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Med

INSPECTION REPORT NO. 7901

Attached

Licensee Name and Address:  
LAKEWOOD HOSPITAL  
14519 DETROIT AVENUE  
LAKEWOOD, OHIO 44107

- Appendix A
- Appendix B
- Appendix C
- Appendix D
- None

Licensee contact: WILFRED GILL, M.D., RSO Telephone no. 216-521-4200

License no. 3A-01192-01 Last amendment and date: NO. 25; 12-2-77

Category: G and Priority: A as of last amendment.

Inspection date(s): 9-20-79 Type of inspection: 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

REMEDIATIONS

See basis in Appendix C or attached memo.

- Change Category to: \_\_\_\_\_
- Change Priority to: \_\_\_\_\_
- Next inspection date: 9-82

PERSONS CONTACTED

WILLIAM FAYEN, M.D., AUTH. USER

PAT DEVLIN, NUC. MED. TECH. SUPERVISOR

\_\_\_\_\_

\_\_\_\_\_

B209220258 820729  
PDR FOIA  
MIHAL82-310 PDR

Inspector: William H. Schultz

Approved: C.J. Paparelli

9-27-79  
Date signed  
9/28/79  
Date signed

AGO

AREAS INSPECTED AND FINDINGS

INSPECTION ITEMS	Acceptable (A) Unresolved (U)	Noncompliance No.	FINDING
<p><u>1. Organization</u></p> <p>Structure of organization as described in requirements?</p> <p>NOTES &amp; REMARKS: ORGN. AS DESCRIBED IN APPLICATION DATED 9-28-77. THIS INCLUDES AUTHORIZED USERS AS WELL AS MEMBERS OF ISOTOPE COMMITTEE. COMMITTEE REQUIRED TO MEET QUARTERLY, HOWEVER, LAST MEETING WAS HELD ON 1-30-78. NONCOMPLIANCE WITH LICENSE CONDITION NO. 15. ADMINISTRATOR IS JOHN S. ZANGHI</p>	Lic Cond <u>15</u>	<p style="text-align: center; border: 1px solid black; border-radius: 50%; padding: 10px; width: fit-content; margin: auto;">N/C</p>	
<p><u>2. Licensee internal audits</u></p> <p>Scope and frequency of audits as required? Conducted by appropriate persons? Records maintained? Reviewed by management? Deficiencies identified &amp; corrected?</p> <p>NOTES &amp; REMARKS: THIS REVIEW INCLUDES FACILITIES, EQUIPMENT &amp; RECORDS. RECORD KEPT OF RESULTS OF THE REVIEW. RECORDS ARE REVIEWED BY MANAGEMENT.</p>	Lic Cond <u>15</u>		
<p><u>3. Training and qualification of personnel</u></p> <p>Training &amp; retraining conducted as required? ✓ Written &amp; oral exams conducted? Examination results reviewed by management? Instructions to workers per 19.12? ✓</p> <p>NOTES &amp; REMARKS: ACADEMIC TRAINING (CERTIFICATION) &amp; ON-THE-JOB TRAINING</p>	Lic Cond <u>15</u>	19.12	<u>A</u>
<p><u>4. Radiation protection procedures</u></p> <p>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? ✓</p> <p>NOTES &amp; REMARKS: DAILY SURVEY OF HANDS &amp; CLOTHING WITH RECORD. ALSO, WEEKLY DIRECT-READING &amp; WIPE SURVEY WITH RECORD. ALL WASTE SURVEYED PRIOR TO DISPOSAL WITH RECORD</p>	Lic Cond <u>15</u>		<u>A</u>

INSPECTION ITEM	CRITERIA	FINDING
5. <u>Use of materials</u>	Lfc Cond <u>9</u>	<u>A</u>
Procurement and use as required? ✓ Special tests (moly breakthrough, leak tests, etc) required? ✓ Dose calibration checks performed? ✓ Posting & labeling as required? ✓	ALL USES AS AUTHORIZED. MOLY BREAKTHROUGH TEST IS NOT REQUIRED SINCE ALL MATERIAL 20.203 IS RECEIVED AS TECHNETIUM 99m.	
NOTES & REMARKS:	FROM PHARMACO NUCLEAR - NO GENERATOR IS USED. DOSE CALIBRATOR CHECKED & SEALED SOURCES ARE LEAK TESTED BY NUCLEAR MEDICINE ASSOCIATES.	
6. <u>Storage of materials</u>	20.207	<u>A</u>
Material secured in both restricted and unrestricted areas? Adequately?	STORAGE ONLY IN HOT LAB. WHICH IS A RESTRICTED AREA	
NOTES & REMARKS:		
7. <u>Facilities</u>	Lfc Cond <u>15</u>	<u>A</u>
As described in lfc cond or application? Any changes made? Adequately?	FACILITIES AS DESCRIBED & ADEQUATE FOR SCOPE OF PROGRAM.	
NOTES & REMARKS:		
8. <u>Instruments</u>	Lfc Cond <u>15</u>	<u>A</u>
Survey meters & instruments adequate for program? Instruments & meters operable? Calibrated? Calibration adequate?	SURVEY METERS ADEQUATE FOR PROGRAM. CALIBRATED ANNUALLY BY NMA	
NOTES & REMARKS:		

