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NRC FORM 313
(10-87)
10 CFR 30, 32, 33, 34,
35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 6-30-90

APPLICATION FOR MATERIAL LICENSE

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.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20545

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:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCLEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2500
ATLANTA, GA 30322

IF YOU ARE LOCATED IN:

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94608

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 JURISDICTION.

<p>1. THIS IS AN APPLICATION FOR (Check appropriate box(es))</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>M. K. Malik, MD 810 Fourth Avenue Ford City, PA 16226 (412) 763-9621</p>
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3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

810 Fourth Avenue
Ford City, PA 16226

<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>Krishnadas Banerjee, Ph.D. - Consulting Physicist</p>	<p>TELEPHONE NUMBER</p> <p>(412) 622-4062</p>
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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</p> <p>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 AND 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)</p> <table border="1"> <tr> <td>FEE CATEGORY</td> <td>7-C</td> <td>AMOUNT ENCLOSED \$</td> <td>580.00</td> </tr> </table>	FEE CATEGORY	7-C	AMOUNT ENCLOSED \$	580.00
FEE CATEGORY	7-C	AMOUNT ENCLOSED \$	580.00		

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

SIGNATURE-CERTIFYING OFFICER	TYPED, PRINTED NAME	TITLE	DATE
<i>x m Krishna</i>	M. K. Malik, MD		7/20/1988

Rec'd 2 AMB 8/11/88

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
APP	Aug. 9 th	7C	"OFFICIAL RECORD COPY" 109323	<i>[Signature]</i>
AMOUNT RECEIVED	CHECK NUMBER			DATE
\$580	187		ML10	8/11/88

9001160127 881029
REG1 LIC30
37-28258-01 PDR

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL RESOURCES
BUREAU OF RADIATION PROTECTION

**APPLICATION FOR RADIOACTIVE MATERIAL LICENSE – MEDICAL
HUMAN USE**

This application form is limited to use by persons desiring a license for human use of radium, radon and accelerator produced radioisotopes.

Licenses for the human use of radium, etc. will be issued to individual physicians and to institutions. Licenses so issued are limited to the individual or institution to whom issued and licensees are subject to the terms and conditions of the license.

This application must be completed in full and signed by the applicant or his authorized representative, and where applicable, by an administrative officer of the institution where the radioactive material is used. Information contained in previous applications filed with the department may be incorporated by reference provided references are clear and specific. Use supplemental sheets where necessary. Mail two copies to: Bureau of Radiation Protection, Pennsylvania Department of Environmental Resources, P. O. Box 2063, Harrisburg, Pennsylvania 17120.

<p>1. Applicant's Name (Hospital & Department or Individual Physician)</p> <p>M. K. Malik, MD</p>	<p>2. <input type="checkbox"/> If this is an application for renewal or amendment, please check box and give the number of the Pennsylvania license being renewed or amended.</p>
<p>3. Mailing Address</p> <p>810 Fourth Avenue Ford City, PA 16226</p> <p style="text-align: center;">Zip Code</p>	<p>4. Area Code and Telephone Number</p> <p>(412) 763-1411</p>
<p>5. Name of individuals using or directly supervising the use of Sources. For each individual, please list PA, MD/DO License number, Specialty Board Eligibility or Certification and dates, and the name of the institution and date where training and experience in the human use of radium, etc., was received. (Physicians in training need not be listed when the supervising physician is named). Submit resume and preceptor statements where applicable.</p> <p>M. K. Malik, MD PA License # 0376986 Internal Medicine December 1983 Enclosed are Supplements A and B which have been submitted to the US NRC.</p>	
<p>6. Name of Radiation Safety Officer (Name one individual. If same as applicant, write "same".)</p> <p>Same</p>	
<p>7. Material will be stored at: (Please specify address if different from above)</p> <p>Same as #3</p>	
<p>8. Material will be used at: (Please specify address if different from above)</p> <p>Same as #3</p>	
<p>9. Is the material subject to transportation by car? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO</p>	
<p>10a. For Institutional License Applicants:</p> <p>Does hospital have a Radiation Safety Committee? <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>Does it review radium use? <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>Has this license application been approved by the committee? <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>Names of Radioisotope Committee Members:</p> <p>Not applicable</p>	<p>10b. For Individual Physician Applicants:</p> <p>Have arrangements been made with a hospital to admit radioactive patients? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>Name of Hospital:</p> <p>Armstrong County Memorial Hospital Is a copy of the instructions furnished to the hospital concerning handling such patients attached? <input type="checkbox"/> YES <input type="checkbox"/> NO</p>

SUBMIT IN DUPLICATE

11. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (IN MILLICURIES)
25 PA Code § 217.46(a) for In Vitro Studies		
25 PA Code § 217, Appendix C, Group I	X	AS NEEDED
25 PA Code § 217, Appendix C, Group II	X	AS NEEDED
RADIUM 226		

12. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 11. (Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Chapter 217.63 (d) NEED NOT BE LISTED.)

