

TO: FILES

THRU: RO McClintock, Senior Radiation Specialist *RM*

SUBJECT: Harvard University, Cambridge, Mass 20-00297-53

FROM: WD Allen, Radiation Specialist

Inspection of subject licensee's broad license on 6/11 and 6/12/74 revealed a tightly controlled and smoothly running broad license. The only weak point of the program seems to be at the laboratory level. Because of the financial structure of the Radiation Safety Department, the users "buy" surveys from the Rad safety group. They faithfully perform monthly surveys, but the adequacy of scope and depth of these surveys are questionable. I got the feeling that they are performed for numbers alone. The next inspector might consider observing a typical lab survey to build a case for some constructive criticism.

During this inspection, I visited the burial ground and animal facility at SouthboroX, as well as some selected I-125 labs at the Harvard Medical School in Boston. The next inspection should review in depth the licensee's efforts with respect to BZ and effluents in I-125 operations - they are currently under scrutiny by the RSO to assure adequacy. The next inspection should pick some other areas of use in Boston, i.e. School of Public Health, and the Reproductive Center.

Recommend reinspection in one year, June, 1975.

*WD Allen*  
WD Allen,  
Radiation Specialist

HARVARD UNIVERSITY  
Harvard Medical School  
Harvard Dental School  
School of Public Health  
Shields Warren Radiation Therapy Center  
Sutro Animal Hospital  
Primate

INDUSTRIAL - ACADEMIC

INSPECTION REPORT NO. 20-753/25 PART 2.790(d) INFORMATION Page 1 of 1  
Attached

At Harvard University  
Cambridge Mass.

☐ Appendix A  
☐ Appendix B  
☐ Appendix C  
☐ Memo

Licensee contact: R. JOHNSON Telephone no. 682-2061

License no. 20-297-50 Last amendment and date: 12/1/77

Category: A(1-A) and Priority: III as of last amendment.

Inspection date(s): 3/20-23/78 Type of inspection: Bureau & routine

#### SUMMARY OF FINDINGS AND ACTION

- |  |  |
|--|--|
| <input type="checkbox"/> No noncompliance, clear SBI issued                      | <input type="checkbox"/> Noncompliance, SBI issued     |
| <input checked="" type="checkbox"/> Noncompliance, Appendix A                    | <input type="checkbox"/> Regional action               |
| <input checked="" type="checkbox"/> Action on previous noncompliance, Appendix B | <input type="checkbox"/> Supplemental info, Appendix C |

#### RECOMMENDATIONS

See basis in Appendix C or attached memo.

- |   |  |
|---|--|
| <input type="checkbox"/> Change Category to: _____                            | <input type="checkbox"/> Change Priority to: _____ |
| <input type="checkbox"/> Next inspection date: <u>3/79</u> ( <u>Special</u> ) | <u>See Program should be at an annual basis</u>    |

#### PERSONS CONTACTED

\* Dr. John Johnson, Animal RSO. Dr. E. Linhoff, Head Biol. Dept. 104  
\* L. S. Postel, Director of Health Service. Dr. R. Knudsen  
R. Johnson, RSO.  
T. O'Brien, RSO.

Ex 6

Inspector: E. Epstein

Approved: AD for R.O. McClintock

4/6/78

B/(1)

8309260160

9pp.

Plan approved: \_\_\_\_\_ Date: \_\_\_\_\_

Licensee: \_\_\_\_\_ License no: \_\_\_\_\_

Inspection Item	Scheduled for inspection	Post-inspection status	Module no.	766 Time Info
Management meeting - Entrance and Exit Interviews (REQUIRED)	✓	NC	927038	20 min
Initial Management Meeting	NA			
Program requirements, NC 28 (REQUIRED)	✓	NC not		30 min
Licensee Event Followup	✓		927008	4 hrs - re-examine by people
Followup on Inspector-identified problems	✓	Hybrid out 5	927018	1 hr
Followup on Noncompliance and Deviations	✓		927028	2 hr
IE Bulletin/Immediate Action Letter Followup	NA		927038	
Followup on Headquarters Requests	NA		927048	
Followup on Regional Requests	NA		927058	
Independent Inspection Effort (REQUIRED)	✓			30 min
Inspector Dispatched to Site	NA		927008	
Followup on Significant Event Occurring During Inspection	NA		927018	

