

TELEPHONE: 452-0601

E. BICKHAM, JR., M.D.
ROBERT T. HENNEY, M.D.
BERT J. NIEL, M.D.
EMERICK E. SABATINI, M.D.
JETER J. AUGUSTIN, M.D.
RAYMOND HISS, JR., M.D.
JESSE L. HUGHES, M.D.
JOSEPH P. MOCK, M.D.
JOSE L. BASELGA, M.D.
ROBERT P. ODENWALD, M.D.
ANIEL D. MAXWELL, M.D.
RICHARD R. DRUMMOND, M.D.
ARY S. STAPLES, M.D.

DRS. GROOVER, CHRISTIE, AND MERRITT, P.C.
1145 19TH STREET, N.W.
WASHINGTON, D.C. 20036

RADIOLOGISTS TO
WASHINGTON HOSPITAL CENTER,
SIBLEY MEMORIAL HOSPITAL, AND SUBURBAN HOSPITAL

PRIVATE OFFICES
5530 WISCONSIN AVE.
4000 MASSACHUSETTS AVE., N.W.
1145 19TH ST., N.W.
110 IRVING ST., N.W.

THOMAS A. GROOVER, M.D. 1910-1940
EDWIN A. MERRITT, M.D. 1910-1960
ARTHUR C. CHRISTIE, M.D. 1910-1950
FRED O. COE, M.D. 1922-1973
EDGAR M. MCPEAK, M.D. 1925-1976
JAMES E. WISLER, M.D. 1934-1972
AUBREY O. HAMPTON, M.D. 1940-1958
F.V. SCHUMACHER, M.D. 1932-1979
KARL C. CORLEY, M.D.
RALPH M. CAULK, M.D.
U. VINCENT WILCOX, M.D.

October 11, 1982

To: Division of Engineering and Technical Programs
United States Nuclear Regulatory Commission Region I
631 Park Avenue, King of Prussia, Pennsylvania 19406

Subject: Inspection No. 82-01, License No. 08-19624-01

1. Application for amendment to the license authorizing Paul L. Chandeysson, M.D. as a user and designating him radiation safety officer has been made.
2. A review of the applicable provision of the regulations and conditions of the license was conducted on 26 Aug. 82. In attendance were the radiation safety officer, radiation safety consultant, and technical personnel working in the restricted areas. Such provisions and conditions will be reviewed at least yearly.
- 3-1. The radiation survey instrument was calibrated on 14 Sep. 82 by an independent laboratory. This calibration will be repeated at least annually.
- 3-2. The dose calibrator was calibrated on 28 Sep. 82 by an independent laboratory. This calibration will be repeated at least annually. The instrumental linearity test was performed on 15 Sep. 82 and found to be satisfactory. This test will be repeated at least quarterly.
- 3-3. A survey of the unrestricted corridor adjacent to the Hot Lab was performed on 23 Aug. 82 with negative results following rearrangement of the lead shielding bricks in the Hot Lab. This survey will be repeated at least weekly.
- 3-4. The provision of Item 2 Appendix G concerning the requirement for disposable gloves being worn when handling radioactive materials was stressed during the review described in paragraph 2. Provisions for access to and disposal of the gloves have been made.
- 3-5. Wipe tests of all received packages of radioactive material and weekly wipe tests of environmental surfaces in the restricted area have been instituted.
4. Full compliance is expected at this time.

8506110417 850109
PDR FOIA
ENGEL84-789 PDR

Paul L. Chandeysson, M.D.
Radiation Safety Officer

OCT 5 1982

Docket No. 30-18996

License No. 08-19624-01

Groover, Christie & Merritt Associates
ATTN: Dr. Gregory T. Henesy
President

1145 19th Street, NW
Washington, D.C. 20010

Gentlemen:

Subject: Inspection No. 82-01

This refers to the routine safety inspection conducted by Mrs. Theresa Hall Darden of this office on August 20, 1982, of activities authorized by NRC License No. 08-19624-01 and to the discussions of our findings held by Mrs. Darden with Dr. Paul Chandeyson 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 the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, measurements made by the inspector, and observations by the inspector.