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Co-57	Flood Source	20 mCi	Flood source and sealed source for dose calibrator

13. Investigative proposal for experimental or non-routine use is appended. YES NO

14. If material will not be obtained in precalibrated form for oral administration or in precalibrated form for parenteral administration, describe identification, processing, and standardization procedures:

All radionuclides will be obtained in a single dose form from NRC approved radiopharmaceutical companies. The prescribed dose will be checked in the dose calibrator before injecting into the patient.

15. BRACHYTHERAPY

Inventory and Source Control. Please specify the procedures to be followed to insure appropriate sources are selected, properly located and inserted, and properly recovered. Indicate what type of records and logs will be kept. If persons other than the applicant user handle the sources in the course of a treatment, such as source preparation or removal of sources from the patient, identify these persons or their job titles, their activities with the sources, and their training and experience.

Not applicable

Are radon seeds recovered from patients? YES NO
If yes, what is their disposition?

- 16. List radiation detection survey meters by type, (ion chamber, GM counter, Scintillation detector, scanner, camera etc.) manufacturer, model, number available and date of last calibration.

See Appendix A

- 17. Method, frequency, & standards used in calibrating instruments listed above:
 1. The survey instruments will be calibrated annually by an outside, NRC approved vendor.
 2. The scinitllation counter will be checked before use with a Cs-137 standard source.
 3. The gamma camera will be checked daily with either a Tc-99m or Co-57 source.
- 18. Specify personnel monitoring provided persons handling radioactive material (Film badge, dosimeter, or thermoluminescent dosimeter; and name of Supplier). R. S. Landauer Company.
 Film Badge (whole body). TLD (finger badge).
 The badges will be changed monthly.

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS IN DUPLICATE

- 19. Facilities and equipment. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached YES NO
See Appendix B
- 20. Radiation protection program. Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source. See Appendix C
- 21. Waste Disposal. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved. See Appendix D
- 22. Institutional Certification
 (Required when radioactive materials are stored or used in Hospitals)
 The Administrative Office of this Institution approves the proposed use of radioactive material as described in this application.

Date _____ By _____
 Title _____

- 23. Users Certification
 The applicant and any official executing this certificate on behalf of the applicant named in item 1 certify that this application is prepared in conformity with Title 25, Rules and Regulations, Article V, Radiological Health and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

M. K. Malik, MD

Applicant named in item 1

Date _____ By: *M. K. Malik*
 Title of certifying official _____

LICENSE FEE REQUIRED
 (See Chapter 218 of 25 PA Code)

(1) LICENSE FEE CATEGORY: _____

(2) LICENSE FEE ENCLOSED: \$ _____

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES
AT MEDICAL INSTITUTIONS ALARA

(Licensee's Name)

(Date)

1. Management Commitment

- a. We, the management of this (medical facility, hospital, etc.), are committed to the program described in this paper for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC)¹ and a Radiation Safety Officer (RSO).
- b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.
- c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.
- d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee (RSC)²

a. Review of Proposed Users and Uses

- (1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
- (2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.
- (3) The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

- (1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.
- (2) The RSC will support the RSO in those instances where it is necessary for the RSO to assert his/her authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

¹ Private practice physician licenses do not include an RSC.

² The RSO on private practice physician licenses will assume the responsibilities of the RSC under Section 2.

c. Review of ALARA Program

- (1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- (2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table O-1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see Section 6).³
- (3) The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

- (1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.
- (2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of Section 6 of this program.
- (3) Quarterly review of records of radiation level surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for ALARA Program

- (1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

- (2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

- (1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
- (2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

4. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

- (1) The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.
- (2) The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of Authorized User to Persons Under His/Her Supervision

- (1) The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all persons under his/her supervision.
- (2) The authorized user will ensure that persons under his/her supervision who are

³The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify further investigations.

subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. **Persons Who Receive Occupational Radiation Exposure**

- a. The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions.
- b. The worker will know what recourses are available if he/she feels that ALARA is not being promoted on the job.

