

LICENSE NO: 37-00147-02

DOCKET NO. (s) 30-2940

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ATTACHED

- Appendix A
- Appendix B
- Appendix C
- Memo

INSPECTION REPORT NO. 85-01  
Paul S. Friedman.  
1422 Chestnut St.  
Phila. Pa. 19138

LICENSEE CONTACT: \_\_\_\_\_ Telephone No: 104-2163

LICENSE NO: \_\_\_\_\_ CATEGORY \_\_\_\_\_ PRIORITY: \_\_\_\_\_  
 \_\_\_\_\_ CATEGORY \_\_\_\_\_ PRIORITY: \_\_\_\_\_  
 \_\_\_\_\_ CATEGORY \_\_\_\_\_ PRIORITY: \_\_\_\_\_

INSPECTION DATE (s): 9-13-85 + 9/27/85 TYPE OF INSPECTION:  SPECIAL  ANNOUNCED  
 ROUTINE  UNANNOUNCED  
 DAYSHIFT  
 OTHER

*Expired license 8/31/85*

SUMMARY OF FINDINGS AND ACTION

- NO NONCOMPLIANCE, CLEAR 591 ISSUED
- NO NONCOMPLIANCE, LETTER
- NONCOMPLIANCE, APPENDIX A
- ACTION ON PREVIOUS NONCOMPLIANCE, APPENDIX B
- NONCOMPLIANCE, 591 ISSUED
- SUPPLEMENTAL INFO, APPENDIX C

RECOMMENDATIONS  
SEE BASIS IN APPENDIX C

- CHANGE CATEGORY TO: \_\_\_\_\_
- NEXT INSPECTION DATE: 10/90
- CHANGE PRIORITY TO: \_\_\_\_\_

PERSONS CONTACTED  
Dave Bryant. Technician  
Dr. Paul Friedman

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INSPECTOR: J. N. Darden  
 APPROVED: \_\_\_\_\_

*B/9*

INSPECTION PLAN AND REPORT NUMBER \_\_\_\_\_ Page \_\_\_\_\_ of \_\_\_\_\_

Plan Approved: \_\_\_\_\_ Date: \_\_\_\_\_

Licensee: \_\_\_\_\_ License No. \_\_\_\_\_

Inspection Items	Scheduled for Inspection	Post Inspection Status	Module No.
Management Meeting - Entrance and Exit Interviews (Required)			30703B
Program Requirements, MC 2860 (Required)			78710B
Followup on Noncompliance and Deviations			92702B
Independent Inspection Effort (Required)			92706B
Transportation			86740B

AREAS INSPECTED AND FINDINGS

Licensee: \_\_\_\_\_ License No: \_\_\_\_\_ Amendment No: \_\_\_\_\_

INSPECTION ITEMS	CRITERIA	FINDING
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1. Organization

Lic Cond \_\_\_\_\_

Structure of organization as described in requirements?

Scope of Program? Patient load?

NOTES & REMARKS:

*Very small program - Approximately 1 Study a month*

2. Licensee Internal Audits

Lic Cond \_\_\_\_\_

Scope and frequency of audits as required?

Conducted by appropriate persons?

Records maintained?

Reviewed by management?

Deficiencies identified and corrected?

NOTES & REMARKS:

*Lic. Application requires at least an annual audit by consultant, but there are no records of annual audits*

3. Training and Qualification of Personnel

Lic Cond \_\_\_\_\_

*N/A*

Training & retraining conducted as required?

Written & oral exams conducted?

Examination results reviewed by management?

Instructions to workers per 19.12?

19.12

Authorized users? On license? Available in emergency?

Lic Cond \_\_\_\_\_

NOTES & REMARKS:

*Tech should be trained in Nuclear Medicine procedures and the requirements of the license*

4. Radiation Protection Procedures

Lic Cond \_\_\_\_\_

*C*

Procedures available and implemented?

Identify radiopharmaceutical and dose(s)?  
Cover handling of patients receiving therapeutic doses? Cover handling of cadavers?

