

2/16/89

SAFETY INSPECTION

DND COPY

<p>1. LICENSEE</p> <p>Indiana University 1100 West Michigan Street Indianapolis, IN 46223</p>	<p>2. REGIONAL OFFICE</p> <p>U.S. NUCLEAR REGULATORY COMMISSION REGION III 799 ROOSEVELT RD. GLEN ELLYN, IL 60137</p>
---	---

<p>3. DOCKET NUMBER(S)</p> <p>03001609 03009792</p>	<p>4. LICENSE NUMBER(S)</p> <p>13-02752-03 13-02752-08</p>	<p>5. DATE OF INSPECTION</p> <p>February 15-16, <del>XXXX</del> 1989</p>
---	--	--

Licensee:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission's (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The findings as a result of this inspection are as follows:

- 1. Within the scope of this inspection, no violations were observed.
- 2. The inspector also verified the steps you have taken to correct the violations identified during the last inspection. We have no further questions on those actions at this time.
- 3. During this inspection certain of your activities, as checked below, were in violation of NRC requirements. **THIS IS A NOTICE OF VIOLATION** which is required to be posted in accordance with 10 CFR 19.11.
  - A. \_\_\_\_\_ was not properly posted to indicate the presence of a \_\_\_\_\_, 10 CFR 20.203(b), (c), (d), (e) or 34.42.
  - B. Containers located in \_\_\_\_\_ were not properly labeled to indicate the presence of radioactive material. 10 CFR 20.203(f)(1), or (f)(2).
  - C. \_\_\_\_\_ of sealed sources were not performed at the proper frequencies. 10 CFR \_\_\_\_\_ License Condition Number \_\_\_\_\_.
  - D. Records of \_\_\_\_\_ were not properly maintained. 10 CFR \_\_\_\_\_ or License Condition Number \_\_\_\_\_.
  - E. Documents were not properly posted or otherwise made available. 10 CFR 19.11.
  - F. Reports or notifications of \_\_\_\_\_ were not made in accordance with 10 CFR \_\_\_\_\_ or License Condition Number \_\_\_\_\_.
  - H. The Licensee's Quarterly inventory records pertaining to ~~XXXX~~ their calibration sources did not contain all of the required information. 10CFR35.59g license #13-02752-03
  - I. The Licensee failed to maintain a leak test record for a leak test performed on a Co-60 teletherapy source on September 15, 1988. ~~XXXXXXXXXXXX~~ 10CFR35.59(d) license #13-02752-08
  - J. \_\_\_\_\_
  - K. \_\_\_\_\_

I hereby state that within 30 days the actions described by me to the inspector will be taken to correct the violations identified in the items checked above. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201. No further response will be submitted unless required by the NRC.

<p><i>Mark J. Richard</i></p> <p>SIGNATURE - LICENSEE</p>	<p>2-16-89</p> <p>DATE</p>	<p><i>D. R. Gibbons</i></p> <p>SIGNATURE - NRC INSPECTOR</p>	<p>2-16-89</p> <p>DATE</p>
---	----------------------------	--	----------------------------

8903060050 890216  
REG3 LIC30  
13-02752-03 FDC

**(8903060050)** *RE 16 pp.*

A/339

NUCLEAR MEDICAL INSPECTION FIELD NOTES

Inspection Report No. 89001

License No. 13-02752-03

Licensee (name and address)

Docket No. 03001609

INDIANA UNIVERSITY

1100 WEST MICHIGAN STREET

INDIANAPOLIS, IN 46223

Licensee Contact M.L. RICHARD

Telephone No. 317-274-4797

Last Amendment No. 55

Date of Amendment MAY 12, 1989

✓ Priority 2

Category G1

Program Codes:   
 (  ) 02110 - Broad ( ) 02201 - Private Practice - Limited   
 ( ) 02120 - Group Hospital ( ) 02220 - N.M. Van   
 ( ) 02121 - Non-Group Hos. ( ) 02209 - InVivo Testing   
 ( ) 02200 - Private Prac- ( ) 02500 - Pharmacy   
 tice - Group ( ) 02210 - Eye Application

Date of Inspection FEB. 14-15, 1989 ( ) Other

Type of Inspection: ( ) Announced (  ) Unannounced ( ) Normal   
 ( ) Initial ( ) Special (  ) Reinspection

Next Inspection Date 02 90

(  ) Normal ( ) Reduced ( ) Extended

Summary of Findings and Action:

(  ) No Violation, Clear 591 issued ( ) Action on Previous Violation   
 (  ) Violation(s), 591 issued ( ) Regional Action   
 ( ) Headquarters Action