6. **Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures**

This institution (not private practice) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The Investigational Levels that we have adopted are listed in Table O-1 below. These levels apply to the exposure of individual workers.

Table O-1

	Investigational Levels (mrems per calendar quarter)	
	Level I	Level II
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

* Not normally applicable to nuclear medicine operations except those using significant quantities of beta-emitting isotopes.

The Radiation Safety Officer will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring not less than once in any calendar quarter as required by § 20.401 of 10 CFR Part 20. The following actions will be taken at the Investigational Levels as stated in Table O-1:

- a. Quarterly exposure of individuals to less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table O-1 values for the Investigational Level I.

- b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

- c. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

- d. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table O-1.

In cases where a worker's or a group of workers' exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The RSC will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds

the newly established Investigational Level II, those actions listed in paragraph 6.c above will be followed.

7. Signature of Certifying Official⁴

I hereby certify that this institution (or private practice) has implemented the ALARA Program set forth above.

⁴The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator) or, in the case of a private practice, the licensed physician.

Signature

M. Khalid Malik

Name (print or type)

M. KHALID MALIK

Title

MD

Institution (or Private Practice) Name and Address:

810 4th AVE
FORD CITY, PA 16226

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

<p>1. APPLICANT PHYSICIAN'S NAME AND ADDRESS</p> <p>FULL NAME M. Khalid Malik, M.D.</p> <p>STREET ADDRESS 810 Fourth Ave.</p> <p>CITY STATE ZIP CODE Ford City PA 16226</p>	<p>KEY TO COLUMN C</p> <p>PERSONAL PARTICIPATION SHOULD CONSIST OF:</p> <p>1-Supervised examination of patients to determine the suitability for radioactive diagnosis and/or treatment and recommendation for prescribed dosage.</p> <p>2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.</p> <p>3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.</p>
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2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D														
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		Name and total number of procedures is given below														
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME																
	LIVER FUNCTION STUDIES																
	FAT ABSORPTION STUDIES																
	KIDNEY FUNCTION STUDIES																
IN VITRO STUDIES																	
OTHER																	
I-125	DETECTION OF THROMBOSIS																
I-131	THYROID IMAGING																
P-32	EYE TUMOR LOCALIZATION																
Co-75	PANCREAS IMAGING																
Yb-169	CISTERNOGRAPHY																
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES																
OTHER																	
Tc-99m	BRAIN IMAGING		<table style="width: 100%; border: none;"> <tr> <td style="width: 80%;"></td> <td style="text-align: right;">Number</td> </tr> <tr> <td>Rest Tc Myocardial Imaging</td> <td style="text-align: right;">45</td> </tr> <tr> <td>Ventriculography</td> <td></td> </tr> <tr> <td>Exercise Tc Ventriculography</td> <td style="text-align: right;">45</td> </tr> <tr> <td>First Pass Radionuclide Angiography</td> <td style="text-align: right;">15</td> </tr> <tr> <td>Tc Infarct Imaging</td> <td style="text-align: right;">15</td> </tr> <tr> <td>Shunt Evaluation Studies</td> <td style="text-align: right;">15</td> </tr> </table>		Number	Rest Tc Myocardial Imaging	45	Ventriculography		Exercise Tc Ventriculography	45	First Pass Radionuclide Angiography	15	Tc Infarct Imaging	15	Shunt Evaluation Studies	15
		Number															
	Rest Tc Myocardial Imaging	45															
	Ventriculography																
	Exercise Tc Ventriculography	45															
	First Pass Radionuclide Angiography	15															
	Tc Infarct Imaging	15															
	Shunt Evaluation Studies	15															
CARDIAC IMAGING	135																
THYROID IMAGING																	
SALIVARY GLAND IMAGING																	
BLOOD POOL IMAGING																	
PLACENTA LOCALIZATION																	
LIVER AND SPLEEN IMAGING																	
LUNG IMAGING																	
BONE IMAGING																	
OTHER																	

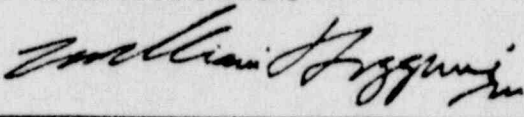
PRECEPTOR STATEMENT (Continued)