## AREAS INSPECTED AND FINDINGS

777108 - Industrial - Academic

Licensee: \_\_\_\_\_ License no: \_\_\_\_\_ Amendment no: \_\_\_\_\_

INSPECTION ITEMS	CRITERIA	FINDING
1. <u>Organization</u>	Lic Cond <u>19</u>	<u>C</u>
Management organization.	Jhuston acts as RSD	
Radiation protection organization.	Ref at inspection of <del>the</del> Shapiro.	
NOTES & REMARKS:	Jhuston has 3 full time assistants he reviews results of their surveys daily and signs off on survey sheets.	
2. <u>Licensee internal audits</u>	Lic Cond <u>19</u>	<u>  </u>
Scope and frequency.		
Management controls.	one licensee suspended from use in 1977 for violating radiation	
NOTES & REMARKS:	Ex 6 procedures and receiving an 206mci I <sup>125</sup> thyroid budded as a result of opened side panel door box per to 3 hrs of li education and in lab T43 day did education 1/9/76. B+K Re. at box	
3. <u>Training and instructions to employees</u>	Lic C	<u>C</u>
Training program, scope and frequency.	yes	
Retraining.	Lic Cond <u>19</u>	
Required tests administered; scores	satisfactory.	
Instructions to workers.	yes	19.12
NOTES & REMARKS:		
4. <u>Radiation protection procedures</u>		<u>C</u>
Operating & emergency procedures	yes	
Implemented.	Lic Cond <u>19</u>	
Security.	yes good security	20.207
NOTES & REMARKS:		

## AREAS INSPECTED AND FINDINGS

Licensee: \_\_\_\_\_ License no: \_\_\_\_\_ Amendment no: \_\_\_\_\_

INSPECTION ITEM	CRITERIA	FINDING
<b>5. Materials, facilities and instruments</b>		
Authorized uses and quantities. <i>yes</i>	Lic Cond <u>19</u>	<u>C</u>
Restricted areas, posting requirements.	20.203	
Survey instruments & dosimeters; operable, properly calibrated.	Lic Cond <u>✓</u>	
NOTES & REMARKS: <i>unwounded used. Inventory - mci</i>	<i>H 3 4,204</i> <i>I 125 315</i> <i>P 32 3464</i> <i>+ many others</i>	<i>over 100 unwounded users</i> <i>&amp; least 6000x film badge series</i> <i>82 new unwounded users in 1977</i>
<b>6. Receipt and transfer of materials</b>		
Procedures implemented, adequate. <i>✓</i>	20.205, 71.57	<u>C</u>
Transfer of byproduct material. <i>✓</i>	30.67	
Labeling and packaging. <i>✓</i>	71.5, 49CFR 170-189	
Records of receipt, transfer, storage, survey, and monitoring. <i>✓</i>	30.57	
NOTES & REMARKS:		
<b>7. Personnel protection - external</b>		
Personnel monitoring control; minimize exposures, control of accumulated dose.	20.101, 20.102, 20.202 <i>✓</i>	<u>C</u>
Surveys conducted, adequate.	20.207	
Records of monitoring, surveys, disposals.	20.401, Lic Cond <u>19</u> <i>✓</i>	
Levels in unrestricted areas.	20.1, 20.106	
NOTES & REMARKS:	<i>Most exposures in P32 are a lot of research DNA.</i>	
<b>8. Personnel protection - internal</b>		
Airborne concentrations in restricted areas.	20.103	<u>C</u>
Exposure of minors. <i>none</i>	20.104	
Posting of airborne radioactivity areas. <i>✓</i>	20.203	
Survey, monitoring requirements; records. <i>✓</i>	20.207, 20.401	
Leak tests of sealed sources. <i>✓</i>	Lic Cond _____	
NOTES & REMARKS:	<i>constructed in I<sup>125</sup> Lab</i> <i>exposed over time + control</i> <i>all flows ARE 1</i> <i>on 40hr scale</i>	<i>full reports on each</i> <i>exposed over time + control</i> <i>206 mci 11/9/76</i> <i>208 mci thyroid (yes) 2/6/78</i> <i>228 mci 5/26/77</i> <i>205 mci 1/3/77</i> <i>2.2x 40hr MFLA</i>
<i>exposures to 40N P<sub>32</sub> has I<sup>125</sup></i>	<i>E+6</i>	
<i>possible 2x value</i>		
<i>remains log sketchy</i>		
<i>use of high spec act</i>		
<i>40 mci 50 mci</i>		