Based on the results of this inspection, it appears that certain of your activities were not conducted in full compliance with NRC requirements, as set forth in the Notice of Violation, enclosed herewith as Appendix A. These violations have been categorized by severity level in accordance with the NRC Enforcement policy (10 CFR 2, Appendix C) published in the Federal Register Notice (47 FR 9987) dated March 9, 1982. You are required to respond to this letter; and, in preparing your response, you should follow the instructions in Appendix A.

From the discussion of our findings at the conclusion of the inspection, it is our understanding that Richard G. Drewyer, M.D., is no longer designated as Radiation Safety Officer. We further understand that Paul Chandeyson, M.D., has been named as Radiation Safety Officer and that you plan to submit to the U.S. Nuclear Regulatory Commission, Region I, Materials Program Section No.2, 631 Park Avenue, King of Prussia, Pennsylvania 19406, a request for an amendment authorizing him as a user on the license and designating him as the Radiation Safety Officer. Please confirm these understandings in your reply to this letter.

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.

~~8210210310~~

2pp,

1E:07

OCT 5 1982

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room.

Your cooperation with us in this matter is appreciated.

Sincerely,

Original Signed By:
John D. Kinneman

for Thomas T. Martin, Director
Division of Engineering and Technical
Programs

Enclosure:
Appendix A, Notice of Violation

cc w/encl:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
District of Columbia ✓

bcc w/encl:
Region I Docket Room (with concurrences)
Chief, Operational Support Section (w/o encl) ✓

for
RI:DETP
Darden/lp
9/27/82

Kinneman
RI:DETP
Kinneman

10/4/82

OCT 5 1982

APPENDIX A
NOTICE OF VIOLATION

Groover, Christie & Merritt Associates
Washington, D.C. 20010

Docket No. 30-18996
License No. 08-19624-01

As a result of the inspection conducted on August 20, 1982, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

- A. 10 CFR 19.12 requires that all individuals working in restricted areas be instructed in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of August 20, 1982, individuals who were working in the restricted area had not been instructed in the applicable provisions of the regulations and the conditions of the license.

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

- B. Condition 14 of License No. 08-19624-01 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated December 30, 1980.

1. Item 10.A of this application requires that survey instruments be calibrated in accordance with the procedures in Appendix D, Section 1, of Regulatory Guide 10.8, Revision 1. Item A.3 of Appendix D, Section 1 requires that survey meters be calibrated at least annually and after servicing.

Contrary to the above, as of August 20, 1982, the survey meter had not been calibrated since April 1980, a period of more than one year.

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

2. Item No. 10.B of this application requires that dose calibrators be calibrated in accordance with procedures contained in Appendix D, Section 2, Regulatory Guide 10.8.

Contrary to the above, as of August 20, 1982, the dose calibrator had not been calibrated, and no tests of instrument linearity had been performed since April 1980, a period of greater than one year.

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

~~82/02/03/5~~
12pp.

3. Item 11.D of this application requires that surveys be made of unrestricted areas to determine radiation levels.

Contrary to the above, as of August 20, 1982, surveys in the unrestricted corridor adjacent to the Hot Lab preparation area had not been performed since April 1981.

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

4. Item 15 of this application requires that radioactive material be handled in accordance with Appendix G of Regulatory Guide 10.8.

Item 2 of Appendix G requires that disposable gloves be worn at all times while handling radioactive materials.

Contrary to the above, on August 20, 1982, personnel in the Nuclear Medicine Department failed to wear disposable gloves while handling radioactive materials.

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

5. Item 17 of this application requires that surveys be performed in accordance with the "Area Survey Procedures" contained in Appendix I of Regulatory Guide 10.8.

Item 5 of Appendix I requires a permanent record of survey results.

Contrary to the above, as of August 20, 1982, a record had not been kept of weekly wipe tests.

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

Pursuant to the provisions of 10 CFR 2.201, Groover, Christie & Merritt Associates is hereby required to submit to this office within thirty days of the date of this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.