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D										
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES												
P-32 (Colloidal)	INTRACAVITARY TREATMENT												
I-131	TREATMENT OF THYROID CARCINOMA												
	TREATMENT OF HYPERTHYROIDISM												
Au-198	INTRACAVITARY TREATMENT												
Co-60 or Co-137	INTERSTITIAL TREATMENT												
	INTRACAVITARY TREATMENT												
I-125 or Ir-192	INTERSTITIAL TREATMENT												
	TELE THERAPY TREATMENT												
Sr-90	TREATMENT OF EYE DISEASE												
	RADIOPHARMACEUTICAL PREPARATION												
Mo-99/ Tc-99m	GENERATOR	5											
Sr-113/ In-113m	GENERATOR												
Tc-99m	REAGENT KITS	5											
Other	Thallium Chloride Human Use	130		<table border="0"> <tr> <td></td> <td align="right">Number</td> </tr> <tr> <td>Rest Thallium Scintigraphy</td> <td align="right">65</td> </tr> <tr> <td>Exercise Thallium Scintigraphy</td> <td align="right">65</td> </tr> <tr> <td>Total Procedures</td> <td align="right">265</td> </tr> <tr> <td>Number of Hours (2x265)</td> <td align="right">530</td> </tr> </table>		Number	Rest Thallium Scintigraphy	65	Exercise Thallium Scintigraphy	65	Total Procedures	265	Number of Hours (2x265)
	Number												
Rest Thallium Scintigraphy	65												
Exercise Thallium Scintigraphy	65												
Total Procedures	265												
Number of Hours (2x265)	530												

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

Fellowship from July 1, 1986 to June 30, 1987. Seven months in Nuclear Cardiology. Total procedures performed under supervision were 265. Actual hours of training were 530 hours. Each procedure = 2 hours approx.

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:	6. PRECEPTOR'S SIGNATURE 
a. NAME OF SUPERVISOR Kim A. Cockins, M.D. Orlando Gabriel, M.D.	
b. NAME OF INSTITUTION West Virginia University	7. PRECEPTOR'S NAME (Please type or print) William Higgins, M.D.
c. MAILING ADDRESS Medical Center	
d. CITY Morgantown, W.V. 26506	8. DATE July 1, 1988
5. MATERIALS LICENSE NUMBER(S) 47-23066-02	



Section of Cardiology

West Virginia University

School of Medicine

Abnash C. Jain, M.D., Chief
L.P. Maxwell, M.D.
Anthony P. Morise, M.D.
Francis H. Oliver, M.D.
Stanley B. Schmidt, M.D.
Mark A. Borsch, M.D.
Kim A. Cockins, M.D.

July 1, 1988

This is to certify that M. Khalid Malik, M.D., served as a fellow in cardiology at West Virginia University Hospital from July 1986 thru June 1987. He performed the following procedures under my supervision in our exercise physiology laboratory and nuclear cardiology laboratory. The procedures include assessment of patients for various tests; receiving, identification, and administration of radiopharmaceuticals, performing with interpretation of the scintigraphic scans, and follow up of the patients.

Name of Procedure	Number of Procedures
Rest Thallium Scintigraphy	65
Exercise Thallium Scintigraphy	65
Rest Radionuclide Myocardial Imaging Ventriculography	45
Exercise Radionuclide Ventriculography (MUGA)	45
First Pass Radionuclide Angiocardiography	15
Radionuclide Shunt Evaluation	15
Technetium Pyrophosphate Infarct Imaging	15
Total Number of Procedures	265

Each procedure involves approximately two hours of time consisting of; evaluation, interviewing the patient, injection, imaging, follow up, and reports.

Kim A. Cockins
Kim A. Cockins, M.D.