## AREAS INSPECTED AND FINDINGS

777120 - Industrial-Academic

Licensee: \_\_\_\_\_ License no: \_\_\_\_\_ Amendment no: \_\_\_\_\_

INSPECTION ITEM	CRITERIA	FINDING
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9. Effluent control, waste disposalC

Release of effluents.	<i>radiation at</i>	20.106
Waste disposal.	<i>was not noted to</i>	20.301, 20.303, 20.304, 20.305
Procedures, records.	<i>Est loss lab filtered</i>	20.401, Lic Cond _____

NOTES &amp; REMARKS:

*was - not noted 75% of*  
*N/A per 197-*  
*was in one other lab not noted*

10. Shipping, shipping incidentsC

Procedures for pickup, receipt, monitoring of packages.	<i>yes</i>	20.205(b) & (c) <i>all packages must be marked per 49CFR 170-189</i>
Transportation of licensed material.		71.6 <i>opening</i>
Incidents, reports, corrective actions.		49CFR 170-189

NOTES &amp; REMARKS:

*yes*11. Notifications and reportsC

To individuals.	19.13
Overexposures, excessive levels & concentrations, incidents.	20.403, 20.405 <i>N.A.</i>
Personnel exposures and monitoring, termination reports.	20.407, 20.408
Theft or loss of licensed material.	20.402

NOTES &amp; REMARKS:

12. Posting of noticesC

Part 20, license & documents, procedures, notice of violations.	<i>seen</i>	19.11(a)
REC-3.	<i>in all labs</i>	19.11(c)

NOTES &amp; REMARKS:

## AREAS INSPECTED AND FINDINGS

777188 - Industrial-Academic

Licensee: \_\_\_\_\_ License no: \_\_\_\_\_ Amendment no: \_\_\_\_\_

INSPECTION ITEM	CRITERIA	FINDING
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13. Environmental monitoring program

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

Implementation of program, scope and frequency as required.  
Records maintained, reviewed by management.

nt

NOTES &amp; REMARKS:

14. Emergency preparednessLic Cond KY

Procedures available for incidents and accidents.  
Training for personnel; coordination with supporting groups and agencies.

associated with Harvard Medical Center

NOTES &amp; REMARKS:

15. Other license conditions

Lic \_\_\_\_\_

Lic Cond 16 incineration is renewed

Lic Cond 18 burials renewed

3.6 x 10<sup>-4</sup> for burial -  
8.3% of NPLC turned

16. Confirmatory measurements

Licensee's surveys verified on sampling basis.

20.106, 20.201

NOTES &amp; REMARKS:

checked mean on radiation lab  
113 labs

at Reg I all in agreement

17. Independent inspection effort

inspected 4 persons involved in 40 hr NPLC

NOTES &amp; REMARKS:

overexposures  
20 laboratories and spoke to  
responsible individuals

## APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

Licensee: Whizad University

License no: \_\_\_\_\_

Reference:

Basis for noncompliance

Report item \_\_\_\_\_

10 CFR \_\_\_\_\_

Lic Cond 19

Type a/c \_\_\_\_\_

Smoking & eating or drinking in hall  
50% of laboratories used

pg 8  
P 7.4 Rules-

Report item \_\_\_\_\_

10 CFR \_\_\_\_\_

Lic Cond 19

Type a/c \_\_\_\_\_

pg 8  
P 9.6. waste from use of recurrent  
some P32 in Pm. Inst # 390-C.  
also smoking in this in 7 inst.  
waste must not create a radiation area  
30 m/s  
at 12" -

