

Associated Physicians, P.C.

MEDICAL CENTERS

24555 Haig Street  
Taylor, Michigan 48180  
(313) 295-4200

22505 Allen Road  
Woodhaven, Michigan 48183  
(313) 671-6217



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Finnish  
RD

DMB CC

May 17, 1985

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United States Nuclear Regulatory Commission  
Region III  
799 Roosevelt Road  
Glen Ellyn, IL 60137

Associated Physicians, P.C.  
24555 Haig  
Taylor, MI 48180  
LICENSE #21-20440-01

Gentlemen:

This is in response to your letter dated April 30, 1985 concerning the inspection conducted by Ms. C.G. Casey and the following actions have been taken to correct the items of noncompliance.

ITEM 1: Method of performing wipe test:

Please refer to enclosed license amendment.

ITEM 2: Limited use of licensed material to Dr. M. Lala;

Please refer to enclosed license amendment.

ITEM 3: An amendment for Groups IV and V were filed per telegram and the appropriate fee was sent to Washington, D.C. on 4/15/85 (see enclosed copies).

ITEM 4: Leak testing of sealed sources:

Our local pharmacy, Syncor, Inc., has provided us with a quarterly service for leak testing. We will receive a written report of each test, performed by their radiation safety officer.

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As of this date, we are in full compliance. Quarterly review of all records by the radiation safety officer will provide adequate measurements to avoid future noncompliances.

Sincerely,

A handwritten signature in cursive script, appearing to read "Michael Lala", followed by a small mark that looks like "MD".

Michael Lala, M.D.

ML/poc



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
799 ROOSEVELT ROAD  
GLEN ELLYN, ILLINOIS 60137

APR 30 1985

Associated Physicians, P.C.  
ATTN: Mr. Paul Szilagyi  
24555 Haig Street  
Taylor, Michigan 48180

License No. 21-20440-01

Gentlemen:

This refers to the routine safety inspection conducted by Ms. C. C. Casey of this office between April 5-16, 1985, of activities authorized by NRC Byproduct Material License No. 21-20440-01 and to the discussion of our findings with you and other members of your staff (via telephone) at the conclusion of the inspection.

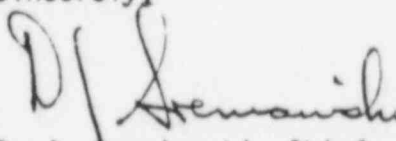
The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel.

During this inspection, certain of your activities appeared to be in non-compliance with NRC requirements, as specified in the enclosed Appendix. A written response is required.

The responses directed by this letter (and the accompanying Notice) are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

  
D. J. Sreniawski, Chief  
Nuclear Materials Safety  
Section 2

Enclosure: Appendix,  
Notice of Violation

cc w/encl:  
Michael Lala, M.D.  
DMB/Document Control Desk (RIDS)

8505030065  
2pp

CONTROL NO. 7 9 0 0 3

4. 10 CFR 35.14(e)(1)(i) requires that your method of testing sealed sources for leakage and/or contamination be capable of detecting the presence of 0.005 microcuries of radioactive material on the test sample.

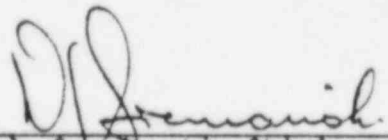
Contrary to the above, it was determined from a review of records and statements made by licensee representatives that this requirement is not being met. Specifically your method of testing your sealed sources was not capable of detecting this level of activity for your cesium-137 source.

This is a Severity Level V violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

Dated

4/26/85

  
D. J. Sreniawski, Chief  
Nuclear Materials Safety  
Section 2

Appendix

NOTICE OF VIOLATION

Associated Physicians, P.C.

License No. 21-20440-01

As a result of the inspection conducted on April 5-16, 1985, and in accordance with the General Policy and Procedures for NRC Enforcement Actions, (10 CFR Part 2, Appendix C), the following violations were identified:

1. License Condition No. 15 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

The referenced application received October 6, 1983 states in Item 17, that you will follow area survey procedures described in Appendix I of Regulatory Guide 10.8. Specifically, Appendix I states that the method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 cm<sup>2</sup> for the contaminant involved. An area will be cleaned if the contamination level exceeds 200 dpm per 100 cm<sup>2</sup>.

Contrary to the above, it was learned from a review of records and statements made by licensee representatives that these requirements are not being met. Specifically, you do not evaluate your area survey wipe tests using a method sufficiently sensitive to detect 200 dpm per 100 cm<sup>2</sup>. Consequently contaminated areas cannot be identified and cleaned.

This is a Severity Level V violation (Supplement VI).