Director Exercise Physiology Lab
Director Nuclear Cardiology Lab

TRAINING OF
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

M. KHALID MALIK, MD

ADDRESS

810 4th Ave.
Ford City, Pa. 16226

2. STATE OR TERRITORY IN
WHICH LICENSED TO
PRACTICE MEDICINE

PA

3. CERTIFICATION

SPECIALTY BOARD
A

Internal Medicine

CATEGORY
B

Internal Medicine

MONTH AND YEAR CERTIFIED
C

December 1983

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING			
		LECTURE LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D	Total Hours of Subject	
a. RADIATION PHYSICS AND INSTRUMENTATION	The description of these programs is on file with the NRC and Agreement States. The dates of the programs are given on the Certificates of completion.			Principles of Radiation	
b. RADIATION PROTECTION				Medical Radiation Instrumentation	
c. MATHEMATICS PERTAINING TO THE USE AND MANAGEMENT OF RADIOACTIVITY				Medical Radiation Protection	
d. RADIATION BIOLOGY				Radiopharmaceuticals and Chemistry	
e. RADIOPHARMACEUTICAL CHEMISTRY					
					Total Hours (Actual Hours May Exceed This Number) 200

5. EXPERIENCE WITH RADIATION (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
SEE THE ATTACHED DOCUMENTATION				

6. TRAINING WAS COMPLETED UNDER THE DIRECT SUPERVISION OF:

NAME Institute For Nuclear Medical Education, Attention: C.H. Rose

ADDRESS 3011 Broadway

CITY: Boulder STATE CO ZIP 80302

TELEPHONE 303-444-1943

Authorized Signature

Charles H. Rose, MA, MSPH, D(ABSNM) Program Director

NUCLEAR MEDICAL EDUCATION PROGRAM
AFFIDAVIT OF ACADEMIC COMPLETION

This document is to attest that

M. KHALID MALIK, MD

has successfully completed the didactic program

THE PRINCIPLES OF RADIATION PHYSICS

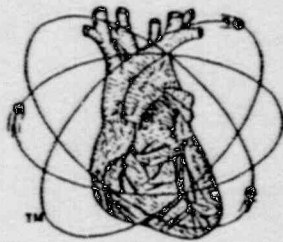
and has provided evidence of achieving the objectives of this program

The program provides the following levels of accomplishment

50 didactic instructional hours (DIH)

5 continuing education units (CEU)

50 continuing medical education units (CME)




Authorized signature

681804

Affidavit

INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

~~9~~ FEBRUARY 1988
Date Commenced



NUCLEAR MEDICAL EDUCATION PROGRAM
AFFIDAVIT OF ACADEMIC COMPLETION

This document is to attest that

M. KHALID MALIK, MD

has successfully completed the didactic program

RADIOPHARMACEUTICALS

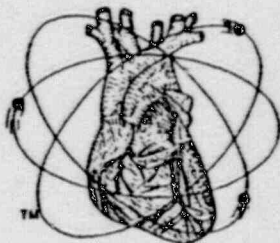
and has provided evidence of achieving the objectives of this program

The program provides the following levels of accomplishment

50 didactic instructional hours (DIH)

5 continuing education units (CEU)

50 continuing medical education units (CME)




Authorized signature

601901
Affidavit

21 MARCH 1988



INSTITUTE FOR NUCLEAR MEDICAL EDUCATION

NUCLEAR MEDICAL EDUCATION PROGRAM
AFFIDAVIT OF ACADEMIC COMPLETION

This document is to attest that

M. KHALID MALIK, MD

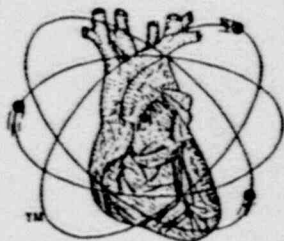
has successfully completed the didactic program

MEDICAL RADIATION PROTECTION

and has provided evidence of achieving the objectives of this program

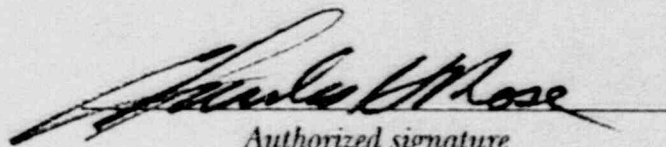
The program provides the following levels of accomplishment

- 50 didactic instructional hours (DIH)
- 5 continuing education units (CEU)
- 50 continuing medical education units (CME)



17 MARCH 1988

Date Commenced



Authorized signature

001232

Affidavit

INSTITUTE FOR NUCLEAR MEDICAL EDUCATION



NUCLEAR MEDICAL EDUCATION PROGRAM
AFFIDAVIT OF ACADEMIC COMPLETION

This document is to attest that

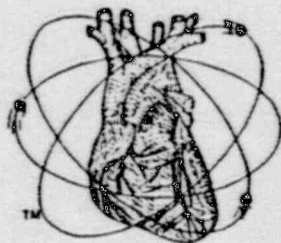
M. KHALID MALIK, MD
has successfully completed the didactic program