Persons contacted: DR. J.P. LINDHOLM - CHAIRMAN RSC   
 M.L. RICHARD - RSO   
 JIMMIE MASON - ASST. RSO   
 BILL ZICKLER - HEALTH PHYSICIST   
 ROBERT WATY - ASST. DEAN SCHOOL OF MEDICINE

Those present at exit interview: \* ALL OF ABOVE

Inspector D.P. Gibson  
(Signature)

February 22, 1989  
(Date Signed)

Approved [Signature]  
(Signature)

2/22/89  
(Date Signed)

1. ORGANIZATION

- a. Organizational structure meets license requirements. (  ) Yes  
 ( ) No (L/C)  
 Remarks:

- b. Use by authorized individuals. (  ) Yes ( ) No (L/C)  
 Remarks: RSC authorize users. during RSC meeting. a  
 ✓ review of the minutes indicated that users have  
 been properly approved.

- c. Radiation Safety Committee meets at required intervals. (  ) Yes ( ) No  
 (35.22 (a)(2))  
 Membership in accordance with 35.22 (a)(1) L/C (  ) Yes ( ) No

- d. Record of Committee meetings. (  ) Yes ( ) No (L/C or 35.22 (a)(4))  
 Remarks:

2. INSPECTION HISTORY

- a. Item(s) of violations or deviations noted during last inspection  
 conducted on JUNE 27, 28, 1985 (  ) Yes ( ) No.  
 Response letter dated AUGUST 16, 1985

b.

<u>Requirement</u>	<u>Type of Violation</u>	<u>Corrective Action Taken</u>		<u>Status</u>	
		( <input checked="" type="checkbox"/> ) Yes	( ) No	Open	Close
✓ L/C 26	RADIOACTIVE WASTE WAS NOT SURVEYED PRIOR TO DISPOSAL				
L/C 25	MONTHLY SURVEYS WERE NOT BEING PERFORMED AS REQUIRED IN THE AREA WHERE BPM WAS USED.				

(continue b. paragraph 20, if needed)

- c. If any item(s) of violations or deviations noted during last inspection  
 were not corrected, explain.

3. SCOPE OF PROGRAM

✓ This is a very large program with diagnostic and therapy. They use a 2.5 Ci Generator at the University hospital and a 1.350 Ci Generator weekly at a school hospital. They perform 104 to 150 implants annually using Co-137, I-125, In-192. They have a 1408 Ci (10-30-84) Co-137 generator used for irradiation of blood samples. They have a Sr-90 eye applicator used infrequently, but used in early 1987

4. INTERNAL AUDITS OR INSPECTIONS

- a. Required by license condition. () Yes () No  
monthly by Rad. safe. staff
- b. Audits or inspections conducted () Yes () No (L/C)
- c. Records maintained. () Yes () No (L/C)

✓ Remarks: The RSO Office and Committee issues periodic progress reports as reviewed quarterly. RSO Reviews the entire radiation program annually

5. TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS

- a. Training program required by license condition. () Yes () No  
all personnel at least 30 hrs basic health physics
- b. Training program implemented. () Yes () No (L/C)

Remarks: a 10 hr radiation is conducted 2 times each year by the RSO staff.

- c. Retraining program required by license condition. () Yes () No
- d. Retraining program implemented. () Yes () No (L/C)

Remarks:

- e. Instruction to workers in accordance with 10 CFR 19.12 () Yes  
() No (19.12)
- Remarks:

6. RADIOLOGICAL PROTECTION PROCEDURES

a. Procedure referenced in license condition. ( Yes ( ) No

b. Used in accordance with referenced procedure. ( Yes ( ) No  
Remarks:

c. Individuals understanding of procedures adequate. ( Yes ( ) No  
Remarks:

d. Examples of key procedures:

(1) ordering and accepting packages RAM ( Adequate ( ) Inadequate

(2) general rules for safe use of RAM ( Adequate ( ) Inadequate

(3) emergency procedures ( Adequate ( ) Inadequate

(4) survey procedures ( Adequate ( ) Inadequate

(5) handling of volatile RAM (e.g., Xe-133, I-131)  
( Adequate ( ) Inadequate

(6) precautions for use of RAM (sealed and unsealed) for therapy  
( Adequate ( ) Inadequate

7. MATERIALS, FACILITIES AND INSTRUMENTS

a. Facilities as described in license application. ( Yes ( ) No (L/C)  
Remarks:

b. Isotope, chemical form, quantity and use as authorized. ( Yes ( ) No (L/C)  
Remarks:

✓ c. Tests required by license condition or regulations.