*N/A*

Close out Surveys on Patients receiving temporary implants?

35.14 (b)(5)(v)

*N/A*

Emergency procedures for spills, etc?

Personnel understand procedures?

*C*

NOTES & REMARKS:

AREAS INSPECTED AND FINDINGS

Licensee: \_\_\_\_\_ License No: \_\_\_\_\_ Amendment No: \_\_\_\_\_

INSPECTION ITEM	CRITERIA	FINDING
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5. Use of Materials

*N/C*

- Procurement and use as required? Authorized form & route of administration? 35.14(b)
- Special tests (moly breakthrough, leak tests, etc) required? 35.14(b)(4)
- Inventory of brachytherapy sources? *NA* 35.14(b)(5)
- Dose calibration checks performed?
- Posting & labeling as required? 20.203

NOTES & REMARKS:

*N/C Ba 133 source = 221 uci / Co-57 - 406 uci*  
*Leak tests*  
*Consistency not done on days of use*  
*Linearity not done since 5/21/83*

6. Storage of Materials

*C*

- Material secured in both restricted and unrestricted areas? Adequately? 20.207

NOTES & REMARKS:

7. Facilities

Lic Cond \_\_\_\_\_

*C*

- As described in lic cond or application?
- Any changes made? Adequacy?

NOTES & REMARKS:

8. Instruments

Lic Cond \_\_\_\_\_

*N/C*

- Survey meters & instruments adequate for program?
- Instruments & meters operable? Calibrated? Calibration adequate?

NOTES & REMARKS:

*Survey meter - Last calibrated 8/21/84*

AREAS INSPECTED AND FINDINGS

Licensee: \_\_\_\_\_ License No: \_\_\_\_\_ Amendment No \_\_\_\_\_

INSPECTION ITEMS	CRITERIA	FINDING
<b>9. <u>Receipt and Transfer of Material</u></b>		
Written procedures for pickup, receiving, opening packages?	20.205	<u>C</u>
Survey of packages when received?	20.205(c)(1)	
Records of survey of packages? <i>OK</i>	20.401(b)	
Transfer of materials proper? Transfer records maintained?	30.41, 30.51	
Authorized containers used? Shipping papers & package labels proper for packages on hand?	71.5	
NOTES & REMARKS:		
<b>10. <u>Personnel Protection - External</u></b>		
Personnel monitoring controls adequate? Exposures minimized?	20.101, 20.202	<u>N/C</u>
Exposure records (NRC-4 or 5) maintained? Available for employee review?	20.102(b), 20.401(a)	
Surveys conducted? Adequate?	20.201	
<i>All None Conducted</i> Records of monitoring, surveys?	20.401	
Levels in unrestricted areas within limits? (Particularly around nuclear med. hot lab rooms of brachytherapy patients)	20.1, 20.105	
NOTES & REMARKS:		
<i>Will send in dosimetry reports to office Received - 10/24/85</i>		
<b>11. <u>Personnel Protection - Internal</u></b>		
Airborne concentrations in restricted areas? (Xe-133, patients treated with I-131)	20.103	
Exposures to minors?	20.104	
Posting of airborne radioactivity areas?	20.203(d)	
Survey, monitoring bioassay adequate for airborne radioactivity, surface contamination? Records maintained?	20.201 20.401	
Procedures for use of Xe-133 followed?	<i>N/A</i>	
NOTES & REMARKS:		