MEDICAL RADIATION INSTRUMENTATION

and has provided evidence of achieving the objectives of this program

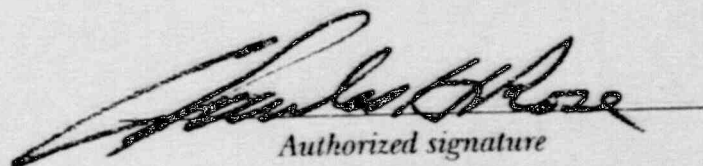
The program provides the following levels of accomplishment

50 *didactic instructional hours (DIH)*
5 *continuing education units (CEU)*
50 *continuing medical education units (CME)*



13 FEBRUARY 1988

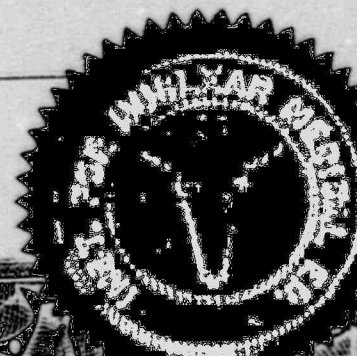
Date Commenced


Authorized signature

631203

Affidavit

INSTITUTE FOR NUCLEAR MEDICAL EDUCATION



ARMSTRONG COUNTY MEMORIAL HOSPITAL
KITTANNING, PA 16201-8808

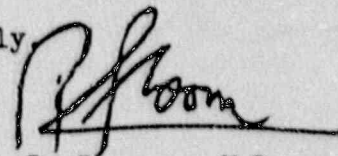
July 26, 1988

U.S. Nuclear Regulatory Commission, Region 1
Nuclear Materials Safety Section B
475 Allendale Road
King of Prussia, PA 19406

To Whom It May Concern:

This is to certify that M. Khalid Malik, M.D. is an active member of the medical staff at Armstrong County Memorial Hospital. He has full admitting privileges including patients who have received radioactive pharmaceuticals.

Sincerely



Roderick B. Groomes, M.D.
Chairman Dept. of Medicine

APPENDIX A

Victoreen GM counter, Model #490, number available one (1)

Ludlum Scintillation Counter, Model #2200, number available one (1)

Gamma Camera, Manufacturer-GE, number available one (1)

APPENDIX C

#20. We will follow the NRC's ALARA principle

The radiation protection program will be covered by Krishnadas Banerjee, Ph.D., radiation safety officer of St. Francis Medical Center. He will do the initial survey and will perform the leak tests of the sealed sources. For Doctor Banerjee's training and experience refer to PA License #76.

APPENDIX D

- #21. Radioactive wastes will be taken back by the radiopharmacy. Cotton balls or bandaids containing trace amounts of radiopharmaceuticals will be stored in the waste can (see diagram) for at least 10 half lives before disposing of it through normal trash. The waste material will be monitored to see that the radiation level is equal to background before disposing of it through normal trash.

APPENDIX J
WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with § 20.303 of 10 CFR Part 20.

1. Liquid waste will be disposed of (check as appropriate)

In the sanitary sewer system in accordance with § 20.303 of 10 CFR Part 20.

By commercial waste disposal service (see also Item 4 below).

Other (specify): _____

2. Mo-99/Tc-99m generators will be (check as appropriate)

Returned to the manufacturer for disposal.

Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.**

* Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).

** These generators may contain long-lived radiotoxic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

Disposed of by commercial waste disposal service (see also Item 4 below).

Other (specify): _____

*** 3. Other solid waste will be (check as appropriate)**

Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

Disposed of by commercial waste disposal service (see also Item 4 below).

Other (specify): _____

4. The commercial waste disposal service used will be

(Name) (City, State)

NRC/Agreement State License No. _____

*Item #5 and 6. Radioactive Material

	By-Product Material	Amount	Purpose
5.a	Material in 35.100	As needed	6.a Medical use
5.b	Material in 35.200	As needed	6.b Medical use

Item #7 - Individual Responsible for Radiation Safety Programs and Their Training and Experience.

7.1 Authorized user for medical use - M. K. Malik, MD
Enclosed you will find completed preceptor forms A and B, along with certificates from the Institute for Nuclear Medical Education, Nuclear Medical Education Program.