(1) molybdenum-99 breakthrough. ( Yes ( ) No (35.204(a))

*BOTH HOSPITALS* (2) performed as required. ( Yes ( ) No  
(L/C and/or 35.204(b))

(3) records maintained. ( Yes ( ) No (35.204(c))  
Remarks:

(4) leak tests (  ) Yes ( ) No

(5) leak tests performed as required. (  ) Yes ( ) No (L/C)  
(35.59 (b)(1), 35.59 (b)(2), 35.59 (c)(1))  
Remarks:

(6) other tests required (e.g., physical inventories; surveys to ensure that patients contain 30 millicuries of Au-198, I-131 before leaving hospital) (L/C or 35.75)

d. Inventory of sealed sources.

(1) Inventory of Group VI sources. (  ) Yes ( ) No (35.59 (g))

(2) Inventory of calibration sources. (  ) Yes ( ) No (35.59 (g))  
*performed monthly, but no proper record (OVNR)*

e. Areas for storage and use of radioactive materials.

(1) Method used to prevent an unauthorized individual from entering a restricted area is adequate. (  ) Yes ( ) No

(2) Radioactive material secured to prevent unauthorized removal from an unrestricted area. (  ) Yes ( ) No (20.207)  
Remarks:

f. Instrumentation.

(1) Operable survey instruments are as described or equivalent to those described in license application. (  ) Yes ( ) No (L/C or 35.120, 35.220, 35.330, or 35.420)  
Remarks:

(2) Capability of radiation survey instruments is adequate for program  
(  ) Yes ( ) No  
Remarks:

(3) Calibration of survey instruments required. (  ) Yes ( ) No

(4) Performed as required. (  ) Yes ( ) No (L/C or 35.51)  
Remarks:

*most are done at 6 mo. intervals.*

*See daily checks at 10 hospitals. The other*  
(5) Dose calibrator checks required. () Yes () No *one in RSO office*

(6) Performed as required. () Yes () No (L/C or 35.50)  
*daily, quarterly manually*

8. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

Receipt of incoming packages during "off-duty" hours by whom?

Where stored? *3 2600 order for year from the RSO office*

Security? *Secured in the RSO office*

a. Survey of incoming packages. () Yes () No (20.205(b)(1)) - L/C  
Remarks:

b. Record of survey. () Yes () No (20.401(b))  
Remarks:

c. Procedure for opening packages. () Yes () No (L/C; 20.205(d))  
Remarks: *Opened by RSO staff and wife  
Tested*

d. BPM transferred in accordance with 10 CFR 30.41. () Yes () No  
(30.41)  
Remarks:

e. Records of receipt and transfer maintained. () Yes () No  
(30.51)  
Remarks:

9. PERSONNEL RADIATION PROTECTION - EXTERNAL  
(Obtain information regarding whole body and extremity monitors)

- a. Film or TLD badge supplier LANUANG Frequency MONTHLY
- b. Reports reviewed by RSO STAFF Frequency AS RECEIVED  
(Are badges assigned to personnel as per licensee's correspondence with NRC?)
- c. NRC inspector reviewed personnel monitoring records for period JULY 1985 to JAN 14, 1988
- d. NRC forms or equivalent.

(1) NRC-4: ( ) Yes (  ) No Complete: ( ) Yes (  ) No

(2) NRC-5: (  ) Yes ( ) No Complete: (  ) Yes ( ) No  
(20.401 (a))

Remarks:

e. Maximum quarterly whole-body exposure. 680

f. Maximum quarterly extremity exposure. 2410

g. Licensee has implemented an ALARA program. (  ) Yes ( ) No (35.20)  
Remarks:

h. Radiation survey of unrestricted areas. (  ) Yes ( ) No  
(20.201(b) to show compliance with 20.105 (b), 35.415(a)(4), 35.315(a)(4))

Remarks: all labs are surveyed at least quarterly by RSO staff with direct and wife test surveys.  
Investigator or users are required to do monthly.

i. Record of surveys maintained. (  ) Yes ( ) No (20.401 (b) to show compliance with 20.105(b) 35.315(a)(4) or 35.415(a)(4))  
Remarks:

j. Radiation survey of use areas (hot lab, therapy treatment area, patient's room, etc.). (  ) Yes ( ) No (L/C or 35.70, 35.59(h), 35.315(a)(4)) Nuclear medicine lab monthly by RSO staff  
Remarks: daily by hospital

2-13-89 AND 2-14-89 A SURVEY INSTRUMENT WAS SENT IN FOR CALIBRATION. IT APPEARS THAT THE DAILY SURVEY WAS POSSIBLY MISSED, IN DEPTH WITH A BORROWED INSTRUMENT. RSO STAFF HAS INTENT TO SEND A REPLACEMENT DURING CALIBRATION.



k. Record of survey maintained. (  ) Yes ( ) No (L/C, 35.70(h), 35.415(a)(4))

10. PERSONNEL RADIATION PROTECTION - INTERNAL

a. Potential for exposure of individuals to airborne radioactive material exists. (  ) Yes ( ) No.