2. License Condition No. 12 limits the use of licensed material to Dr. Michael Lala.

Contrary to the above, it was learned from statements made by licensee representatives that this requirement is not being met. Specifically, two physicians not named in this license have routinely used licensed material during Dr. Lala's absence.

This is a Severity Level IV violation (Supplement VI).

3. License Condition No. 12 limits the use of licensed material to Dr. Michael Lala. Specifically, Dr. Lala is authorized for the materials and uses included in 10 CFR 35.100, Schedule A, Groups I, II, and III and in vitro studies.

Contrary to the above, it was learned from statements made by licensee representatives that this requirement is not being met. Specifically, on November 28, 1984 and on February 6, 1985 Dr. Lala authorized the administration of sodium iodide I-131 for hyperthyroidism, a use not authorized in this license.

This is a Severity Level IV violation (Supplement VI).

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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		KEY TO COLUMN C PERSONAL PARTICIPATION SHOULD CONSIST OF: 1-Supervised examination of patients to determine the suitability for radionuclide diagnosis and/or treatment and recommendation for prescribed dosage. 2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radionuclide dose, taking measurements and plotting of data. 3-Adequate period of training to enable physician to manage, supervise patients and follow patients through diagnosis and/or treatment.
FULL NAME <u>Adolfo Melicor</u>		
STREET ADDRESS <u>3287 BERKSHIRE DR.</u>		
CITY <u>BIRMINGHAM</u>	STATE <u>MI</u>	
ZIP CODE <u>48210</u>		

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	64	<p><i>Nuclear studies at Grace are read and the Grace are read and the</i></p> <p><i>The nuclear studies at Grace are read and the</i></p> <p><i>Grace are read and the</i></p> <p><i>The nuclear studies at Grace are read and the</i></p> <p><i>Grace are read and the</i></p> <p><i>The nuclear studies at Grace are read and the</i></p> <p><i>Grace are read and the</i></p> <p><i>The nuclear studies at Grace are read and the</i></p> <p><i>Grace are read and the</i></p> <p><i>The nuclear studies at Grace are read and the</i></p>
	DETERMINATION OF RED BLOOD CELL VOLUME	3	
	LIVER FUNCTION STUDIES	2	
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES	7	
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING	87	
P-32	EYE TUMOR LOCALIZATION		
Sr-75	PANCREAS IMAGING	1	
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER	<i>Cerebral blood flow</i>	42	<p><i>The nuclear studies at Grace are read and the</i></p> <p><i>Grace are read and the</i></p> <p><i>The nuclear studies at Grace are read and the</i></p> <p><i>Grace are read and the</i></p> <p><i>The nuclear studies at Grace are read and the</i></p> <p><i>Grace are read and the</i></p> <p><i>The nuclear studies at Grace are read and the</i></p> <p><i>Grace are read and the</i></p> <p><i>The nuclear studies at Grace are read and the</i></p> <p><i>Grace are read and the</i></p>
Tc-99m	BRAIN IMAGING	110	
	CARDIAC IMAGING	2	
	THYROID IMAGING	14	
	SALIVARY GLAND IMAGING	1	
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	18	
	LUNG IMAGING	63	
	BONE IMAGING	48	
	<i>Gallium 67 Tumor nuclear scans</i>	6	

# 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 sheet.) D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloidal)	INTRACAVITARY TREATMENT	2	
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM	1	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
	TELETHERAPY TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mn-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Quint			

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

May + June 1977 } 4 mos = ~ 640 hours  
 Sept. + Oct 1977 }

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

a. NAME OF SUPERVISOR

B.T. Weyhing Grace Hospital

b. NAME OF INSTITUTION

18700 Meyers

c. MAILING ADDRESS

Detroit, Mich 48235

d. CITY

## 5. PRECEPTOR'S SIGNATURE

B.T. Weyhing MD

7. PRECEPTOR'S NAME (Please type or print)

B.T. Weyhing MD

8. DATE

5/8/85

## 5. MATERIALS LICENSE NUMBER(S)

21-04127-02



TRAINING AND EXPERIENCE  
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER  ADOLPHO MELICOR	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE MICHIGAN
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3. CERTIFICATION		
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
NONE	BOARD ELIGIBLE IN RADIOLOGY AND NUCLEAR MEDICINE	

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
a. RADIATION PHYSICS AND INSTRUMENTATION	GRACE HOSPITAL 18700 MEYERS DETROIT MICHIGAN 48235	100	150
b. RADIATION PROTECTION			50
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			50
d. RADIATION BIOLOGY			20
e. RADIOPHARMACEUTICAL CHEMISTRY		50	50

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
	This item is covered under Preceptor Statement, Page 7, Item # 3			