

REGION I Form 198-C
(July 82)

LICENSE NO: 37-00147-03

DOCKET NO. (s) 030-28887

PAGE _____ OF _____

ATTACHED

- ☐ Appendix A
☐ Appendix B
☒ Appendix C
☐ Memo

INSPECTION REPORT NO. 87-001

PAUL S. FRIEDMAN, M.D.

1422 CHESTNUT STREET

PHILADELPHIA, PA 19102

LICENSEE CONTACT: DAVE BRYANT, NMT

Telephone No: 215-564-2163

LICENSE NO: 37-00147-03

CATEGORY G

PRIORITY: 3

CATEGORY _____

PRIORITY: _____

CATEGORY _____

PRIORITY: _____

INSPECTION DATE (s): 9/90 9/25/87

TYPE OF INSPECTION:

- ☐ SPECIAL ☐ ANNOUNCED
☒ ROUTINE ☒ UNANNOUNCED
☒ DAYSHIFT
☐ OTHER

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: 9/90

☐ CHANGE PRIORITY TO: _____

PERSONS CONTACTED

DAVE BRYANT, NMT

DR. FRIEDMAN, RSO

INSPECTOR: [Signature]

APPROVED: [Signature]

11/20/87

B/11

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

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78710B - Medical

AREAS INSPECTED AND FINDINGS

Licensee: PAUL S. FRIEDMAN, M.D. License No: 37-0047-03 Amendment No: ____
RADIOLOGY ASSOCIATES

INSPECTION ITEMS	CRITERIA	FINDING
1. <u>Organization</u>	Lic Cond	<u>C</u>
Structure of organization as described in requirements?	1-2 PTS. SCANNED / MONTH	
Scope of Program? Patient load?	Tc-99m UNIT DOSES + I-131 CAPS FOR THYROID SCANS	
NOTES & REMARKS:		
2. <u>Licensee Internal Audits</u>	Lic Cond	<u>C</u>
Scope and frequency of audits as required?	QUARTERLY SEMI-ANNUAL AUDITS PERFORMED BY NPI AS PER AGREEMENT FROM PREVIOUS INSPECTION. DR. FRIEDMAN + TECH FIND THE AUDIT EXTREMELY HELPFUL. AUDITOR IDENTIFIES DEFICIENCIES + ITEMS OF NON-COMPLIANCE + FOLLOWS UP CORRECTIVE ACTION.	
Conducted by appropriate persons?		
Records maintained?		
Reviewed by management?		
Deficiencies identified and corrected?		
NOTES & REMARKS:		
3. <u>Training and Qualification of Personnel</u>	Lic Cond	<u>C</u>
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:		
4. <u>Radiation Protection Procedures</u>	Lic Cond	<u>C</u>
Procedures available and implemented?		
Identify radiopharmaceutical and dose(s)?		
Cover handling of patients receiving therapeutic doses? Cover handling of cadavers?		
Close out Surveys on Patients receiving temporary implants?	35.14 (b)(5)(v)	
Emergency procedures for spills, etc? Personnel understand procedures?		
NOTES & REMARKS:		

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEM	CRITERIA	FINDING
<u>5. Use of Materials</u>		
Procurement and use as required? Authorized form & route of administration?	35.14(b)	<u>C</u>
Special tests (moly breakthrough, leak tests, etc) required?	35.14(b)(4)	DOSE CALIBRATOR TESTS PERFORMED AT PROPER FREQUENCY
Inventory of brachytherapy sources?	35.14(b)(5)	
Dose calibration checks performed?		
Posting & labeling as required?	20.203	
NOTES & REMARKS:		
<u>6. Storage of Materials</u>		
Material secured in both restricted and unrestricted areas? Adequately?	20.207	<u>C</u> SEALED SOURCE STORED IN LOCKED STRONG BOX
NOTES & REMARKS:		
<u>7. Facilities</u>		
As described in lic cond or application?	Lic Cond _____	<u>C</u>
Any changes made? Adequacy?		
NOTES & REMARKS:		
<u>8. Instruments</u>		
Survey meters & instruments adequate for program?	Lic Cond _____	<u>C</u>
Instruments & meters operable? Calibrated? Calibration adequate?		SURVEY METER CALIBRATED + OPERABLE
NOTES & REMARKS:		