Remarks: *Hood are checked during the quarterly survey and annually.*

b. Monitoring for airborne radioactivity conducted. (  ) Yes ( ) No (20.201(b)) to show compliance with all sections of 20.103 - (L/C, or 35.205)

Remarks:

c. Records of monitoring maintained. (  ) Yes ( ) No (20.401(b) or L/C or 35.205(d))

Remarks:

d. Bioassay program implemented as described in correspondence with NRC (  ) Yes ( ) No (L/C or 35.315(a)(8))

11. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

a. Radioactivity in effluents to unrestricted areas. (  ) Yes ( ) No

b. Release in accordance with regulatory limits. (  ) Yes ( ) No (20.106(a))

Remarks:

c. State solid waste disposal method. *held for decay, disposed by RSO staff. No incineration since Nov, 1967.*

d. State liquid waste disposal method. *some in sewer.*

e. Disposal of solid and liquid waste in accordance with regulatory requirements (decay in storage). (  ) Yes ( ) No (L/C or 35.92)

Remarks:

f. Records of disposal. () Yes ( ) No (30.51 or 35.92(b))

Remarks:

g. Survey of waste prior to disposal. () Yes ( ) No  
(20.201(b) to show compliance with 20.301 35.92(a)(2))

Remarks:

UNIV. HOSP. LAST 1-13-89 FOR 12-29-88  
R. L. " 2-13-89 FOR 2-7-89 TCM

✓ h. Records of surveys maintained. () Yes ( ) No (20.401(b) or 35.92(b))

Remarks:

The inspectors inspected the waste storage area. It is in a very secured area and contains over 200 barrels of wood. Most are E-125 waiting for decay.

## 12. NOTIFICATIONS AND REPORTS

a. Licensee in compliance with 10 CFR 19.13 (reports to individuals).  
() Yes ( ) No (19.13)

Remarks:

b. Licensee in compliance with 10 CFR 20.405 (overexposures).  
() Yes ( ) No (20.405(a))

Remarks:

c. Licensee in compliance with 10 CFR 20.403 (incidents).  
() Yes ( ) No (20.403)

Remarks:

d. Licensee in compliance with 10 CFR 20.402 (theft or loss).  
() Yes ( ) No (20.402(a) or 20.402(b))

Remarks:

- e. Licensee in compliance with 10 CFR 35.33 and 35.44 (misadministration). (  ) Yes ( ) No (35.33a,b,c or d) and 35.44)

Remarks:

10-7-86 REPORTED 1 for 2nd quarter 1986  
9-17-87 " 1 for 9-8-87

13. POSTING OF NOTICES

- Notices to workers posted. (  ) Yes ( ) No (19.11(a) or (b)) (19.11(c))

Remarks:

14. CONFIRMATORY MEASUREMENTS/INDEPENDENT MEASUREMENTS

- a. Measurements made by inspector. (  ) Yes ( ) No

b. Survey instrument E 120 NRC Serial No. 007931

- c. Describe type and results of measurements and compare with licensee's measurements. CAMERA COUNTE BUB TO 1.2 mpp/Hr CONTACT

✓ OTHER AREA BUB TO 0.9 mpp/Hr

15. POSTING AND LABELING

- Posting and labeling in accordance with 10 CFR 20.203. (  ) Yes ( ) No (20.203 or 35.60 or 35.66)

Remarks:

16. LICENSE CONDITIONS

- a. All license conditions reviewed during inspection. (  ) Yes ( ) No

b. Activities were conducted in accordance with license conditions, except as noted elsewhere in this report (  ) Yes ( ) No

17. BULLETINS AND INFORMATION NOTICES

- a. Bulletins and Information Notices issued during current year.
- b. Bulletins and Information Notices received by licensee.  Yes  
 No.  
 Remarks:
- c. Licensee took appropriate action in response to Bulletins and Information Notices.  Yes  No  
 Remarks: *INFO ONLY*

