

Mark Jeffrey Krell, M.D.
33 Overlook Road, Suite L-06
Summit, NJ 07901
908-508-1234

Licensing Assistant Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

LL 31036
03036914

02201

Re: NRC New License Application - Additional Information

March 19, 2005

(29-31036-01)

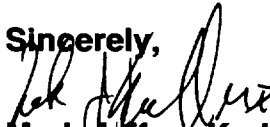
Dear Sir / Madam:

Enclosed is additional information regarding our new NRC License Application. Enclosed for your review are, NRC form 313 , facility diagram, and Delegation of Authority.

Our location of use will be:
Mark J. Krell, M.D,
1 Springfield Avenue , STE 2A
Summit , NJ 07901

We would like to request that this license be expedited so that we may begin nuclear medicine imaging on June 1, 2005. Thank you for your consideration.

Please contact our Physics Consultant, Elaine Rovazzi, M.S. @ (973) 322-5118 for any further information.

Sincerely,

Mark Jeffrey Krell, M. D.
Owner/Management

05 APR 11 10:05

RECEIVED
REGION 1

136765
NMSS/RGNI MATERIALS-002

**Mark Jeffrey Krell, M.D.
33 Overlook Road, Suite L-06
Summit, NJ 07901
908-508-1234**

U.S.N.R.C. Materials Application
Supplementary Information
March 19, 2005

Items #7 through 11 - Materials and Purpose

<u>By Product</u>	<u>Material</u>	<u>Amount</u>	<u>Purpose</u>
	Materials in 35.200	As needed	Cardiovascular Clinical Procedures

Purpose for which Licensed material will be used: Cardiovascular Clinical Procedures 35.200 only. Mo/Tc generators will not be used at this facility.

Item #7 **Radiation Safety Officer:**

Please list Mark Jeffrey Krell, M.D. as the Radiation Safety Officer and Authorized User (35.200, Cardiovascular Clinical Procedures).
Delegation of Authority attached.
Previously named as Authorized user and Radiation Safety Officer on Cardiac Testing Centers NRC license # 29-20960-01

The individual named is competent to independently function as authorized users for 10 CFR 35.200.

Item #9 **Facility Diagram:** Attached

Radiation Monitoring Instruments: Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.

Item #10 **Occupational dose:** 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.

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908-508-1234**

Area Surveys: We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CRR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 20.35.70

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 20.301.

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 20.1101

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 10 CFR 35.92. Those materials not returned to the central radiopharmacy shall be disposed of via decay-in-storage (DIS) .

LIST OF EQUIPMENT

HOT LAB :

1. (1) Dose Calibrator
2. (1) Detection Survey Meter
3. (1) Measurement Survey Meter
3. (2) Pro Tec II Syringe Shields #007-800 3cc and #007-900 5cc
4. (1) Mini table shield double lead glass #042-316
5. (1) Lead Lined Waste Container (20 qts) #039-100
6. (1) Ludlum Nal Well Wipe Test Counter #075-578
7. (1) Lead Shielded Syringe Holder #009-220
8. (2) Lead Lined Syringe Storage Containers #050-200

IMAGING ROOM :

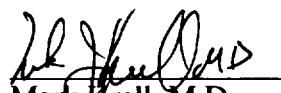
1. (1)G. E. Myosite Gamma Camera

**Mark Jeffrey Krell, M.D.
1 Springfield Avenue
Summit , NJ 07901
908-508-1234**

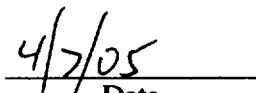
**Memo To: All Employees
From: Mark Jeffrey Krell, M.D.
Management
Subject: Delegation of Authority**

Mark Krell, 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; identifying radiation safety problems; initiating, recommending , or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

Adequate funding is authorized for all expenditures related to recommendations made by the Radiation Safety Officer in order to facilitate the objectives of the radiation safety program and related regulatory requirements.