Licensee: _____ License No: _____ Amendment No _____

INSPECTION ITEMS	CRITERIA	FINDING
9. Receipt and Transfer of Material		
Written procedures for pickup, receiving, opening packages?	20.205	C RECORDS OF PACKAGE RECEIPT SURVEYS MAINTAINED
Survey of packages when received?	20.205(c)(1)	
Records of survey of packages?	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:		
10. Personnel Protection - External		
Personnel monitoring controls adequate? Exposures minimized?	20.101, 20.202	C - FILM BADGE RECORDS INDICATE NO EXCESSIVE EXPOSURES - RAD. LEVEL SURVEYS RECORDED AFTER EACH ADMINISTRATION
Exposure records (NRC-4 or 5) maintained? Available for employee review?	20.102(b), 20.401(a)	
Surveys conducted? Adequate?	20.201	
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:		
11. Personnel Protection - Internal		
Airborne concentrations in restricted areas? (Xe-133, patients treated with I-131)	20.103	C - LEAK TEST PERFORMED AT PROPER INTERVAL - AREA WIPE TESTS PERFORMED AFTER EACH ADMINISTRATION
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?		
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 RETURNED TO SYNCOR
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:		
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. Confirmatory Measurements

NRC Instrument: _____

Calibration Due Date: _____

17. Independent Inspection Effort18. 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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[illegible]

APPENDIX B - LICENSEE ACTION ON PREVIOUS INSPECTION FINDINGS

Licensee: PAUL S. FRIEDMAN, M.D.

License No: 37-00147-03

Identification and summary of action taken

Status

Report No: 85-01 Type n/c: _____ Describe: INADEQUATE TRAINING

Action taken: THE INSPECTOR INTERVIEWED THE NUCLEAR MED. TECH. WHO INDICATED ADEQUATE KNOWLEDGE OF PROCEDURE + LICENSE CONDITIONS. THE INSPECTOR REVIEWED RECORDS DOCUMENTING NUC. MED. IN-SERVICE PERFORMED BY NPI AUDITOR. OPEN CLOSED

Report No: 85-01 Type n/c: _____ Describe: FAILURE TO PERFORM LEAK TEST

Action taken: THE INSPECTOR REVIEWED RECORDS THAT INDICATED THAT LEAK TESTS OF SEALED SOURCES HAD BEEN PERFORMED AT PROPER INTERVALS BY LICENSEE CONTRACT CONSULTANT, NPI. OPEN CLOSED

Report No: 85-01 Type n/c: _____ Describe: FAILURE TO CALIBRATE SURVEY METER

Action taken: THE INSPECTOR REVIEWED RECORDS THAT INDICATED THAT THE LICENSEES SURVEY METER HAD BEEN CALIBRATED AT THE PROPER FREQUENCY OPEN CLOSED

Report No: 85-01 Type n/c: _____ Describe: FAILURE TO PERFORM CONSTANCY TEST

Action taken: THE INSPECTOR REVIEWED RECORDS THAT INDICATED THAT THE DAILY CONSTANCY TEST OF THE DOSE CALIBRATOR HAD BEEN PERFORMED ON EACH DAY THAT PATIENT DOSES HAD BEEN ASSAYED. OPEN CLOSED

Report No: 85-01 Type n/c: _____ Describe: FAILURE TO PERFORM LINEARITY TEST

Action taken: THE INSPECTOR REVIEWED RECORDS THAT INDICATED THAT A LINEARITY TEST HAD BEEN PERFORMED ON THE DOSE CALIBRATOR AT THE PROPER FREQUENCY OPEN CLOSED

Report No: 85-01 Type n/c: _____ Describe: FAILURE TO PERFORM RADIATION SURVEYS

Action taken: THE INSPECTOR REVIEWED RECORDS THAT INDICATED THAT "WEEKLY" RADIATION SURVEYS HAVE BEEN PERFORMED AFTER EACH USE OF LICENSED MATERIAL OPEN CLOSED

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APPENDIX C - SUPPLEMENTARY INFORMATION

Licensee: Paul S. Friedman, M.D.License No: 37-00147-03☐ Uncorrected/repeated noncompliance☐ Unresolved items☐ Unusual occurrence, conditions, etc☒ Inspector's comments☐ Basis for change of Category or Priority

~~Audit~~ ~~Semi-Annual~~ ^{Quarterly} AUDITS HAVE HAD A POSITIVE IMPACT ON LICENSEE'S PROGRAM. LICENSEE STATED THAT THEY WISH TO CONTINUE THE AUDIT PROGRAM. I will put a PARAGRAPH IN INSPECTION LETTER STATING THAT THEIR COMMITMENT CONCERNING THIS AUDIT PROGRAM, WITH THE NRC HAS BEEN FULFILLED AND THAT THEY SHOULD NOT CONSIDER THEMSELVES UNDER THIS OBLIGATION ANY LONGER.