INSPECTION ITEMS	CRITERIA	FINDING
<u>A</u>		
<u>B. Receipt and transfer of material</u>		
Written procedures for pickup, receiving, opening packages? ✓	20.205	
Survey of packages when received? NOT REQD.	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	
<u>NOTES &amp; REMARKS:</u>		
ALL ISOTOPES FROM PHARMACO NUCLEAR IN SINGLE DOSE SYRINGES. NO RECEIVING SURVEY IS REQUIRED. ALL RECORDS ARE MAINTAINED AS REQUIRED.		

<u>A</u>		
<u>10. Personnel protection - external</u>		
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? ✓		
Surveys conducted? Adequate? ✓	20.201	
Records of monitoring, surveys? ✓	20.401	
Levels in unrestricted areas within limits? ✓	20.1, 20.105	
<u>NOTES &amp; REMARKS:</u>		
MONTHLY R.S. LANGAUER FILM BADGE SERVICE. REVIEWED FOR 1978 AND 1979. MAX. ANNUAL BODY EXPOSURE WAS 860 MREM AND MAX. ANNUAL RING WAS 1630 MREM		

<u>A</u>		
<u>11. Personnel protection - internal</u>		
Airborne concentrations in restricted areas? NO	20.103	
Exposures to minors? NO	20.104	
Posting of airborne radioactivity areas? N/A	20.203(d)	
Survey, monitoring adequate for airborne radioactivity, surface contamination? Records maintained?	20.201 20.401	
<u>Bioassay</u>		
<u>NOTES &amp; REMARKS:</u>		
N/A - NO AIRBORNE CONTAMINATION PROBLEM		

INSPECTION ITEM	CRITERIA	FINDING
12. <u>Effluent controls, waste disposal</u>	20.106, 20.303 20.301, 20.303, 20.304, 20.305 20.401, Lic Cond _____ 20.401	<u>A</u>
Release of effluents controlled? N/A Waste disposals controlled? YES Procedures, records maintained? ✓ Surveys made? Adequate? ✓		
<p>NOTES &amp; REMARKS: ESSENTIALLY EVERYTHING IS RETURNED TO THE SUPPLIER PHARMACO NUCLEAR. IF SMALL AMOUNTS OF ACTIVITY ARE REMOVED FROM SYRINGE THE VIAL IS DELAYED TO BACKGROUND IN STORAGE</p>		
13. <u>Notifications and reports</u>	19.13 20.403, 20.405 20.407; 20.408 20.402	<u>A</u>
To individuals. N/A Over-exposures, excessiv. levels & concentrations, incidents. N/A Personnel exposures and monitoring, termination reports. N/A Theft or loss of licensed material. N/A		
NOTES & REMARKS:		
14. <u>Posting of notices</u>	19.11(a) 19.11(c)	<u>A</u>
Part 20, license & documents, procedures, notice of violations posted? ✓ NRC-3 posted? ✓		
NOTES & REMARKS:		
15. <u>Other license conditions</u>	Lic	<u>A</u>
<p>• ALL LICENSE CONDITIONS WERE REVIEWED AND NO PROBLEMS WERE NOTED</p>		

INSPECTION ITEMS	CRITERIA	FINDING
<u>16. Confirmatory measurements</u>	GENERAL SURVEY OF HOT LAB & STORAGE AREA WITH EBERLINE MODEL E500-B, NRC NO. 0006A0 LAST CALIBRATED 8-25-79. RADIATION LEVEL ABOVE STORAGE AREA WAS 1.0 MR/HR. GENERAL HOT LAB AREA WAS 0.01 MR/HR.	<u>A</u>
<u>17. Independent inspection effort</u>	WALK-THRU OF ALL FACILITIES - NO PROBLEMS NOTED	<u>A</u>
<u>18. Incidents and events</u>	Any incidents of misadministrations, contamination, etc. not otherwise covered by reports?	<u>A</u>
	NONE	