7.3 Radiation Safety Officer - M. K. Malik, MD

Item #8 - Training for Individuals Working in or Frequenting Restricted Areas.

We will establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8, Revision 2.

The nuclear medicine technician will be trained once a year, or whenever a new procedure is to be performed, or when there are new rules and regulations from the NRC or the state.

No other person in the department will be allowed to enter the nuclear medicine section, and therefore, there will be no need to train any other person.

Item #9 - Facilities and Equipment

9.1 Enclosed you will find an annotated drawing of the nuclear medicine department.

9.2 The survey meter will be calibrated by an NRC approved outside vendor once yearly. The consulting physicist will check it every quarter. The survey meter will be checked against the calibrating source attached to the panel of the GM counter. If this reading varies by more than 20% from the reading obtained from the calibration laboratory, the instrument will be repaired and recalibrated.

9.3 Dose Calibrator Calibration. We will establish and implement the model procedure for calibrating our dose calibrator which was published in Appendix C to Regulatory Guide 10.8, Revision 2.

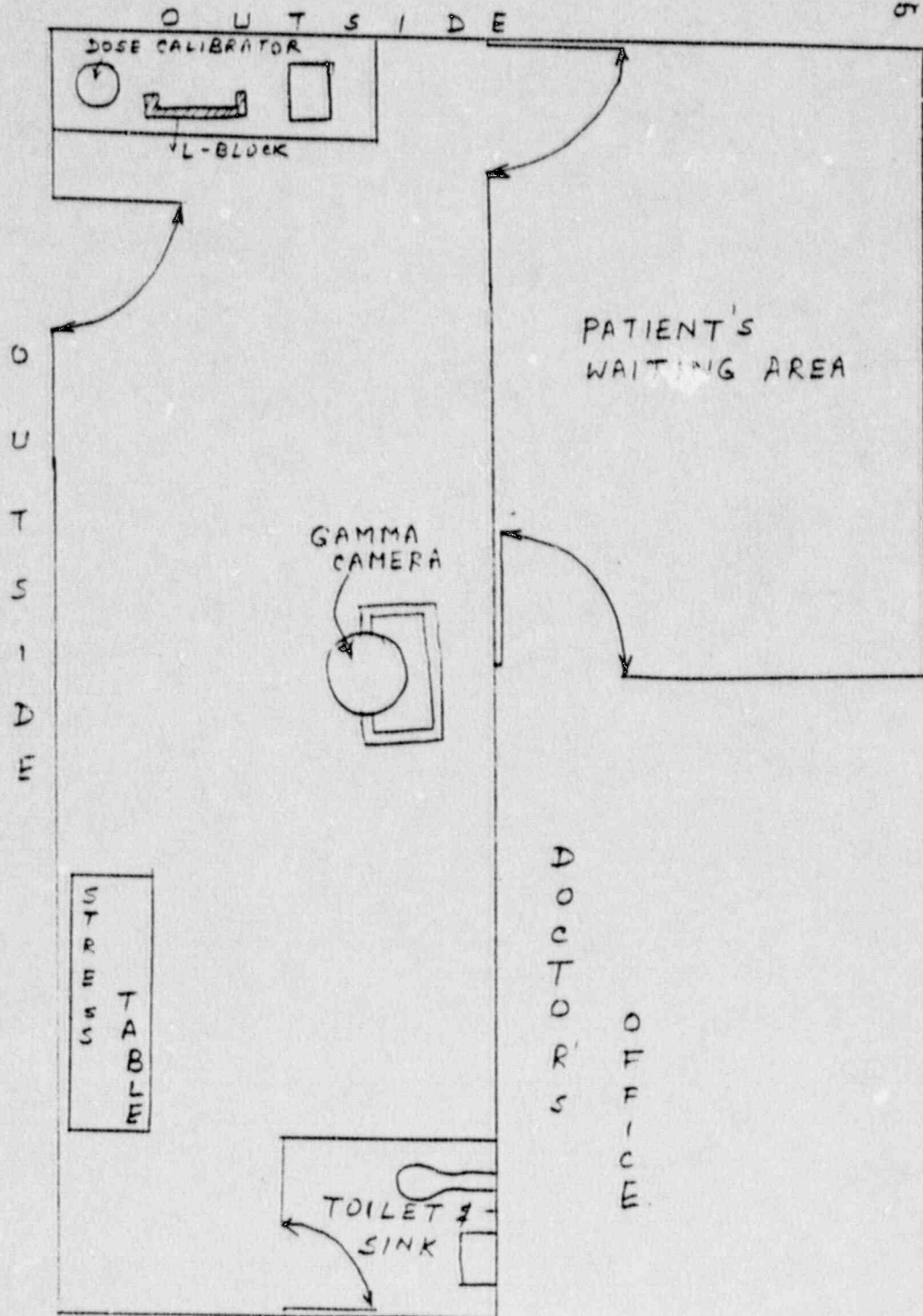
Although we will do the initial linearity check of the dose calibrator using the decay method, we may in the future use Cali-Check filters for linearity checks.