Report item \_\_\_\_\_

10 CFR \_\_\_\_\_

Lic Cond 19

Type a/c \_\_\_\_\_

PP 7.4 pg 7

at least one person reported for thyroid  
monitoring 6 days after iodine water  
#125 inflammation as he performs act hands  
did not decontaminate or remove hands

Report item \_\_\_\_\_

10 CFR \_\_\_\_\_

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

Type a/c \_\_\_\_\_

Report item \_\_\_\_\_

10 CFR \_\_\_\_\_

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

Type a/c \_\_\_\_\_



APPENDIX B - LICENSEE ACTION ON PREVIOUS INSPECTION FINDINGS

Licenses: \_\_\_\_\_ License no: \_\_\_\_\_

Identification and summary of action taken \_\_\_\_\_ Status \_\_\_\_\_

Report no: 76-01 Type n/c: 20.105 Describe: \_\_\_\_\_

Action taken:

*No. current item is 3 m/bw noted at Blount. for storage of P32 waste. No such in this inspection item. Similar to present noncompliance.*

~~OPEN~~  
**CLOSED**

Report no: 76-01 Type n/c: 20.207 Describe: \_\_\_\_\_

Action taken:

*storage of P32 waste not secured*

~~OPEN~~  
**CLOSED**

Report no: 76-01 Type n/c: 20.113 Describe: \_\_\_\_\_

Action taken:

*J125 overexposures. Overexposures since 12/76 that reportable under new rules*

~~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 INFO

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

License no: \_\_\_\_\_

☐ Uncorrected/repeated noncompliance☐ Unresolved items☐ Unusual occurrence, conditions, etc☒ Inspector's comments☐ Basis for change of Category or Priority

Licensee's notes not to be  
handed to note items noted by supervisor.  
Also a very lax enforcement policy  
by the scope committee

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✓ Docket No. 30-00753

APR 19 1978

President and Fellows of Harvard College  
Harvard University  
ATTN: Dr. S. Postel  
Director of Health Services  
Cambridge, Massachusetts 02138

Gentlemen:

Subject: Inspection 30-00753/78-01

This refers to the inspection conducted by Mr. E. Epstein of this office on March 20-23, 1978, at Harvard University, including Harvard Medical School, Harvard Dental School, School of Public Health, Shields Warren Radiation Lab, and the Animal Primate Center, of activities authorized by NRC License No. 20-00297-53, and to the discussions of our findings held by Mr. Epstein with Dr. J. Shapiro of your staff 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.

In addition, our inspector took wipe samples of floors and equipment located in your facilities. These samples were analyzed in our Regional Office Laboratory in King of Prussia, Pennsylvania. The basic purpose of these independent measurements was to verify your capability for identifying and evaluating radioactive contamination in your facilities. The results of our analyses indicate compliance with the applicable levels in Part 20 and were in agreement with your analyses.

Our inspector also verified the steps you had taken to correct the items of noncompliance brought to your attention in a letter dated May 21, 1976. We have no further questions regarding your action at this time.

~~2309240150~~  
2 pp.

OFFICE ▶	MRPS-EMS Kinneman:kk	MRPS-EMS McClintock				
SURNAME ▶						
DATE ▶	4/18/78	4/19/78				

President and Fellows of  
Harvard College

2

APR 19 1978

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 items of noncompliance have been categorized into the levels as described in our correspondence to you dated December 31, 1974. This notice is sent to you pursuant to the provisions of Section 2.201 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations. Section 2.201 requires you to submit to this office, within twenty (20) days of your receipt of this notice, a written statement or explanation in reply including: (1) corrective steps which have been taken by you and the results achieved; (2) corrective steps which will be taken to avoid further items of noncompliance; and (3) the date when full compliance will be achieved.