INSPECTION ITEMS	FINDING
19. <u>Summary of Licensed Program</u>	
Kind of program; number of people; rate of use or quantities on hand; places and frequency of use; type, quantity and use as authorized; and in accord with procedure 78710B.	<u>A</u>
2 FULL TIME TECHS & 1 PART TIME TECH.	
ALL USES AS AUTHORIZED	
PRINCIPALLY SCANNING PROCEDURES WITH OCCASIONAL THERAPY. $I^{131}$ ABOUT 8 mCi/TREATMENT AND $P^{32}$ ABOUT 7 mCi/TREATMENT.	
20. <u>Source of Information for Items Inspected</u>	
In accordance with items checked in Appendix D.	

APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

NOTE: Bases for noncompliances to be documented here, not under Notes & Remarks for each individual item

Reference	Basis for noncompliance
Report item <u>1</u> 10 CFR _____ Lic Cond <u>15</u> Type n/c <u>INF</u>	LIC. COND. NO. 15 REQUIRES THAT LICENSEE SHALL POSSESS & USE LICENSED MATERIAL IN ACCORDANCE WITH STATEMENTS, REPRESENTATIONS & PROCEDURES CONTAINED IN APPLICATION DATED 9-28-77. THIS APPLICATION STATED ISOTOPE COMMITTEE WOULD MEET QUARTERLY, HOWEVER, LAST COMMITTEE MEETING WAS HELD ON 1-30-78.
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 _____	
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	

APPENDIX B - LICENSEE ACTION ON PREVIOUS INSPECTION FINDINGS

Identification and summary of action taken	Status
<p>Report no: <u>7601</u> Type n/c: <u>DEF.</u></p> <p>Action taken: RECORD NOW MAINTAINED OF ALL SURVEYS OF WASTE PRIOR TO DISPOSAL.</p>	<p>Describe: <u>NO RECORD OF SURVEY OF WASTE BEFORE DISPOSAL.</u></p> <p>OPEN CLOSE</p>
<p>Report no: _____ Type n/c: _____</p> <p>Action taken: _____</p>	<p>Describe: _____</p> <p>OPEN CLOSED</p>
<p>Report no: _____ Type n/c: _____</p> <p>Action taken: _____</p>	<p>Describe: _____</p> <p>OPEN CLOSED</p>
<p>Report no: _____ Type n/c: _____</p> <p>Action taken: _____</p>	<p>Describe: _____</p> <p>OPEN CLOSED</p>
<p>Report no: _____ Type n/c: _____</p> <p>Action taken: _____</p>	<p>Describe: _____</p> <p>OPEN CLOSED</p>

APPENDIX D - SOURCE OF INFORMATION

(✓) appropriate item

1. Discussions with:

- a. Hospital Administrator
- b. Heads of Departments in which BPM is used.
- c. Isotope Committee Members
- d. Radiation Safety Officer
- e. Authorized Users
- f. Physicians working under the supervision of authorized users.
- g. Chief Nuclear Medicine Technologist
- h. Medical Technologist
- i. Student trainees in Nuclear Medicine Technology
- j. Others; Specify \_\_\_\_\_

2. Records Review

- a. Radiological Protection Procedures
- b. Emergency Procedures
- c. BPM Receipt
- d. BPM Transfer
- e. BPM Use
- f. BPM Inventory
- g. Waste Disposal
- h. Instrumentation - Calibration, Results, Schedules
- i. Special Tests - Moly breakthrough, etc.
- j. Leak Tests
- k. Radiation Surveys
- l. Personal Monitoring
- m. Effluent Evaluation
- n. Shipping Incidents
- o. Notification and Report
- p. Others; Specify \_\_\_\_\_

APPENDIX C - SUPPLEMENTARY INFO -----

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- |   |   |
|---|---|
| <input type="checkbox"/> Uncorrected/repeated noncompliance       | <input type="checkbox"/> Unresolved items     |
| <input type="checkbox"/> Unusual occurrence, conditions, etc      | <input type="checkbox"/> Inspector's comments |
| <input type="checkbox"/> Basis for change of Category or Priority |   |
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APPENDIX D - SOURCE OF INFORMATION  
(continued)

3. Observations

- a. Dose Preparation
- b. Dose Calibrator Usage
- c. Administration of Dose to Patient
- d. Use of Instruments
- e. Laboratory Facilities and Equipment
- f. Others; Specify \_\_\_\_\_

4. Independent Measurements

- a. Direct Radiation
- b. Smear Surveys
- c. Dosimetric Readings, Where Appropriate
- d. Others; Specify \_\_\_\_\_