

**♥ The ALARA Group**  
**Accreditation, Licensing, and Radiological Associates**  
**Specialists in Cardiovascular Laboratory Accreditation**

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Br. 2

November 28, 2006

Licensing Assistance Team  
Division Of Nuclear Materials Safety  
U.S. Nuclear Regulatory Commission, Region I  
475 Allendale Road  
King Of Prussia, Pa 19406-1415

03037319

Re: Request for an Amendment to Radioactive Materials License #37-31179-01

To Whom It May Concern:

Enclosed please find an original and one copy of a request for an amendment to radioactive materials license #37-31179-01.

We would like to add P. Todd Makler, Jr, MD, as an Authorized User for the uses described herein. An application to amend the PA license accordingly has been forwarded to the PA DEP. Dr. Makler is presently an AU for 35.100, 35.200 and 35.300 on NRC Materials License #37-00467-36. He is also certified by the American Board of Nuclear Medicine (1976, attached).

The person to be contacted regarding this application is Jeffrey Mandler, President, Cardiovascular Solutions. He can be reached at (610) 296-1176. Please inform Mr. Mandler of the amendment fee and it will be forwarded without delay. Thank you for evaluating this amendment request. Your usual timely attention to these matters is always appreciated.

Cordially,



Kevin F. Smith, MPH, PhD  
Document Preparer  
Senior Specialist, The ALARA Group  
Consultant Radiation Health Physicist, Cardiovascular Solutions, Inc.

Cc: Jeffrey Mandler, President, Cardiovascular Solutions  
File

Enclosures

139778  
NMSS/RGNI MATERIALS-002

<p><b>NRC FORM 313</b> #10-2005) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40</p> <p style="text-align: center;"><b>U.S. NUCLEAR REGULATORY COMMISSION</b></p> <p style="text-align: center; font-size: 1.2em;"><b>APPLICATION FOR MATERIAL LICENSE</b></p>	<p><b>APPROVED BY OMB: NO. 3150-0120</b> Estimated burden per response to comply with this mandatory collection request: 4.4 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 <a href="mailto:infocollects@nrc.gov">infocollects@nrc.gov</a>, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10292, (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.</p> <p style="text-align: right;"><b>EXPIRES: 10/31/2008</b></p>
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**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><b>APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</b></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><b>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:</b></p> <p><b>IF YOU ARE LOCATED IN:</b></p> <p>ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, 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:</p> <p>LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415</p>	<p><b>IF YOU ARE LOCATED IN:</b></p> <p>ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:</p> <p>MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352</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 BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 511 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TX 76011-4005</p>
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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><b>1 THIS IS AN APPLICATION FOR (Check appropriate item)</b></p> <p><input type="checkbox"/> A. NEW LICENSE</p> <p><input checked="" type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER <u>37-31179-01</u></p> <p><input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p>	<p><b>2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)</b></p> <p>Riaz Baqir, MD Cardiovascular Solutions Inc. 20 Mystic Lane, Second Floor Malvern, Pa 19365</p>
<p><b>3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</b></p> <p>1015 Chestnut Street Jefferson Building, Suite 1400 Philadelphia, PA, 19107</p>	<p><b>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</b></p> <p>Jeffrey Mandler, Administration</p> <p><b>TELEPHONE NUMBER</b></p> <p>(610) 296-1176</p>

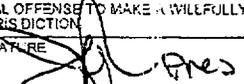
**SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.**

<p><b>5. RADIOACTIVE MATERIAL</b> 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><b>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED</b></p>						
<p><b>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.</b></p>	<p><b>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</b></p>						
<p><b>9. FACILITIES AND EQUIPMENT.</b></p>	<p><b>10. RADIATION SAFETY PROGRAM</b></p>						
<p><b>11. WASTE MANAGEMENT.</b></p>	<p><b>12. LICENSE FEES (See 10 CFR 170 and Section 170.31)</b></p> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="width:70%;">FEE CATEGORY</td> <td style="width:10%;">AMOUNT ENCLOSED</td> <td style="width:20%;">\$</td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> </table>	FEE CATEGORY	AMOUNT ENCLOSED	\$			
FEE CATEGORY	AMOUNT ENCLOSED	\$					