18. TRANSPORTATION ( 10 CFR 71.5a and 49 CFR 171-178)

- |  | <u>Yes</u>                          | <u>Violation</u>         |
|--|-------------------------------------|--------------------------|
| a. License makes shipments of RAM?<br>If "Yes", complete the following items.  | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| b. Such shipments consisted of:  |                                     |                          |
| <input checked="" type="checkbox"/> radwaste   |                                     |                          |
| <input checked="" type="checkbox"/> sources/products   |                                     |                          |
| <input type="checkbox"/> other _____   |                                     |                          |
| c. For radwaste, shipments are:  |                                     |                          |
| <input type="checkbox"/> by licensee, using common carrier   |                                     |                          |
| <input checked="" type="checkbox"/> through Radwaste Broker<br>name of Broker <u>ADCO</u>  |                                     |                          |
| d. Licensee is aware of 10 CFR 61:<br>Radwaste requirements for generators? <input checked="" type="checkbox"/> <input type="checkbox"/>   | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Licensee has classified and characterized<br>its radwaste? (20.311(d)) <input checked="" type="checkbox"/> <input type="checkbox"/>  | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <p><i>SHIPS 2-3 times/year 27 to 55 drums 200 to 850 mci/yr</i></p> <p><input checked="" type="checkbox"/> 10-5-88 50 DRUMS 430.2167 mci TOTAL<br/>             128.062 mci H-3<br/>             17.173 mci C-14</p> <p>3-18-88 34 DRUMS 229.93541 mci TOTAL<br/>             44.8658 mci H-3<br/>             211.6706 mci C-14</p> <p>12-1-87 52 DRUMS 352.56 mci TOTAL</p> <p>6-3-87 49 DRUMS 613 mci TOTAL</p> <p>1-20-87 47 DRUMS 743.13749 mci TOTAL</p> |                                     |                          |

19. LIST OF VIOLATION(S)

20. CONTINUATION OF REPORT ITEMS - USE BACK OF PAGE IF NECESSARY

✓ The licensee performs 80 to 90 implants each year. most procedures are less than 36 hours. This includes 3 6/24 treatment with T<sub>2</sub>-192 wires.



7. Are periodic audits conducted of the radiation safety program by the licensee and/or a contractor and do the audits appear adequate?  
(  ) Yes                      (    ) No                      (    ) N/A
8. Are licensee's radiation exposures in accordance with ALARA?  
(  ) Yes                      (    ) No                      (    ) N/A
9. Are reportable events (10 CFR 20.402, 20.403, 20.405) kept to a level commensurate with the licensee's workload?  
(  ) Yes                      (    ) No                      (    ) N/A
10. Are the number of repeat violations kept to a minimum and has the licensee successfully implemented corrective actions on previous violations?  
(  ) Yes                      (    ) No                      (    ) N/A
11. Are safety-related allegations kept to a minimum level? Does the licensee have an adequate system to follow up on complaints?  
(  ) Yes                      (    ) No                      (    ) N/A
12. Are licensee's reports and responses to violations complete, candid and timely?  
(  ) Yes                      (    ) No                      (    ) N/A
13. Are misadministrations (diagnostic or therapeutic) kept to a level commensurate with the licensee's workload?  
(  ) Yes                      (    ) No                      (    ) N/A
14. Does the licensee have sufficient instrumentation to safely manage the program and are those instruments properly maintained? (e.g., Is there a preventive maintenance/quality assurance program?)  
(  ) Yes                      (    ) No                      (    ) N/A
15. Does the licensee have an adequate program in place to store radioactive waste safely? (e.g., Are materials properly labeled and inventoried? Is exposure to the elements controlled?)  
(  ) Yes                      (    ) No                      (    ) N/A

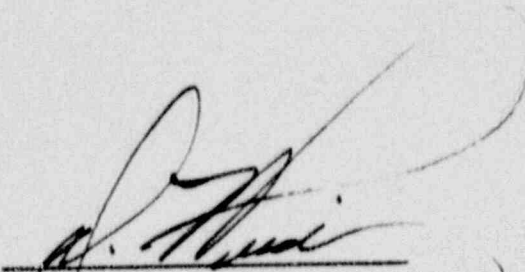
Inspector's Comments: (Required for any factor given a negative response)

Action Required: (As deemed by Region III management, i.e., telephone contact, licensee management meeting, increased inspection effort, etc.)

Action Taken:

2 MINOR VIOLATIONS, IDENTIFIED  
59) ISSUED IN THE FIELD

Section Chief Signature:



Date:

2/22/89