

Washington Radiology Associates,

916 19th Street, N.W., Suite 200
Washington, D.C. 20006

2141 K Street, N.W., Suite 900
Washington, D.C. 20037

Radiologist to:
Betty Ford Breast Diagnostic Center
and the Department of Radiology
Columbia Hospital for Women and MDCI

WRA • WUA

3022 Williams Drive, Suite 204
Fairfax, VA 22031
(703) 641-9133
FAX (703) 280-5098

Washington Ultrasound Associates

3022 Williams Drive, Suite 104
Fairfax, Virginia 22031

10215 Fernwood Road, Suite 50
Bethesda, Maryland 20817

MS/6
Q8
030-32755

April 17, 1992

Mr. William Davidson
Nuclear Regulatory Commission, Region I
Division of Radiation Safety and Safeguards
475 Allendale Road
King of Prussia, PA 19408-1414

Dear Mr. Davidson:

This letter is to follow up our conversation of Friday, April 17, 1992, concerning Washington Radiology Associates, P.C.'s application for a license to perform nuclear medicine procedures.

1. WRA will not be using generators for the radiopharmaceuticals. We will only use unit doses which will be delivered to us by a nuclear medicine pharmacy. No multi-dose vials will be used.
2. WRA confirms that we will be utilizing a backup GM meter from our radiation physicist at Mid Atlantic Radiation Physics. This meter will measure from 0-1R per hour.
3. We will provide the NRC with a preceptor statement for Dr. Leonard M. Glassman confirmed by Dr. Gary L. Rose.
4. WRA confirms that we will comply with the appropriate regulations in Appendix M and also agree that we will record the expiration dates and prescribed dosages for our patients.
5. The set up of the nuclear medicine room will include a desk and hot lab area in the corner of the suite, which will have lead blocks and an L-shield that will be utilized for the preparation of radiopharmaceuticals and the storage of any radioactive waste.

We have also been in touch with our physicists to confirm that they will begin working on the procedural information relative to the well counter sensitivity testing for our facility. They have assured us that they will prepare the necessary information within the next week.

In addition, per your recommendation, we will be establishing a quality management program in our new facility, hut, as indicated, this will not impact on the issuance of our license by the end of the month.

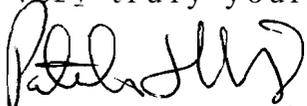
OFFICIAL RECORD COPY ML 10

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Page Two
April 17, 1992

Thank you very much for your timely attention and consideration to these matters.

Very truly yours,

A handwritten signature in black ink, appearing to read "Patrick J. Waring". The signature is written in a cursive style with a large initial "P" and "W".

Patrick J. Waring
Administrator

cc: Gary L. Rose, MD
Miles McCord, Mid Atlantic Radiation Physics

030-32755

MID-ATLANTIC RADIATION PHYSICS, INC.
7233 HANOVER PARKWAY, SUITES C & D • (301) 345-6803 • GREENBELT, MD 20770

April 17, 1992

Mr. William Davidson
Nuclear Regulatory Commission, Region I
Division of Radiation Safety and Safeguards
475 Allendale Road
King of Prussia, PA 19408-1414

RE: Request of Additional Information for WRA License Application - Minimum
Sensitivity for Survey Meter Used for Wipe Testing

Dear Mr. Davidson:

A test was performed on the above date using the Technical Associates TBM-23 survey meter (S/N 129196) with a Technical Associates P-23 end-window probe (S/N 129197) to determine if this detector system would be capable of detecting a minimum of 200 DPM.

The efficiency of the detector was performed in a lead cave to minimize background levels using Cs-137 and Sr-90 reference sources. The sources were identified as ICN 77239 P218S disk source having an activity of 0.005 μ Ci on 09/01/71 and NEN disk source having an activity of 0.0191 μ Ci on 01/73, respectively. The background measured 10 CPM. Count rates for the above mentioned sources measured 800 CPM and 2000 CPM, respectively.

The efficiency of the P-23 detector was calculated to be 9.55%. Therefore, using this efficiency factor, the following action levels will be observed:

200 DPM = 19 net CPM
2000 DPM = 191 net CPM
22,000 DPM = 2101 net CPM

It is the opinion of the undersigned that this survey meter and probe combination are appropriate to be used for wipe testing purposes provided that wipe counts are measured in a lead cave and that standard and reproducible geometry is utilized. It should be noted that there may be a rare occasion to use I-131, but this nuclide will not be utilized on a regular basis. The predominate nuclides to be utilized will be Tc-99m and Ga-67. The minimum recommended action levels for these nuclides is 2000 DPM as per Table N-1 in NRC Guide 10.8.

Sincerely,

Alan W. Goldey

Alan W. Goldey, B.S.

116396
FAX Rec'd 4-17-92

APR 23 1992

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NRC FORM 312M SUPPLEMENT
(8-80)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

Approved by COM
312M-1001
Expires 8-30-88

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

Gary Leyton Rose

2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE

Washington, D.C.