**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.**

<b>CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE</b>	<b>SIGNATURE</b>	<b>DATE</b>
Jeffrey Mandler, President, Cardiovascular Solutions, Inc		11/29/06

FOR NRC USE ONLY					
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
<b>APPROVED BY</b>				<b>DATE</b>	

**ITEM 5: RADIOACTIVE MATERIAL**

<u>Byproduct Material</u>	<u>Chemical/Physical Form</u>	<u>Maximum Amount</u>
Any byproduct material permitted by 10 CFR 35.200	Any	As needed
Licensee will obtain unit doses of Tc-99m.		
Cesium-137 in sealed source will be used.		(<200 uCi, 7.4mBq).
Others (presently regulated by PA DEP):		
Licensee will occasionally obtain unit doses of Tl-201.		As needed
Co-57 in sealed source will be used.		(10mCi/370mBq)

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

10 CFR 35.200 Medical Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive is Not Required.

The applicant will use unit doses of Tc-99m cardiac imaging compounds for planar and SPECT myocardial perfusion imaging both at rest and after exercise/pharmacological stress.

Cesium-137 in sealed source will be used for dose calibrator quality assurance testing

Others:

Licensee will occasionally obtain unit doses of Tl-201 for planar and SPECT myocardial perfusion imaging.

Co-57 in sealed source will be used for gamma camera quality control.

Co-57 in sealed source will be used for dose calibrator quality assurance testing.

**ITEM 7: INDIVIDUAL(S) RESPONSIBLE  
FOR RADIATION SAFETY PROGRAM  
AND THEIR TRAINING AND EXPERIENCE**

**Item 7: Authorized User**

P. Todd Makler, Jr., MD

Dr. Makler is presently listed as an authorized user for 10 CFR 35.200 on NRC license #: 37-00467-36.

*Dr. Todd Makler, Jr.*

*has met the requirements of this Board and is certified as qualified to practice as a specialist in all aspects of clinical and laboratory*

# *Nuclear Medicine*

*including but not limited to Radiobioassay, Nuclear Imaging, in Vivo Measurements & Therapy with unsealed Radionuclides.*

*Joseph J. Cowan MD*



*S. J. Rubin*

03777  
NUMBER

10/27/76  
DATE

J. SHAWEN

007

# The American Board of Nuclear Medicine

Incorporated 1971

A conjoint Board organized with the sponsorship of the American Board of Internal Medicine, American Board of Pathology, American Board of Radiology and the Society of Nuclear Medicine  
hereby certifies that

**Todd Makler, Jr.**

has met the requirements of this Board and is  
certified as qualified to practice as a specialist in  
all aspects of clinical and laboratory

**Nuclear Medicine**

including but not limited to Radiobioassay, Nuclear Imaging,  
in Vivo Measurements & Therapy with unsealed Radionuclides.

Joseph J. Powell



J. J. Powell

Commonwealth of Pennsylvania  
 Department of State  
 Bureau of Professional and Occupational Affairs  
 PO Box 2649, Harrisburg PA 17105-2649

04-445464

License Type: Medical Physician and Surgeon

License Status: Active

Initial License Date: 06/17/1974

Expiration Date: 12/31/2006

License Number: MD035326L

P. TODD MAKLER, JR.  
 [REDACTED]

*Carol L. Mevada*  
 Commissioner of Professional and Occupational Affairs

*[Signature]*  
 Signature

\* DISPLAY THIS CERTIFICATE PROMINENTLY - NOTIFY AGENCY WITHIN 10 DAYS OF ANY CHANGE \*

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