## AREAS INSPECTED AND FINDINGS

Licensee: \_\_\_\_\_ License No: \_\_\_\_\_ Amendment No: \_\_\_\_\_

INSPECTION ITEM	CRITERIA	FINDING
<b>12. <u>Effluent Controls, Waste Disposal</u></b>		
Release of effluents controlled? (particularly Xe-133, radioiodine where used)	20.106, 20.33	<u>C</u>
Waste disposals controlled? ✓	20.301, 20.303, 20.304, 20.305	
Procedures, records maintained?	20.401, Lic Cond _____	
Surveys made? Adequate?	20.401	
NOTES & REMARKS: <i>Waste returned to Nuc. Pharmacy</i>		
<b>13. <u>Notifications and Reports</u></b>		
To individuals? ✓	19.13	<u>C</u>
Overexposures, excessive levels & concentrations, incidents? ✓	20.403, 20.405	
Personnel exposures and monitoring, termination reports?	20.407, 20.408	
Theft or loss of licensed material? ✓	20.402	
Misadministrations? ✓	35.41-35.45	
NOTES & REMARKS:		
<b>14. <u>Posting of Notices</u></b>		
Part 20, license & documents, procedures, notice of violations posted?	19.11(a)	<u>C</u>
NRC-3 posted?	19.11(c)	
NOTES & REMARKS:		
<b>15. <u>Other License Conditions</u></b>		

AREAS INSPECTED AND FINDINGS

Licensee: \_\_\_\_\_ License No: \_\_\_\_\_ Amendment No: \_\_\_\_\_

INSPECTION ITEMS	CRITERIA	FINDING
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16. Confirmatory Measurements

NRC Instrument: \_\_\_\_\_ Calibration Due Date: \_\_\_\_\_

17. Independent Inspection Effort

*Surveyed HM Room & Hot Lab Area -  
All levels below Bg.*

18. Incidents and Events

Any incidents of misadministrations,  
contamination, etc., not otherwise  
covered by reports?

35.41 -35.45  
20.402, 20.403, 20.405

INSPECTION REPORT NUMBER \_\_\_\_\_

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APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

Licensee: \_\_\_\_\_

License No: \_\_\_\_\_

Reference	Basis for noncompliance
Report item <u>B.1</u> 10 CFR _____ Lic Cond _____ Type n/c _____	Dose Calibrator Constancy not done on day of use & linearities not done as required
Report item <u>B.</u> 10 CFR _____ Lic Cond _____ Type n/c _____	Failure to do leak tests on sealed sources > Cs 137 > 100 uci.
Report item <u>C.2</u> 10 CFR _____ Lic Cond _____ Type n/c _____	Survey not done of prep. area
Report item <u>C.3</u> 10 CFR _____ Lic Cond _____ Type n/c _____	Survey meter out of calibration
Report item <u>A</u> 10 CFR _____ Lic Cond _____ Type n/c _____	Training: Tech not trained in Nuc. med. Techniques & Lic. Requirements
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	



INSPECTION REPORT NUMBER \_\_\_\_\_

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APPENDIX B - LICENSEE ACTION ON PREVIOUS INSPECTION FINDINGS

Licensee: \_\_\_\_\_

License No: \_\_\_\_\_

Identification and summary of action taken	Status
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Report No: <u>81-01</u> Type n/c: _____      Describe: _____	
Action taken: <i>All items are still open - corrective action was not effective</i>	OPEN <u>85-61</u>
<i>1. Survey meter not calibrated</i>	CLOSED
<i>2. Daily (when used) constancy not performed</i>	
<i>3. 4% linearity not done</i>	
<i>4. Survey of prep. areas not done</i>	

Report No: _____      Type n/c: _____      Describe: _____	
Action taken:	OPEN
	CLOSED

Report No: _____      Type n/c: _____      Describe: _____	
Action taken:	OPEN
	CLOSED

Report No: _____      Type n/c: _____      Describe: _____	
Action taken:	OPEN
	CLOSED

Report No: _____      Type n/c: _____      Describe: _____	
Action taken:	OPEN
	CLOSED

Report No: _____      Type n/c: _____      Describe: _____	
Action taken:	OPEN
	CLOSED

APPENDIX C - SUPPLEMENTARY INFORMATION

Licensee: \_\_\_\_\_

License No: \_\_\_\_\_

- ( ) Uncorrected/repeated noncompliance
- ( ) Unusual occurrence, conditions, etc
- ( ) Basis for change of Category or Priority

- ( ) Unresolved items
- (✓) Inspector's comments

Very small program where many of the license requirements slip thru the cracks. The licensee promised to utilize the services of a consultant to bring the program into compliance and to get the technologist trained in Nuclear Medicine procedures