INSPECTION REPORT NO. 82-01

Attached

☐ Appendix A☐ Appendix B☐ Appendix C☐ Memo

Dr. Grover, Christie & Merritt
1145 19th St NW
Washington DC 20010

Licensee contact: Dr. Paul Chanleysson, MD, RSO Telephone no. License no. 06-19624-01 Last amendment and date: L / APP. 2/24/81Category: G, and Priority: IV, as of last amendment.Inspection date(s): Aug 20, 1982 Type of inspection: Routine / Unannounced

SUMMARY OF FINDINGS AND ACTION

☐ No noncompliance, clear 591 issued☒ Noncompliance, Appendix A☐ Action on previous noncompliance, Appendix B☐ Noncompliance, 591 issued☐ Regional action Hq action☐ Supplemental info, Appendix C

RECOMMENDATIONS

See basis in Appendix C or attached memo.

☐ Change Category to: ☐ Change Priority to: ☐ Next inspection date: Aug. 1984

PERSONS CONTACTED

Charles WATSON, NMTRoberta Hansen, RT, NMTPaul Chanleysson, MD, RSOLetter to
Dr. Gregory T. Henesy, PresidentInspector: Terica Hall DardenApproved: [Signature]8/20/829/14/82

Plan Approved: _____

Date: _____

Licensee: _____

License No: _____

Inspection Items	Scheduled for Inspection	Post-Inspection Status	Module No.	766 Time Info
Management Meeting - Entrance and Exit Interviews (Required)			30703B	3.0 1.5
Program Requirements, MC 2860 (Required)			78710B	2.5 2.5
Followup on Noncompliance and Deviations			92702B	
Independent Inspection Effort (Required)			92706B	1.0
Transportation			86740B	
Licensee Event Followup			92700B	
Followup on Inspector-Identified Problems			92701B	
IE Bulletin/Immediate Action Letter Followup			92703B	
Followup on Headquarters Requests			92704B	
Followup on Regional Requests			92705B	
Inspector Dispatched to Site			93700B	
Followup on Significant Event Occurring During Inspection			93701B	
Initial Management Meeting			38800B	

AREAS INSPECTED AND FINDINGS

Licensee: _____ License no: _____ Amendment no: _____

INSPECTION ITEMS	CRITERIA	FINDING
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1. Organization

Structure of organization as described in requirements?

Lic Cond _____

NOTES & REMARKS:

Paul Chandeysson, MD. - RSD (1 month)
Unauthorized user - Will send in Paper Work

2. Licensee internal audits

Lic Cond _____

Scope and frequency of audits as required?

Conducted by appropriate persons? Records maintained? Reviewed by management?

Deficiencies identified & corrected?

NOTES & REMARKS:

Use of a Physicist Consultant
Called in as needed. Physicist
does not seem aware of License
conditions

3. Training and qualification of personnel

Lic Cond _____

Training & retraining conducted as required? ☒Written & oral exams conducted? Examination results reviewed by management? ☒Instructions to workers per 19.12? ☒

19.12

NOTES & REMARKS:

Application Item 12 B commits to minimal - annual training
Review of Pts 19.20 and License Conditions. Technologist admits
that License has never been reviewed and that there has been
no other written or oral training since April program inception 4/81

4. Radiation protection procedures

Lic Cond _____

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

Emergency procedures for spills, etc?
Personnel understand procedures?

NOTES & REMARKS:

AREAS INSPECTED AND FINDINGS

Licensee: _____ License no: _____ Amendment no: _____

INSPECTION ITEM	CRITERIA	FINDING
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5. Use of materials

Lic Cond _____

N/CProcurement and use as required? OKSpecial tests (moly breakthrough, leak tests, etc) required? NADose calibration checks performed? Not sincePosting & labeling as required? OK

20.203

Linearly or Annual Accuracy
Installation April 1981

NOTES & REMARKS:

Constancy is performed daily6. Storage of materials

Material secured in both restricted and unrestricted areas? Adequately?

