

LICENSE NO: 29-20597-01

DOCKET NO. (s) 030-19962

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ATTACHED

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

INSPECTION REPORT NO. 84-01

St Mary's Hospital

Orange, N.J.

LICENSEE CONTACT: Dr. Wad. Miller / TRANN WEBER

Telephone No: 201-266-3060 ^{Nuclear Med}

LICENSE NO: 29-20597-01

CATEGORY G PRIORITY: 3

CATEGORY _____ PRIORITY: _____

CATEGORY _____ PRIORITY: _____

INSPECTION DATE (s): 7/19/84

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 ^X

- ^{n/a} ☐ ACTION ON PREVIOUS NONCOMPLIANCE, APPENDIX B
☐ NONCOMPLIANCE, 591 ISSUED ^{*}
☐ SUPPLEMENTAL INFO, APPENDIX C

RECOMMENDATIONS
SEE BASIS IN APPENDIX C

^{*} (No one present in room 541)

☐ CHANGE CATEGORY TO: _____ ☐ CHANGE PRIORITY TO: _____

☒ NEXT INSPECTION DATE: 7/87

Mr. Charles Brennan, Vice President - by phone only 7/27/84

Trann Weber #1 Nuclear Medicine Tech

Joseph P. ASTAPPAXI #2 Tech

"Maggie" - student temporarily at St Mary's as for OTJ training as part of Nucl Med school.

Dr. Wad. M. Miller (M.D.) authorized user T E R S O ?

Dr. Natiello M.D. - recently hired physician in Radiology

INSPECTOR: C. Starns

APPROVED: J. Miller

7/27/84

^{*} (Mr. Brennan was on vacation on day of inspection)

INSPECTION PLAN AND REPORT NUMBER _____

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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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787108 - Medical

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEMS

CRITERIA

FINDING

1. Organization

Lic Cond _____

Structure of organization as described in requirements?

Scope of Program? Patient load?

NOTES & REMARKS:

(The license for this nuclear medicine program at St Marys was issued in May 1983. Previously, the nuclear medicine was done under one license covering the nuclear medicine at other hospitals in the Orange area, such as Orange General, and Orange Memorial as well as St Marys.

2. Licensee Internal Audits

Lic Cond _____

Scope and frequency of audits as required?

Conducted by appropriate persons?

Records maintained?

Reviewed by management?

Deficiencies identified and corrected?

NOTES & REMARKS:

The same techs worked at each of these hospitals on various days of the week.

According to Weber, Dr. Mansden, the consulting physicist comes at random unannounced times, and he does observe the techs, techniques, procedures etc., and make recommendations (and she was apparently very receptive to this).

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

Authorized users? On license? Available in emergency?

Lic Cond _____

NOTES & REMARKS:

Tech lectures to nurses housekeeping comes in at 7:30 A.M., when techs are present.

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?

Close out Surveys on Patients receiving temporary implants?

35.14 (b)(5)(v)

no implants

Emergency procedures for spills, etc?
Personnel understand procedures?

NOTES & REMARKS:

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEM	CRITERIA	FINDING
5. Use of Materials		
Procurement and use as required? Authorized form & route of administration?	35.14(b) —	procured in individual doses from Syneos
Special tests (moly breakthrough, leak tests, etc) required?	35.14(b)(4) —	(no generator)
Inventory of brachytherapy sources?	35.14(b)(5) —	none used
Dose calibration checks performed?	20.203	Co-57, Cs-137, and Ba-133 daily. (Co-137 on all settings)
Posting & labeling as required? <i>C</i>		linearities guaranteed
NOTES & REMARKS:		
6. Storage of Materials		
Material secured in both restricted and unrestricted areas? Adequately?	20.207	According to Weber, the techs made a point for one of them to be always present — but if not, door locked
NOTES & REMARKS:		
7. Facilities		
As described in lic cond or application?	Lic Cond _____	— well-equipped
Any changes made? Adequacy?		good housekeeping
NOTES & REMARKS:		
8. Instruments		
Survey meters & instruments adequate for program?	Lic Cond _____	Victoreon Model 998 G-41
Instruments & meters operable? Calibrated?		(includes R/hr range)
Calibration adequate?		— twice a year by Dr. Hansen
NOTES & REMARKS:		