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Amer Board of Radiology	Diagnostic Radiology	6/81
Amer Board of Nuclear Medicine	Nuclear Medicine	9/83

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 (Months) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Nuclear Medicine Residency Sepulveda V.A. Hospital / U.C.L.A. Los Angeles, Calif 90024 June 1981 - Jan 1983		
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Tc-99m	30mCi	Los Angeles, Calif / Washington, D.C.	1 1/2 years	University Hospital 2 yrs Private practice 9 yrs
Gallium	10mCi			
Thallium	5mCi			
Iodine	1mCi			
I-131 I-123	200mCi 350uCi			

NRC FORM 312M SUPPLEMENT B
B-01

U. S. NUCLEAR REGULATORY COMMISSION

Approved by CNB
31622001
Expires 6-30-93

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.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME
Leonard M. Glanman

STREET ADDRESS
2801 New Mexico Ave, N.W.

CITY STATE ZIP CODE
Washington, D.C. 20007

KEY TO COLUMN C
PERSONAL PARTICIPATION SHOULD CONSIST OF:

1. Personal examination of patients or observed the technician for radiographic diagnosis under treatment and recommendation for treatment change.

2. Consultation in case selection and actual participation of case to the patient including explanation of the nuclear test, related measurements and timing of case.

3. Subsequent period of watching to assure procedure to complete and follow patients through diagnosis under course of treatment.

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 details to be added in column B or column C)
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	~25	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	0	
	LIVER FUNCTION STUDIES	0	
	FAT ABSORPTION STUDIES	0	
	KIDNEY FUNCTION STUDIES	0	
	IN VITRO STUDIES	0	
OTHER	<i>Indium 111</i>	~5	
I-125	DETECTION OF THROMBOSIS	0	
I-131	THYROID IMAGING	0	
F-18	EYE TUMOR LOCALIZATION	0	
Sc-75	PANCREAS IMAGING	0	
Yb-109	OSTEOGRAPHY	0	
Ka-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	0	
OTHER			
Tc-99m	BRAIN IMAGING	0	
	CARDIAC IMAGING	0	
	THYROID IMAGING	1	
	SALIVARY GLAND IMAGING	0	
	BLOOD POOL IMAGING	~25	
	PLACENTA LOCALIZATION	0	
	LIVER AND SPLEEN IMAGING	~12	
	LUNG IMAGING	~12	
BONE IMAGING	~100		
OTHER	<i>Gallium</i>	~5	

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 (Strontium)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	0	
P-32 (Cobalt)	INTRACAVITARY TREATMENT	0	
I-131	TREATMENT OF THYROID CARCINOMA	0	
	TREATMENT OF HYPERTHYROIDISM	0	
Au-198	INTRACAVITARY TREATMENT	0	
Co-60 or Co-137	INTERSTITIAL TREATMENT	0	
	INTRACAVITARY TREATMENT	0	
I-125 or Ir-192	INTERSTITIAL TREATMENT	0	
	TELETHERAPY TREATMENT	0	
Cs-137 or Co-137	TELETHERAPY TREATMENT	0	
	TELETHERAPY TREATMENT	0	
Sr-90	TREATMENT OF EYE DISEASE	0	
	RADIOPHARMACEUTICAL PREPARATION	0	
Mo-99/ Tc-99m	GENERATOR	0	
	GENERATOR	0	
Sr-113/ Yt-113m	GENERATOR	0	
	GENERATOR	0	
Tc-99m	REAGENT KITS	0	
Other			

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

1-92 → present at Columbia Hospital for Women, Dept of Nuclear medicine ~ 1 hour/day (resident + staff)

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

1. NAME OF SUPERVISOR
Gary L. Rose

2. NAME OF INSTITUTION
Columbia Hospital for Women

3. MAILING ADDRESS
2425 L. St. NW.

4. CITY
Washington, DC 20037

5. PRECEPTOR'S SIGNATURE
[Signature]

7. PRECEPTOR'S NAME (Print type or typed)
Gary Rose

8. DATE
4/17/92

9. MATERIALS LICENSE NUMBER(S)
08-15994-01 expires 1/31/95

DATE 4-17-92

TELEPHONE OR VERBAL CONVERSATION RECORD

TIME 10:00 A.M. P.M.

INCOMING CALL

OUTGOING CALL

VISIT

PERSON CALLING

W. DAVIDSON

OFFICE/ADDRESS

RT

PHONE NUMBER

EXTENSION

PERSON CALLED GARY ROSE - RSO

PAT WARINF - ADM

OFFICE/ADDRESS

WASHINGTON RAD. ASSOC.

PHONE NUMBER

EXTENSION

703-644-9133

CONFERENCE CALL

CONVERSATION

SUBJECT

DEFICIENCY QUESTION FOR NEW LICENSE

SUMMARY

Q: Are you using generator for TC-99m?

A: No

Q Unit or bulk does?

A: Unit does only - no bulk does

Q: Are you aware that you need a Qm program?

A: No, but we will submit one

- I also asked them to add expiration date and prescribed dosage to the list of records kept according to Appendix M.1 of Reg Guide 10.3 Rev 2.

- I told them that I would send them a preceptor statement form (313 sup AB) that needed to be filled out for Dr. Classroom.

- Additionally I requested that they send procedures & dates showing that their wipe measuring set-up is sensitive enough to "see" 200 dpm of T-131.

- Pat Warinf said this info would be sent as a letter.

REFERRED TO:

ACTION REQUESTED

Letter

ADVISE ME OF ACTION TAKEN.

INITIALS

WD

DATE

4-17-92

ACTION TAKEN

INITIALS

DATE

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