20.207

NOTES & REMARKS:

One entrance to main office past receptionist, but 77 m Dept not locked. Committed to installing lock on that lab door for better security7. Facilities

Lic Cond _____

CAs described in lic cond or application? ✓Any changes made? Adequacy? OK

NOTES & REMARKS:

8. InstrumentsLic Cond 14-N/CSurvey meters & instruments adequate for program? ✓

Instruments & meters operable? Calibrated? Calibration adequate?

NOTES & REMARKS:

Dose Calibrator and GM Survey Meter not calibrated since April 1981 -

AREAS INSPECTED AND FINDINGS

Licensee: _____ License no: _____ Amendment no: _____

INSPECTION ITEMS	CRITERIA	FINDING
9. Receipt and transfer of material		<u>N/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? ✓	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:

Committed to 10.5 Appen. F - No wipes done
 All Material comes in prepared dose from Pharmatopes
 Incomplete Receipt records

10. Personnel protection - external

Personnel monitoring controls adequate? ✓	20.101, 20.202
Exposures minimized? ✓	
Exposure records (NRC-4 or 5) maintained? ✓	20.102(b), 20.401(a)
Available for employee review?	20.201
Surveys conducted? Adequate?	20.401
Records of monitoring, surveys?	20.1, 20.105
Levels in unrestricted areas within limits?	

NOTES & REMARKS:

No surveys or wipes done, no hand monitoring
 Techs do not use gloves
 Committed to 10.8 App. G.

11. Personnel protection - internal

Airborne concentrations in restricted areas? N/A	20.103
Exposures to minors?	20.104
Posting of airborne radioactivity areas? ✓	20.203(d)
Survey, monitoring adequate for airborne radioactivity, surface contamination? Records maintained?	20.201 20.401

NOTES & REMARKS:

AREAS INSPECTED AND FINDINGS

Licensee: _____ License no: _____ Amendment no: _____

INSPECTION ITEM	CRITERIA	FINDING
<u>12. Effluent controls, waste disposal</u>		_____
Release of effluents controlled?	20.106, 20.303	
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:	All waste is returned to pharmacies	
<u>13. Notifications and reports</u>		<u>Q</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	
NOTES & REMARKS:		
<u>14. Posting of notices</u>		_____
Part 20, license & documents, procedures, notice of violations posted? OK	19.11(a)	
NRC-3 posted? b/k	19.11(c)	
NOTES & REMARKS:		
<u>15. Other license conditions</u>	Lic	_____

AREAS INSPECTED AND FINDINGS

Licensee: _____ License no: _____ Amendment no: _____

INSPECTION ITEMS	CRITERIA	FINDING
16. <u>Confirmatory measurements</u>		

17. Independent inspection effort

Availability for emergency implant removal
Special Area Contaminations

Surveyed entire RI area with
Geiger Counter meter. Found some contaminated area
absolutely covering. In the ~~hall~~ corridor part
of the hot lab. There are readings ≤ 1.5 mR/hr.

18. Incidents and events

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

none

1.5
+ 1.0
= 2.5

HL
6.00

APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

Licensee: _____

License no: _____

Reference

Basis for noncompliance

Report item B-1

10 CFR _____

Lic Cond 14 - Item 10AType n/c IVNo gmi meter calibration
since April 1980Report item B-2

10 CFR _____

Lic Cond 14 - I, 10BType n/c IVNo Dive calculator Lenseulgar,
annual calibration since
April 1980Report item B-3

10 CFR _____

Lic Cond 14 - I, 11DType n/c IV

No survey of unrestricted areas

Report item A-1

10 CFR _____

Lic Cond 14-12-BType n/c IV

Inadequate Training

Report item B-410 CFR L/C 14 I 15Lic Cond B-5Type n/c I

No Glasses Used

No urine test records

APPENDIX B - LICENSEE ACTION ON PREVIOUS INSPECTION FINDINGS

Licensee: _____ License no: _____

Identification and summary of action taken	Status
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Report no: _____ Type n/c: _____ Describe: _____	OPEN
Action taken: _____	CLOSED

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

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

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

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

APPENDIX C - SUPPLEMENTARY INFO _____

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 doing C-II - Livers, Breasts, Lungs, Thyroid scans; uses all prepared X-rays - more tightly. They have the program could be controlled. They have recently hired a full time NM Tech. Physician who will also serve as RSO. The present NM Tech is leaving, so some personnel turnover is assured. Their consulting physicist serves in an "as needed" capacity. He has ~~not~~ been consulted occasionally, been consulted by phone.