Mark Krell, M.D.
Management/RSO



Date

<p>NRC FORM 313 U. S. NUCLEAR REGULATORY COMMISSION (8-1989) 10 CFR 30, 32, 33 34, 35, 36, 39 and 40</p> <p style="text-align: center;">APPLICATION FOR MATERIAL LICENSE</p>		<p>APPROVED BY OMB: NO. 3198-0128 EXPIRES: 10/31/2005</p> <p>Estimated burden per response to comply with this mandatory information collection request: 7.4 hours. Submission 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-4 E9), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to hq1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOS-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a response used to impose an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.</p>			
<p>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.</p>					
<p>APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</p> <p>DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U. S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001</p> <p>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:</p> <p>IF YOU ARE LOCATED IN:</p> <p>CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:</p> <p>LICENSING ASSISTANT SECTION NUCLEAR MATERIALS SAFETY BRANCH U. S. NUCLEAR REGULATORY COMMISSION, REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415</p> <p>ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:</p> <p>SAM MURNI ATLANTA FEDERAL CENTER U. S. NUCLEAR REGULATORY COMMISSION, REGION II 61 FORSYTH STREET, S.W., SUITE 23185 ATLANTA, GEORGIA 30303-8831</p>		<p>IF YOU ARE LOCATED IN:</p> <p>ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:</p> <p>MATERIALS LICENSING SECTION U. S. NUCLEAR REGULATORY COMMISSION, REGION III 801 WARRENVILLE RD. LISLE, IL 60532-4351</p> <p>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:</p> <p>NUCLEAR MATERIALS LICENSING SECTION U. S. NUCLEAR REGULATORY COMMISSION, REGION IV 611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TX 76011-8084</p> <p style="text-align: right;">LL 31036 03036914 02201 (29-31036-01)</p>			
<p>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>					
<p>1 THIS IS AN APPLICATION FOR (Check appropriate item)</p> <p><input checked="" type="checkbox"/> A NEW LICENSE <input type="checkbox"/> B AMENDMENT TO LICENSE NUMBER _____ <input type="checkbox"/> C RENEWAL OF LICENSE NUMBER _____</p>		<p>2 NAME AND MAILING ADDRESS OF APPLICANT (include Zip code)</p> <p>Mark J. Krell MD 33 Overlook Road Suite L-06 Summit NJ 07901</p>			
<p>3 ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p> <p>Mark J. Krell M.D. 1 Springfield Avenue STE 2A Summit NJ 07901</p>		<p>4 NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION (include title)</p> <p>Elaine Rovazzi, MS, DABR CONSULTING PHYSICIST</p> <p>TELEPHONE NUMBER 973-322-5118</p>			
<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>					
<p>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.</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. LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY <u>7C</u> AMOUNT ENCLOSED \$ <u>1900.00</u></p>			
<p>13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.</p> <p>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.</p> <p>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.</p>					
<p>CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE</p> <p>MARK J. KRELL, MD</p>		<p>SIGNATURE</p> <p><i>Mark J. Krell MD</i></p>			
		<p>DATE</p> <p>4/7/05</p>			
<p>FOR NRC USE ONLY</p>					
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
APPROVED BY			\$	DATE	

Effective 4-18-05

until 4-15-05

SUMMIT CARDIOLOGY, LLC

Specialists in Cardiovascular Disease and Invasive Cardiology

Mark J. Krell, MD, FACC

American Board of Internal Medicine
American Board of Internal Medicine, Cardiovascular Disease
American Board of Internal Medicine, Interventional Cardiology
Fellow, American College of Cardiology
Diplomat, Certification Council of Nuclear Cardiology

Angela T. Moccia, MSN, APN

Acute Care Nurse Practitioner
Adult Health Nurse Practitioner
Critical Care Registered Nurse

Laurie A. Dacunzo, MSN, APN

Acute Care Nurse Practitioner

The renovations on our new office are complete.

Effective Monday, April 18, 2005

our new address is

One Springfield Ave.

2nd floor

Summit, NJ 07901

Phone (908) 273-1999

Fax (908) 273-1332

Our new state of the art facility will offer:

Exercise Stress Testing
Nuclear Stress Testing
Pharmacologic Stress Testing
Echocardiography
Carotid Ultrasound
Lower Extremity Ultrasound
Holter Monitoring
Arrhythmia Detection

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.2 (continued)

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	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. _____)	___ curies 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.

Table C.2 (continued)

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Depleted uranium	Metal	___ kilograms	Shielding in a linear accelerator.
	Any radionuclide in excess of 30 millicuries for use in calibration, transmission, and reference sources. (List radionuclide: _____)	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	For use in a Manufacturer _____ Model No. _____ for calibration and checking of licensee's survey instruments.
	Americium-241	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries per source and ___ millicuries total	Use as an anatomical marker.
	Plutonium (principal radionuclide Pu-238)	Sealed sources	___ millicuries per source and ___ grams total	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.
	Other	Form or Manufacturer/ Model No.	___ millicuries	Purpose of use _____

