

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

INSPECTOR: G. 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

INSPECTION REPORT NUMBER _____

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787108 - Medical

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEMS	CRITERIA	FINDING
<p>1. <u>Organization</u></p> <p>Structure of organization as described in requirements?</p> <p>Scope of Program? Patient load?</p> <p>NOTES & REMARKS:</p>	<p>Lic Cond _____</p>	<p>Very small program - Approximately 1 study a month</p>
<p>2. <u>Licensee Internal Audits</u></p> <p>Scope and frequency of audits as required?</p> <p>Conducted by appropriate persons?</p> <p>Records maintained?</p> <p>Reviewed by management?</p> <p>Deficiencies identified and corrected?</p> <p>NOTES & REMARKS:</p>	<p>Lic Cond _____</p>	<p>Lic. Application requires at least an annual audit by consultant, but there are no records of annual audits</p>
<p>3. <u>Training and Qualification of Personnel</u></p> <p>Training & retraining conducted as required?</p> <p>Written & oral exams conducted?</p> <p>Examination results reviewed by management?</p> <p>Instructions to workers per 19.12?</p> <p>Authorized users? On license? Available in emergency?</p> <p>NOTES & REMARKS:</p>	<p>Lic Cond _____</p>	<p>N/A</p> <p>Tech should be trained in Nuclear Medicine procedures and the requirements of the license</p>
<p>4. <u>Radiation Protection Procedures</u></p> <p>Procedures available and implemented?</p> <p>Identify radiopharmaceutical and dose(s)?</p> <p>Cover handling of patients receiving therapeutic doses? Cover handling of cadavers?</p> <p>Close out Surveys on Patients receiving temporary implants?</p> <p>Emergency procedures for spills, etc?</p> <p>Personnel understand procedures?</p> <p>NOTES & REMARKS:</p>	<p>Lic Cond _____</p>	<p>N/A</p> <p>35.14 (b)(5)(v)</p>

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEM	CRITERIA	FINDING
5. Use of Materials		
Procurement and use as required? Authorized form & route of administration?	35.14(b)	<i>N/C</i>
Special tests (moly breakthrough, leak tests, etc) required?	35.14(b)(4)	
Inventory of brachytherapy sources? <i>NA</i>	35.14(b)(5)	
Dose calibration checks performed?		
Posting & labeling as required?	20.203	
NOTES & REMARKS:		
<i>N/C Ba 133 Source = 221 uci / Co-57 - 206 uci</i> <i>Leak Tests</i> <i>Consistency not done on days of use</i> <i>Linearity not done since 2/22/83</i>		
6. Storage of Materials		
Material secured in both restricted and unrestricted areas? Adequately?	20.207	<i>C</i>
NOTES & REMARKS:		
7. Facilities		
As described in lic cond or application?	Lic Cond _____	<i>C</i>
Any changes made? Adequacy?		
NOTES & REMARKS:		
8. Instruments		
Survey meters & instruments adequate for program?	Lic Cond _____	<i>N/C</i>
Instruments & meters operable? Calibrated?		
Calibration adequate?		
NOTES & REMARKS:		
<i>Survey meter - Last calibrated 8/21/84</i>		

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No _____

INSPECTION ITEMS	CRITERIA	FINDING
<hr/>		
9. <u>Receipt and Transfer of Material</u>		<u>C</u>
Written procedures for pickup, receiving, opening packages?	20.205	
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:		
<hr/>		
10. <u>Personnel Protection - External</u>		<u>N/C</u>
Personnel monitoring controls adequate? Exposures minimized?	20.101, 20.202	
Exposure records (NRC-4 or 5) maintained? Available for employee review?	20.102(b), 20.401(a)	
Surveys conducted? Adequate?	20.201	
<i>N/A 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</i> <i>Received - 10/24/85</i>		
<hr/>		
11. <u>Personnel Protection - Internal</u>		
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?	20.201	
Records maintained?	20.401	
Procedures for use of Xe-133 followed?		
NOTES & REMARKS:		

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEM	CRITERIA	FINDING
12. <u>Effluent Controls, Waste Disposal</u>		<u>C</u>
Release of effluents controlled? (particularly Xe-133, radioiodine where used)	20.106, 20.33	
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>		
13. <u>Notifications and Reports</u>		<u>C</u>
To individuals? ✓	19.13	
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:		
14. <u>Posting of Notices</u>		<u>C</u>
Part 20, license & documents, procedures, notice of violations posted?	19.11(a)	
NRC-3 posted?	19.11(c)	
NOTES & REMARKS:		
15. <u>Other License Conditions</u>		

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEMS	CRITERIA	FINDING
16. <u>Confirmatory Measurements</u>		_____

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

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APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

Licensee: _____

License No: _____

Reference	Basis for noncompliance
Report item <u>B.1</u>	Dose Calibrator
10 CFR _____	Constancy not done on day of use
Lic Cond _____	4ly linearities not done as required
Type n/c _____	
Report item <u>B.</u>	Failure to do leak tests on sealed sources > Cs 137 > 100 uci.
10 CFR _____	
Lic Cond _____	
Type n/c _____	
Report item <u>C2</u>	Survey not done of prep. area
10 CFR _____	
Lic Cond _____	
Type n/c _____	
Report item <u>C3</u>	Survey meter out of calibration
10 CFR _____	
Lic Cond _____	
Type n/c _____	
Report item <u>A</u>	Training: Tech not trained in Nuc. med. techniques & Lic. Requirements
10 CFR _____	
Lic Cond _____	
Type n/c _____	
Report item <u>A</u>	
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
Report No: <u>81-01</u> Type n/c: _____ Describe: _____ Action taken: <u>All items are still open - corrective</u> <u>action was not effective</u> <u>1. Survey meter not calibrated</u> <u>2. Daily (when used) constancy not performed</u> <u>3. 414 linearity not done</u> <u>4. Survey of prep. areas not done</u>	<u>OPEN 85-61</u> 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
Report No: _____ Type n/c: _____ Describe: _____ Action taken: _____	OPEN CLOSED

(July 82)

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APPENDIX C - SUPPLEMENTARY INFORMATION

Licensee: _____ License No: _____

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- | | |
|---|--|
| <input type="checkbox"/> Uncorrected/repeated noncompliance | <input type="checkbox"/> Unresolved items |
| <input type="checkbox"/> Unusual occurrence, conditions, etc | <input checked="" type="checkbox"/> Inspector's comments |
| <input type="checkbox"/> Basis for change of Category or Priority | |

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