NOV 22 1982

Docket No. 30-19490

License No. 08-19896-01

Paul H. Pevsner, M.D.
Watergate Radiology, P.C.
2524 Virginia Avenue
Washington, D.C. 20037

Dear Dr. Pevsner:

Subject: Inspection No. 82-01

This refers to your letter dated November 2, 1982, in response to our letter dated October 5, 1982.

Thank you for informing us of the corrective and preventive actions documented in your letter. These actions will be examined during a future inspection of your licensed program.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:
John D. Kinneman

for Thomas T. Martin, Director
Division of Engineering and
Technical Programs

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
✓ District of Columbia

bcc:
✓ Region I Docket Room (with concurrences)

for RI:DETP
Darden/gwc
11/17/82

Kinneman
RI:DETP
Kinneman
11/19/82

~~82-1290670~~
1p.

34
IE:07

WATERGATE RADIOLOGY, P.C.

2524 VIRGINIA AVENUE, N.W.

WASHINGTON, D.C. 20037

(202) 242-8408

PAUL H. PEVSNER, M.D.
DOROTHY F. COONEY, M.D.

November 2, 1982

Thomas T. Martin, Director
Division of Engineering of Technical Programs
United States Nuclear Regulatory Commission
Region One
631 Park Avenue
King of Prussia, PA 19406

Dear Mr. Martin,

This is in response to your letter of October 5, 1982 regarding inspection Number 82-01 made by Mrs. T. H. Darden on August 16, 1982 regarding activities authorized by NRC, License Number 08-19896-01.

The two deficiencies were the absence of ring badges and failure to use syringe shields during injection of radionuclide.

The ring shields were ordered immediately and have been in use since September of 1982, and we now routinely use one of our two syringe shields during injection of radionuclide materials.

Both the ring badges and the syringe shields are available for inspection in our offices.

I have instructed our technologist in the applicable provisions of the commission's regulations and licenses and they are posted in the room and available for perusal.

If you have any further questions, please feel free to contact me directly.

Yours truly,



Paul H. Pevsner, M.D.

82H290676

lp.

OCT 5 1982

License No. 08-19896-01

Docket No. 30-19490

Paul H. Pevsner, M.D.
Watergate Radiology, P.C.
2524 Virginia Avenue
Washington, D.C. 20037

Dear Dr. Pevsner:

Subject: Inspection No. 82-01

This refers to the routine safety inspection conducted by Mrs. T. H. Darden of this office on August 16, 1982, of activities authorized by NRC License No. 08-19896-01 and to the discussions of our findings held by Mrs. Darden with yourself 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 the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, measurements made by the inspector, and observations by the inspector.

Based on the results of this inspection, it appears that certain of your activities were not conducted in full compliance with NRC requirements, as set forth in the Notice of Violation, enclosed herewith as Appendix A. These violations have been categorized by severity level in accordance with the NRC Enforcement policy (10 CFR 2, Appendix C) published in the Federal Register Notice (47 FR 9987) dated March 9, 1982. You are required to respond to this letter; and, in preparing your response, you should follow the instructions in Appendix A.

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.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room.

Your cooperation with us in this matter is appreciated.

Sincerely,

Original Signed By:
John D. Kinneman

for Thomas T. Martin, Director
Division of Engineering and Technical
Programs

Enclosure:
Appendix A, Notice of Violation

8210210042
2pp, 1E:07

OCT 5 1982

cc w/encl:

Public Document Room (PDR)

Nuclear Safety Information Center (NSIC)

District of Columbia ✓

bcc w/encl:

Region I Docket Room (with concurrences)

Chief, Operational Support Section (w/o encl) ✓

Kinneman
for
RI:DETP
Darden/lp
9/20/82

Kinneman
RI:DETP
Kinneman
10/4/82

OCT 5 1982

APPENDIX A
NOTICE OF VIOLATION

Paul H. Pevsner, M.D.
Washington, D.C. 20037

Docket No. 30-19490
License No. 08-19896-01

As a result of the inspection conducted on August 15, 1982, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

- A. 10 CFR 19.12 requires that all individuals working in restricted areas be instructed in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of August 16, 1982, individuals who were working in the restricted area had not been instructed in the applicable provisions of the regulations and the specific conditions of the license.