For daily constancy checks, we will use Co-57 and Cs-137. The dose calibrator will be checked weekly against Ba-133. The activity of the Co-57 can be anywhere from 50 uCi to 5 mCi. The activity of Cesium and Barium will be anywhere from 50 to 200 uCi.

Att: 9-1.

K. MALIK, M. D.
810 FOURTH AVENUE
FORD CITY, PA 16226
NUCLEAR MEDICINE LAB

SCALE: 1" = 4'
1ST FLOOR
(NOTHING ABOVE
OR BELOW).



- 9.4 Personnel Monitoring Program. We will establish and implement the model personnel external exposure monitoring program published in Appendix D of Regulatory Guide 10.8, Revision 2.

Item 10 - Radiation Safety Program

- 10.2 ALARA Program. Enclosed you will find the ALARA program signed by me.
- 10.3 Leak Tests. Doctor Banerjee will perform the leak testing of the sealed sources. See NRC license #37-01072-01.
- 10.4 Safe Use of Radiopharmaceuticals. We will establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2.
- 10.5 Spill Procedure. We will establish and implement the model spill procedure published in Appendix J to Regulatory Guide 10.8, Revision 2.
- 10.6 Ordering and Receiving. The nuclear medicine technologists will order radiopharmaceuticals in the single dose form from an NRC approved radiopharmaceutical company.

The materials will be delivered only when the nuclear medicine laboratory is open. The technician will verify that he or she has received what has been ordered. The activity of the source will be logged in the nuclear medicine lab book.

- 10.7 Opening Packages. We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2.
- 10.8 Unit Dosage Records. We will establish and implement the model procedure for unit dosage records that was published in Appendix M.1 to Regulatory Guide 10.8, Revision 2.
- 10.9 Multi-dose Vial Records. We will establish and implement the model procedure for multi-dose vial record system that was published in Appendix M.2 to Regulatory Guide 10.8, Revision 2.
- 10.10 Molybdenum Concentration Records. Since we will be purchasing radiopharmaceuticals in the single dose form from a radiopharmaceutical company, the radiopharmaceutical company will make sure that the molybdenum concentration is below the NRC limit.
- 10.11 Not applicable
- 10.12 Area Survey Procedures. We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2.
- 10.13 Air Concentration Control. Not applicable

10.14 Radiopharmaceutical Therapy. Not applicable

10.15 Implant Therapy. Not applicable

10.16 Other Safety Procedures. Not applicable

Item #11 - Waste Management

11.1 Waste Disposal. The radiopharmaceutical company will accept any unused radiopharmaceutical or trace amounts of radiopharmaceuticals remaining in the used syringes.

Band-aids, or cotton balls containing trace amounts of radionuclides will be allowed to decay for 10 half lives in the waste basket and then disposed of as normal trash. During the disposal, the radiation level outside the package containing this radioactive material will be measured with the GM counter to make sure that the radiation level is equal to background.

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

PROGRAM CODE: -----
STATUS CODE: 3
FEE CATEGORY: -----
EXP. DATE: 0
FEE COMMENTS: -----
.....

LICENSE FEE TRANSMITTAL

A. REGION 1

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: MALIK, M. KHALID, M.D.
RECEIVED DATE: 880801
DOCKET NO.: 3030721
CONTROL NO.: 109323
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED

AMOUNT: \$ 580.00
CHECK NO.: 187

3. COMMENTS

SIGNED [Signature]
DATE 88/08/04

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1-7)

1. FEE CATEGORY AND AMOUNT: 2C \$ 580

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT -----
RENEWAL -----
LICENSE ✓ -----

3. OTHER -----

SIGNED [Signature]
DATE 8/11/88