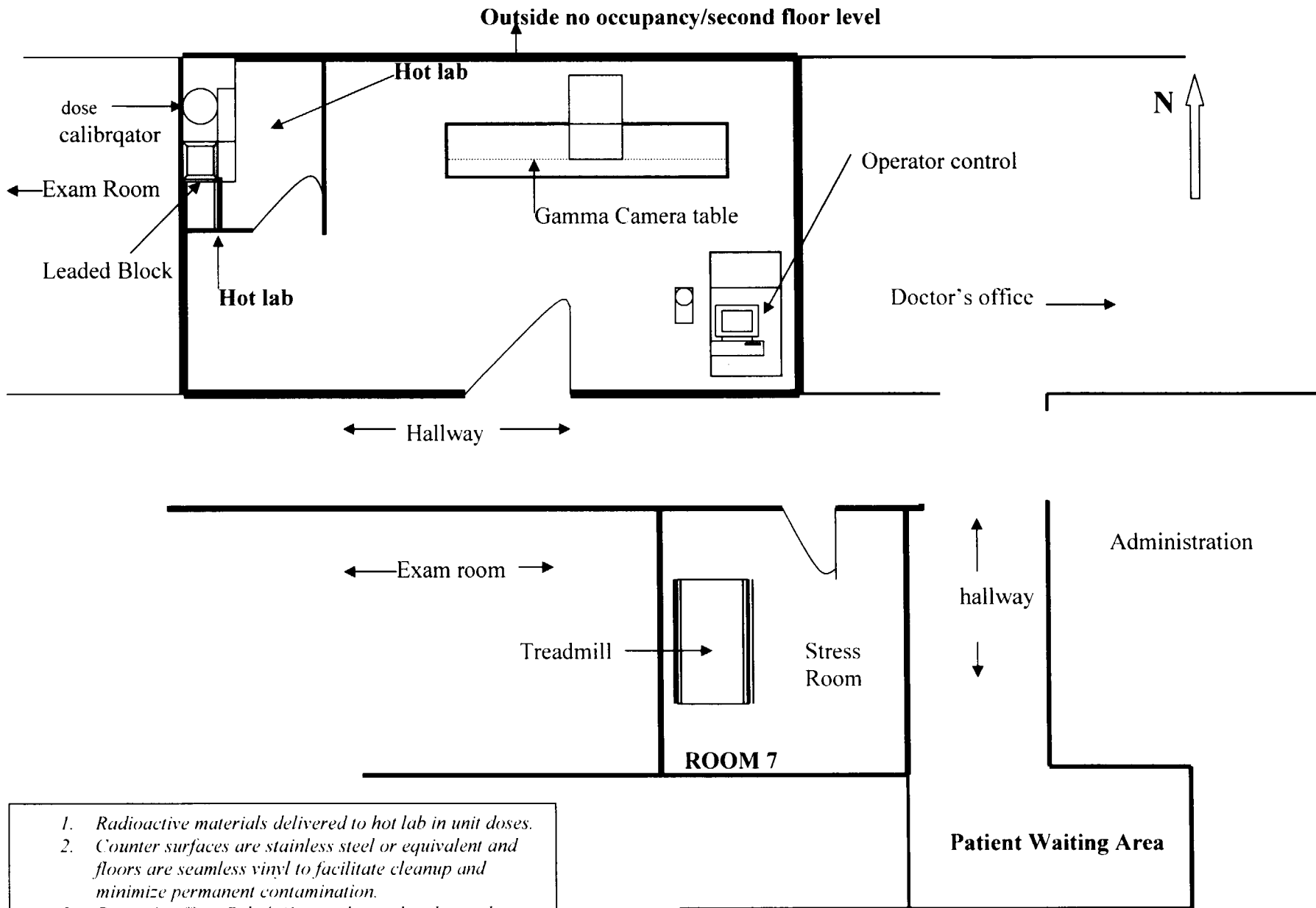
ITEM 10.3. Safe Use of Unsealed Licensed Material

We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301

ITEM 10.4. Spill 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.

Dr. Kahf's Office: Nuclear Cardiology Exam Room 8 and Stress Room 7
Second Floor, Rooms 7 and 8
401 Haledon Avenue
Haledon, NJ 07508



1. Radioactive materials delivered to hot lab in unit doses.
2. Counter surfaces are stainless steel or equivalent and floors are seamless vinyl to facilitate cleanup and minimize permanent contamination.
3. Doctor's office (Rehab Center) located underneath facility and no occupancy above facility (roof).

ITEM 11. 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 CFR 35.92

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

2/23/2005, and to inform you that the initial processing which includes an administrative review has been performed.

New License Application (03036816)
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 136505.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

BETWEEN: : (FOR LFMS USE)
 : INFORMATION FROM LTS
 : -----
 :
 License Fee Management Branch, ARM : Program Code: 02201
 and : Status Code: 3
 Regional Licensing Sections : Fee Category: _____
 : Exp. Date: 0
 : Fee Comments: _____
 : Decom Fin Assur Reqd: _
 :

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
 Applicant/Licensee: KAHF, A. NIZAR, M.D.
 Received Date: 20050225
 Docket No: 3036876
 Control No.: 136505
 License No.:
 Action Type: New Licensee

2. FEE ATTACHED
 Amount: 31900.00
 Check No.: 3241

3. COMMENTS

Signed Walter J. Ford
 Date 2/25/05

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/_)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:
 Amendment _____
 Renewal _____
 License _____

3. OTHER _____

Signed _____
 Date _____