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>Mark J. Krell M.D.</u> Previously named as RSO on Cardiac Testing Center's NRC License #29-20960-01	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.	<input checked="" 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.	<input checked="" 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>Mark J. Krell MD</u></p> <hr/> <p>Previously named on Cardiac Testing Center's License #29-20960-01 as an authorized user.</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><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p>
<p>Item 7: Authorized Nuclear Pharmacists</p> <p>Names: <u>N/A</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><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
<p>Item 7: Authorized Medical Physicists</p> <p>Names: <u> N/A </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 as an AMP for the units requested.</p> <p style="text-align: center;">OR</p> <p>Copy of the certification(s) for the board(s) recognized by NRC in 10 CFR 35.51(a) or 10 CFR 35.961(a) or (b).</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.961(c) for the units requested.</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.51(b) for the units requested.</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor AMP, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AMP 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><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>
<p>Item 9: Facility Diagram</p>	<p>A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. The following information is included:</p> <ul style="list-style-type: none"> • 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, as provided above under the heading "Discussion"; • Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is 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, etc.). <p>In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.</p>	<p><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

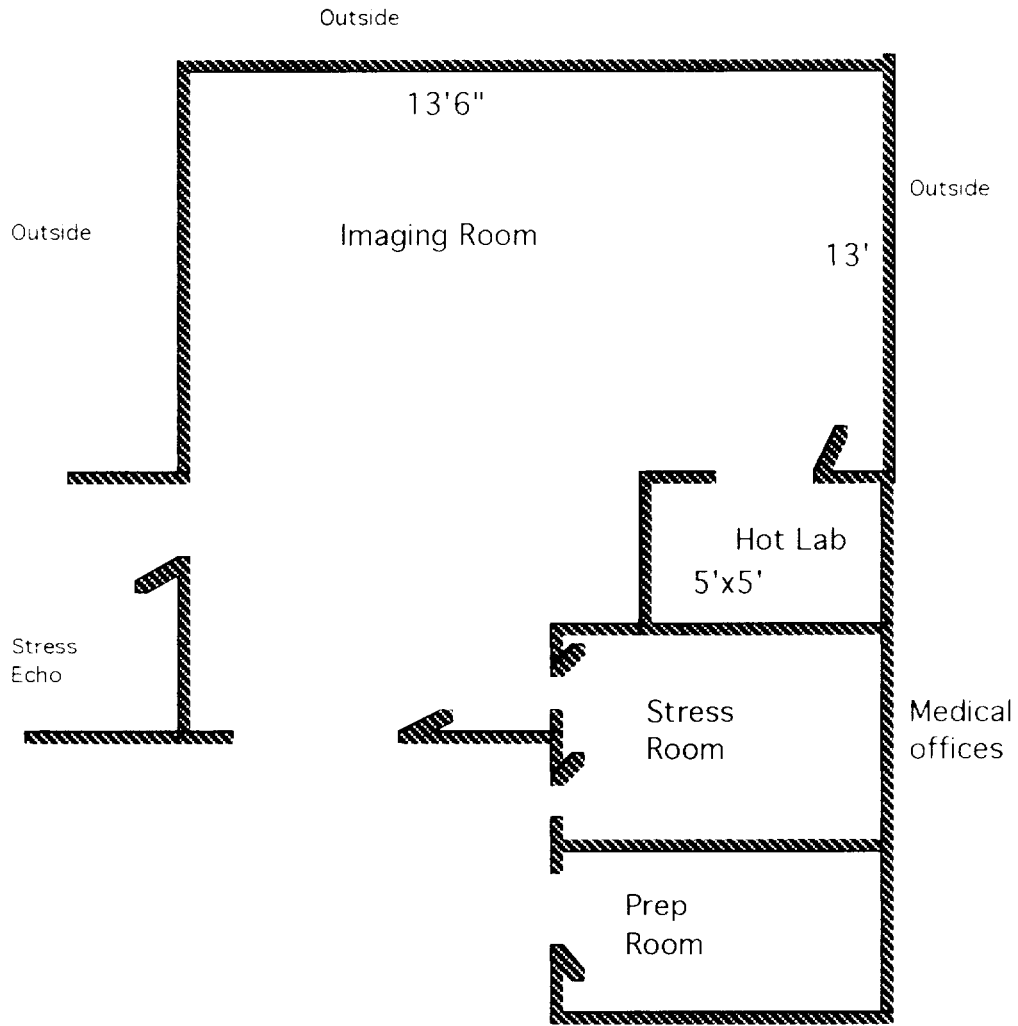
Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
<p>Item 9: Radiation Monitoring Instruments</p> <p><i>Geiger Mueller Range 1-1000 mR/hr Ludlum 2200 NaI Well Counter sensitivity 22dpm/cm²</i></p>	<p>A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."</p> <p style="text-align: center;">AND/OR</p> <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."</p> <p style="text-align: center;">AND</p> <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.</p> <p style="text-align: center;">AND</p> <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."</p>	<p><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p>
<p>Item 9: Dose Calibrator and Other Dosage Measuring Equipment</p>	<p>A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."</p>	<p><input checked="" type="checkbox"/></p>
<p>Item 9: Therapy Unit - Calibration and Use</p>	<p>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.</p>	<p><input type="checkbox"/></p>
<p>Item 9: Other Equipment and Facilities</p>	<p>Attached is a description identified as Attachment 9.4, of additional facilities and equipment.</p> <p>For manual brachytherapy facilities, we are providing a description of the emergency response equipment.</p> <p>For teletherapy, GSR, and remote afterloader facilities, we are providing a description of the following:</p> <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. 	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>
<p>Item 10. Safety Procedures and Instructions</p>	<p>Attached procedures required by 10 CFR 35.610</p>	<p><input type="checkbox"/></p>