AREAS INSPECTED AND FINDINGS

Licensee: License No: Amendment No

INSPECTION ITEMS	CRITERIA	FINDING									
9. <u>Receipt and Transfer of Material</u>											
Written procedures for pickup, receiving, opening packages?	20.205	(monitoring includes swiffs)									
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	(no shipping)									
NOTES & REMARKS:											
10. <u>Personnel Protection - External</u>											
Personnel monitoring controls adequate? Exposures minimized?	20.101, 20.202	Exposures kept down e.g. totals for 1984 as of 6/14/84: <table><tr><td>WEBER →</td><td>WHOLE BODY</td><td>RIN</td></tr><tr><td>#264 →</td><td>140</td><td>930</td></tr><tr><td></td><td>220</td><td>280</td></tr></table>	WEBER →	WHOLE BODY	RIN	#264 →	140	930		220	280
WEBER →	WHOLE BODY		RIN								
#264 →	140		930								
	220		280								
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	direct reading device well below limits									
NOTES & REMARKS:											
11. <u>Personnel Protection - Internal</u>											
Airborne concentrations in restricted areas? (Xe-133, patients treated with I-131)	20.103	Xe-133 traps checked by collecting at exhaust with G. by caps only									
Exposures to minors?	20.104										
Posting of airborne radioactivity areas?	20.203(d)	swipes weekly									
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. Effluent Controls, Waste Disposal		
Release of effluents controlled? (particularly Xe-133, radioiodine where used)	20.106, 20.33	(See Item 11, above)
Waste disposals controlled?	20.301, 20.303, 20.304, 20.305	
Procedures, records maintained?	20.401, Lic Cond	held for decay: then to normal
Surveys made? Adequate?	20.401	after monitoring & after discussing procedures at some length with tech, it appears that surveys were adequate (with GM in low B.G. area)
NOTES & REMARKS:		
13. Notifications and Reports		
To individuals?	19.13	
Overexposures, excessive levels & concentrations, incidents?	20.403, 20.405	none
Personnel exposures and monitoring, termination reports?	20.407, 20.408	n/c
Theft or loss of licensed material?	20.402	none
Misadministrations?	35.41-35.45	"definitely" none according to Weber, who described the measures taken to avoid misadministrations
NOTES & REMARKS:		
14. Posting of Notices		
Part 20, license & documents, procedures, notice of violations posted?	19.11(a)	See App. A
NRC-3 posted?	19.11(c)	
NOTES & REMARKS:		
15. Other License Conditions		
	Cond 14	according to Weber, no carcinoma of thyroid treatments since she has been at St. Mary's. (However, a rather high dose (30-40 mCi) of I-131 was used for purpose of "destroying a stubborn thyroid nodule")

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEMS

CRITERIA

FINDING

16. Confirmatory Measurements*Low levels in Nuclear Medicine*NRC Instrument: *Ludlum GM*Calibration Due Date: *~ 9/84*17. Independent Inspection Effort

Discussed several topics at length, such as monitoring techniques; interpretation of dose calibrator results; relative merits and potential hazards of ^{133}Xe vs Tc ^{aerosol} ~~aerosol~~ for lung studies et.

18. Incidents and Events

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

none

35.41 - 35.45
20.402, 20.403, 20.405

none

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APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

Licensee: _____

License No: _____

Reference

Basis for noncompliance

Report item _____

10 CFR 19.11

Lic Cond _____

Type n/c _____

Neither NAC-3 or other documents posted.

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 _____

Report item _____

10 CFR _____

Lic Cond _____

Type n/c_____

Licensee: _____

License No: _____

Status

Describe: _____

OPEN

CLOSED

mla

Describe: _____

OPEN

CLOSED

Describe: _____

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(July 82)

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APPENDIX C - SUPPLEMENTARY INFORMATION

Licensee: _____

License No: _____

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

*Both techs appeared to be competent
and conscientious, and had a good
working relationship.*