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.

Should you have any questions concerning this inspection, we will be pleased to discuss them with you.

Sincerely,

Robert O. McClintock, Chief  
Materials Radiological Protection  
Section

Enclosure: Appendix A, Notice of Violation

bcc w/encl:  
IE Mail & Files (For Appropriate Distribution)  
Central Files  
Public Document Room (PDR)  
Local Public Document Room (LPDR)  
REG:I Reading Room  
Commonwealth of Massachusetts

OFFICE ►						
SURNAME ►						
DATE ►						

APPENDIX A

NOTICE OF VIOLATION

President and Fellows of Harvard College  
Cambridge, Massachusetts 02138  
License No. 20-00297-53

Based on the results of an NRC inspection conducted on March 20-23, 1978, it appears that certain of your activities were not conducted in full compliance with the conditions of your NRC license as indicated below:

Condition 19 of your license requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in your application dated April 9, 1974. Enclosed with this application is your manual entitled "Regulations for Use of Radioisotopes at Harvard University."

1. Section 7.4, "Hygiene," on page 8 of this manual forbids smoking, eating, storing, and preparation of food in laboratories or rooms while work with unsealed radioactive sources is in progress or where contamination may exist.

Contrary to this requirement, on March 21-23, 1978, smoking, eating, drinking, and storage of food was observed in several laboratories where work with unsealed sources was in progress.

2. Section 7.4, "Hygiene," on page 7 of this manual requires that personnel working in areas containing radioactive material "wash up" before eating, smoking, or leaving work and make hand and shoe counts with appropriate equipment upon completing operations.

Contrary to this requirement, on March 21, 1978, individuals were observed leaving laboratories containing radioactive material without washing and without surveying their hand and shoes before leaving.

8309260156  
2 pp.

OFFICE ►					
SURNAME ►					
DATE ►					



3. Section 9.b, "Storage of Radioisotopes," on page 8 of this manual requires that radioisotopes be stored in a suitable container and that the direct radiation from the container not create a Radiation Area.

Contrary to this requirement, on March 21, 1978, waste containing phosphorus-32 was stored in one of your laboratories in an open plastic container causing a radiation level of 30 mrem/hr at one foot from the container, thus creating a Radiation Area.

These are infractions.

OFFICE ►						
SURNAME ►						
DATE ►						

Docket Nos. 30-00753 ✓  
70-00083

DEC 01 1978

President & Fellows of Harvard College  
Harvard University  
ATTN: Warren E. C. Wacker, M.D.  
Director of University Health Services  
Cambridge, Massachusetts 02138

Gentlemen:

Subject: Inspection 78-02

This refers to the inspection conducted by Dr. L. F. Friedman of this office on November 14 and 15, 1978, of activities authorized by NRC License Nos. 20-00297-53, S194-71 and to the discussions of our findings held by Dr. Friedman with yourself and other members of your staff at the conclusion of the inspection.

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

Our inspector also verified the steps you have taken to correct the items of noncompliance brought to your attention in the enclosure to our letter dated April 19, 1978. We have no further questions regarding your action at this time.

Within the scope of this inspection, no items of noncompliance were observed.

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 will be placed in the Public Document Room.

7901150164  
2 pp.

OFFICE ▶	FFMS	FEMS				
SURNAME ▶	<i>Friedman</i> Friedman/clc	<i>McClintock</i> McClintock				
DATE ▶	11/30/78	12/1/78				

President & Fellows of Harvard College 2

DEC 01 1978

No reply to this letter is required; however, should you have any questions concerning this inspection, we will be pleased to discuss them with you.

Sincerely,

Robert O. McClintock, Chief  
Materials Radiological Protection  
Section

bcc:  
IE Mail & Files (For Appropriate Distribution)  
Central Files  
Public Document Room (PDR)  
Nuclear Safety Information Center (NSIC)  
REG:I Reading Room  
Commonwealth of Massachusetts (2)

OFFICE ▶						
SURNAME ▶						
DATE ▶						