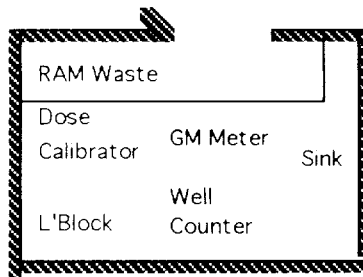
Table C.3 (continued)

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>	<input checked="" type="checkbox"/> <input 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 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 <i>N/A</i>	<p>Name of the proposed employee and types of activities requested:</p> <hr/> <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>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Item 10: Minimization of Contamination <i>N/A</i>	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"/>

Mark Jeffrey Krell, M.D.
1 Springfield Avenue
Summit, NJ
(908) 508-1234



Enlarged view of Hot Lab 5'x5'



Curriculum Vitae

Mark Jeffrey Krell, MD

HOME:



OFFICE:

33 Overlook Road, Suite L-06
Summit, NJ 07901
(908) 508-1234 phone
(908) 508-1237 fax

EDUCATION:

1975 – 1979 M.D. Degree, New York University School of Medicine, NY, NY
1974 – 1975 Ph.D Program, City University of New York, NY, NY
1970 – 1974 Bachelor of Science, Brooklyn College, City University of New York, Brooklyn, NY
Major: Chemistry
1967 – 1970 Stuyvesant High School, NY, NY

EXPERIENCE:

2003 – Present Private Practice: **Cardiology:** Summit Cardiology, LLC
33 Overlook Rd. Suite L-06, Summit, NJ 07901
2000 – 2003 Private Practice: **Cardiology:** Morris County Cardiology
Consultants, 33 Overlook Road, Summit, NJ 07901
1985 – 2000 Private Practice: **Cardiology:** Cardiology Diagnostic Associates,
29 South Street, New Providence, NJ 07974
1982 – 1985 Fellow, **Cardiology**, University of Michigan, Ann Arbor, MI
1980 – 1982 Resident, **Internal Medicine**, University of Michigan, Ann Arbor,
MI
1979 – 1980 Intern, **Internal Medicine**, University of Michigan, Ann Arbor,
MI

**PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.**

re: Mark Jeffrey Krell

1974 – 1975 Instructor and Research Associate, Chemistry Division,
Department of Arts and Sciences, Brooklyn College, CUNY,
Brooklyn, NY

AWARDS:

Dean's Honor List for three years while at Brooklyn College

Graduated Cum Laude from Brooklyn College

House Staff Teaching Award; June 2001, Selected by the **Family Practice Residents** for Outstanding Contribution to Medical Education

House Staff Teaching Award; June 2002, Selected by the **Internal Medicine Residents** for Outstanding Contribution to Medical Education

SCHOLARSHIP:

1970 – 1974 Regents Scholar, State of New York

LECTURES:

1982 – 1983 Hurley Hospital, Flint, Michigan

CERTIFICATION:

Dec 2003 American Board Certification – Interventional Cardiology (Board Certified)

April 1991 American Society of Cardiovascular Interventionists

Sept. 1991 Society of Nuclear Medicine

Sept. 1986 American Board Certification – Cardiovascular Disease (Board certified)