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

- B. Condition 13 of License No. 09-19896-01 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated October 1, 1981.

1. Item 15 of this application requires that patient doses containing radioactive material be prepared and administered using lead syringe shields.

Contrary to the above, as of August 16, 1982, personnel failed to use syringe shields during the administration of patient doses containing radioactive material.

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

2. Item 24 of this application requires that exposures to the extremities of personnel be evaluated by the use of finger ring badges.

Contrary to the above, as of August 16, 1982, finger ring badges had not been assigned to evaluate the dose to the extremities of technicians administering radiopharmaceuticals.

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

8210210047
/ 2pp

OCT 5 1982

Pursuant to the provisions of 10 CFR 2.201, Paul H. Pevsner, M.D. is hereby required to submit to this office within thirty days of the date of this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.

REGION I Form 198-C
(July 82)

LICENSE NO: 08-19896-21

DOCKET NO. (s) 30-19490

PAGE _____ OF _____

ATTACHED

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

INSPECTION REPORT NO. 82-01

Paul H. Pevsner, MD
2524 Virginia Ave N.W.
Washington DC 20037

LICENSEE CONTACT: Dr. P. Pevsner, MD

Telephone No: 804-688-1013

LICENSE NO: 08-19896-01

CATEGORY G

PRIORITY: XX

CATEGORY _____

PRIORITY: _____

CATEGORY _____

PRIORITY: _____

INSPECTION DATE (s): Aug 16, 1982

TYPE OF INSPECTION:

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

Initial Inspection

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: Aug 1984

☐ CHANGE PRIORITY TO: _____

PERSONS CONTACTED

Paul H. Pevsner MD
RJ Tech

INSPECTOR: Teresa Wheeler 8/16/82

APPROVED: [Signature]

9/14/82

INSPECTION PLAN AND REPORT NUMBER _____

Page _____ of _____

Plan Approved: _____

Date: _____

License No. _____

Licensee: _____

Inspection Items	Scheduled for Inspection	Post Inspection Status	Module No.
Management Meeting - Entrance and Exit Interviews (Required)			30703B <i>1.5 hrs</i>
Program Requirements, MC 2860 (Required)		<i>1.2</i>	78710B <i>1.25 hrs</i>
Followup on Noncompliance and Deviations			92702B
Independent Inspection Effort (Required)			92706B
Transportation			86740B

INSPECTION REPORT NUMBER _____

Page ____ of ____

787108 - Medical

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEMS	CRITERIA	FINDING
1. <u>Organization</u>	Lic Cond _____	<u>C</u>
Structure of organization as described in requirements?		
Scope of Program? Patient load?		
NOTES & REMARKS:	<i>Small - to be physically expect growth</i>	
2. <u>Licensee Internal Audits</u>	Lic Cond _____	<u>N/C</u>
Scope and frequency of audits as required?		
Conducted by appropriate persons?		
Records maintained?		
Reviewed by management?		
Deficiencies identified and corrected?		
NOTES & REMARKS:	<i>Need King Bridge Will monitor</i>	
3. <u>Training and Qualification of Personnel</u>	Lic Cond <u>N/C</u>	<u>N/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:	<i>Dr. will be sending Tech to Nuclear Medicine course at Bethesda. Good ship</i>	
4. <u>Radiation Protection Procedures</u>	Lic Cond _____	<u>N/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:	<i>Syringe shields available but not used - considered for better of syringe caps.</i>	