July 1985 License to practice Medicine, State of New Jersey

re: Mark Jeffrey Krell

June 1984	American Board Certification – Cardiology (Board eligible)
Sept. 1982	American Board Certification – Internal Medicine (Board Certified)
July 1980	License to practice Medicine, State of Michigan
July 1980	Federal Narcotics License

AFFILIATION:

1985 – Present	Overlook Hospital, Summit NJ
1990 – Present	Morristown Memorial Hospital, Morristown NJ
1985 – 1989	Newark Beth Israel Medical Center, Newark NJ
1980 – 1985	Mercy-Memorial Hospital, Monroe, MI
1983 – 1985	Bayer Memorial Hospital, Ypsilanti, MI
1982 – 1983	Wayne County General Hospital, Wayne, MI

MEMBERSHIPS:

American College of Physicians
American College of Cardiology
American College of Chest Physicians
Society of Nuclear Medicine
Society of Nuclear Cardiology
American Society of Cardiovascular Interventionists

PUBLICATIONS:

Gram Negative Bacillary Meningitis – M. Krell, J. Sheagren
American College Of Physicians – presented 10/82

Assessment of Percutaneous Transluminal Coronary Angioplasty with Quantitative Stress Thallium Tomography – L. Bean, M. Krell, J. Juni, W. O'Neill, V. Legrand, J. McMeekin, R. Ackerman, M. Gross, A. Buda, B. Pitt
American Heart Association – presented 11/84

Re: Mark Jeffrey Krell

Phenylephrine and A-V Sequential Pacing in the Induction of Ischemia – M. Krell,
W. O'Neill, J. Walton, N. Laufer, B. Pitt
American College of Cardiology – submitted 9/84

Weekly Outpatient Dobutamine Infusions for Chronic Congestive Heart Failure
J. Hodgson, M. Krell, E. Bates, N. Laufer, W. O'Neill, B. Pitt
American College of Cardiology – submitted 9/84

Tomographic Thallium Assessment of the Functional Significance of Coronary Stenoses - M. Krell, A. Fung, R. Ackerman, J. Botti, B. Pitt, A. Buda, J. Juni, W. O'Neill
American College of Cardiology – submitted 9/84

RESEARCH PROJECTS:

Weekly Outpatient Infusions of Dobutamine in Severe Chronic Congestive Heart Failure:
7/83 – present

Evaluation of PTCA with Quantitative Stress Tomographic Thallium
11/83 – 5/84

Evaluation of Acute Thrombolytic therapy
11/83 – present

Phenylephrine an AV Sequential in the Induction of Ischemia
7/83 – 5/84

Bicycle Exercise vs. Atrial Pacing vs. Phenylephrine and AV Sequential Pacing in the
Induction of Ischemia During Cardiac Catherterization
5/84 – present

Captopril vs. Digoxin vs. Placebo in the Treatment of Mild Congestive Heart Failure
7/83 – present

Experimental Oral Inotropes vs. Placebo in the Treatment of Moderate Congestive Heart
Failure
5/84 – present

PERSONAL:

[REDACTED]

References available upon request.
June 2004

Mark Jeffrey Krell 9/13/04

PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.

CERTIFICATION COUNCIL OF NUCLEAR CARDIOLOGY

Incorporated 1996

CERTIFIES THAT

Mark J. Krell, MD

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS COUNCIL
AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,

IS HEREBY DESIGNATED

A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

NUCLEAR CARDIOLOGY

FOR THE PERIOD 1998 THROUGH 2008

A. Skandran

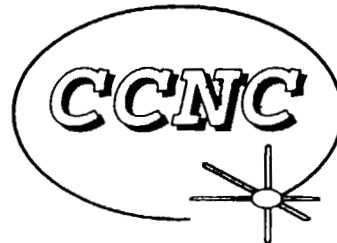
PRESIDENT

C. Gerry DeLong, MD

SECRETARY



CERTIFICATE # 1053



OCTOBER 25, 1998

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

4/7/2005, and to inform you that the initial processing which includes an administrative review has been performed.

New License Application (03036914)
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** 136765.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

: Program Code: 02201
: Status Code: 3
: Fee Category: _____
: Exp. Date: 0
: Fee Comments: _____
: Decom Fin Assur Req'd: _
:.....

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: KRELL, MARK J., M.D.
Received Date: 20050411
Docket No: 3036914
Control No.: 136765
License No.: 29-31036-01
Action Type: New Licensee

2. FEE ATTACHED

Amount: 1900.00
Check No.: 1567

3. COMMENTS

Signed Rebecca J. Ford
Date 7/11/2005

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 _____