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEM	CRITERIA	FINDING
5. <u>Use of Materials</u>		<u>C</u>
Procurement and use as required? Authorized form & route of administration?	35.14(b)	
Special tests (moly breakthrough, leak tests, etc) required? - <i>Are any prepared sources</i>	35.14(b)(4)	
Inventory of brachytherapy sources?	35.14(b)(5)	
Dose calibration checks performed? <i>OK</i>		
Posting & labeling as required? <i>OK</i>	20.203	
NOTES & REMARKS:		

6. Storage of Materials

Material secured in both restricted and unrestricted areas? Adequately? *OK* 20.207

NOTES & REMARKS:

7. Facilities

Lic Cond _____

As described in lic cond or application? *OK*Any changes made? Adequacy? *NO*

NOTES & REMARKS:

8. Instruments

Lic Cond _____

Survey meters & instruments adequate for program? *OK*Instruments & meters operable? Calibrated? *✓*
Calibration adequate?

NOTES & REMARKS:

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No _____

INSPECTION ITEMS	CRITERIA	FINDING
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? ✓	20.401(b)	
Transfer of materials proper? Transfer records maintained? <i>NA</i>	30.41, 30.51	
Authorized containers used? Shipping papers & package labels proper for packages on hand?	71.5	
NOTES & REMARKS:		

10. <u>Personnel Protection - External</u>		<u>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	
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. <u>Personnel Protection - Internal</u>		<u>C</u>
Airborne concentrations in restricted areas? (Xe-133, patients treated with I-131) <i>NA</i>	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?		
NOTES & REMARKS:		

See Xe-133 being considered

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:		

13. <u>Notifications and Reports</u>		<u>C</u>
To individuals?	19.13	
Overexposures, excessive levels & concentrations, incidents? <i>none</i>	20.403, 20.405	
Personnel exposures and monitoring, termination reports?	20.407, 20.408	
Theft or loss of licensed material? ✓	20.402	
Misadministrations? <i>None</i>	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. Other License Conditions

INSPECTION REPORT NUMBER _____

Page ____ of ____

787108 -- Medical

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 _____

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 02-01

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APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

Licensee: Paul H. Persner, D.O.

License No: 08-19876-01

Reference _____ Basis for noncompliance _____

Report item A 1

Personnel training
P.P. 19, 20 & L.C.

10 CFR _____

Lic Cond 13 Item 12

Type n/c _____

Report item ~~B~~ B1

No Ring bridges as of day of
operation - and day of inspection

10 CFR _____

Lic Cond 13 - Item 34

Type n/c _____

Report item ~~A~~ B2

Has syringe shields, but do not use.
MD feels they are too bulky

10 CFR _____

Lic Cond 13 Item 15

Type n/c _____

Report item _____

10 CFR _____

Lic Cond _____

Type n/c _____

Report item _____

10 CFR _____

Lic Cond _____

Type n/c _____

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

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

Report No: _____

Type n/c: _____

Describe: _____

Action taken:

OPEN

CLOSED

(July 82)

INSPECTION REPORT NUMBER _____

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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 doing ^{mostly} bone scans with Tc 99.
~~Small~~ ^{Small} thyroid scans performed with Tc 99. Technologist
will be attending formal Nuclear Med. Training.

JAN 17 1983

Docket No. 30-01315

License No. 08-01709-04

Georgetown University
ATTN: Matthew F. McNaulty, Sc.D.
Chancellor, The Medical Center
3800 Reservoir Road
Washington, D. C. 20007

Gentlemen:

Subject: Inspection No. 30-01315/82-01

This refers to your letter dated December 8, 1982, in response to our letter dated November 4, 1982.

Thank you for informing us of the corrective and preventive actions documented in your letter. These actions will be examined during a future inspection of your licensed program.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:
John D. Kinneman

for Thomas T. Martin, Director,
Division of Engineering and
Technical Programs

cc:
Warren Schadt, Ph.D., Director, Radiation Control ✓
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
District of Columbia ✓

bcc:
Region I Docket Room (w/concurrences)

for RI:DETP RI:DETP RI:DETP
Ladun/dmg Johansen Kinneman
1/7/83 1/12/83 1/12/83

8301250514

1p.

35

1E:07