

DOCKET NO. (s) 030-01317
030-06895

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ATTACHED

- Appendix A
- Appendix B
- Appendix C
- Memo

INSPECTION REPORT NO. 88-01
Walter Reed Army Medical Center
Department of the Army
Washington, D.C. 20012

LICENSEE CONTACT: _____ Telephone No: _____

LICENSE NO: 08-01738-02 *Leadiator* CATEGORY _____ PRIORITY: _____
08-01738-03 *Medinal* CATEGORY _____ PRIORITY: _____
 _____ CATEGORY _____ PRIORITY: _____

INSPECTION DATE (s): _____ 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
- ACTION ON PREVIOUS NONCOMPLIANCE, APPENDIX B
- NONCOMPLIANCE, 591 ISSUED
- SUPPLEMENTAL INFO, APPENDIX C

RECOMMENDATIONS
SEE BASIS IN APPENDIX C

CHANGE CATEGORY TO: _____ CHANGE PRIORITY TO: _____
 NEXT INSPECTION DATE: _____

PERSONS CONTACTED

*Information in this record was deleted
 in accordance with the Freedom of Information
 Act, exemptions 2 & 6
 FOIA-2006-0238*

INSPECTOR: John Pelchat

APPROVED: John S. Glavin

Portions Ex. 2 & 6 *MM/16*

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEMS	CRITERIA	FINDING
1. <u>Organization</u>	Lic Cond _____	_____
Structure of organization as described in requirements?	<i>Major Gerald Connock RSO</i>	
Scope of Program? Patient load?	<i>Major Terry Minton - Nuclear Pharmacist</i>	
NOTES & REMARKS:	<i>Blag 2</i>	
<i>2-3 brachytherapy proc / month</i>	<i>35-40 patients / day Tc (85%) 13 wk Th Ga 67</i>	
<i>2 Tc 99 7.45 Ci gen</i>	<i>I-131 diag uptake 2-3 wk oral soln 2-3 therapy 1m III WBC</i>	
	<i>I-125 Cr 51</i>	<i>130 mls</i>
	<i>RIA Laboratory</i>	<i>2 P-32 therapy 730 / month</i>
2. <u>Licensee Internal Audits</u>	Lic Cond _____	_____
Scope and frequency of audits as required?	<i>Weekly surveys by RSO staff. Reviewed by</i>	
Conducted by appropriate persons?	<i>NOIC (Non comm. officer in charge) Audited RSO</i>	
Records maintained?		
Reviewed by management? <i>Problem findings result in contact by RSO</i>		
Deficiencies identified and corrected?	<i>Yes</i>	
NOTES & REMARKS:		
3. <u>Training and Qualification of Personnel</u>	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:		
4. <u>Radiation Protection Procedures</u>	Lic Cond _____	_____
Procedures available and implemented?		
Identify radiopharmaceutical and dose(s)? <i>Rad Pharm labeled as req. Patient pos. 1 Dcd by spelling last name</i>		
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:		

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEM	CRITERIA	FINDING
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5. Use of Materials

Procurement and use as required? Authorized form & route of administration?	35.14(b)	<i>Yes only authorized uses of RAM</i>
Special tests (moly breakthrough, leak tests, etc) required?	35.14(b)(4)	<i>No records incomplete but backup records show testing performed as required</i>
Inventory of brachytherapy sources? Combined w/ leak test records performed @ reg frequency	35.14(b)(5)	<i>Linearity tests performed as required. All results within $\pm 5\%$.</i>
Dose calibration checks performed? Accuracy tests performed w/ NBS sources every 6 months. Security to results available	20.203	<i>Posting & labeling as required</i>
NOTES & REMARKS: <i>All syringes & needles labeled as required</i>		

6. Storage of Materials

Material secured in both restricted and unrestricted areas? Adequately?	20.207	<i>Research areas are have access control ID badges required. Staff challenges non-routine personnel</i>
NOTES & REMARKS:		

7. Facilities

Lic Cond _____

As described in lic cond or application?
Any changes made? Adequacy?

NOTES & REMARKS:

8. Instruments

Lic Cond _____

Survey meters & instruments adequate for program? *Appropriate instrumentation available*
Instruments & meters operable? Calibrated? *Yes*
Calibration adequate? *Yes*

NOTES & REMARKS:

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEMS	CRITERIA	FINDING
9. Receipt and Transfer of Material		
Written procedures for pickup, receiving, opening packages? <i>Yes</i>	20.205	<i>Complete tracking system on PC</i>
Survey of packages when received? <i>Yes</i>	20.205(c)(1)	<i>for tracking receipt of RAM</i>
Records of survey of packages? <i>Yes</i>	20.401(b)	<i>compare receipt vs auth limits</i>
Transfer of materials proper? Transfer records maintained? <i>Only return to vendors</i>	30.41, 30.51	<i>Licenses of RAM receivers maintained</i>
Authorized containers used? Shipping papers & package labels proper for packages on hand? <i>Yes</i>	71.5	<i>Note - under timely renewal Quadrex in FL expired 6/30/85</i>
NOTES & REMARKS:		
10. Personnel Protection - External		
Personnel monitoring controls adequate? <i>Yes</i> Exposures minimized? - <i>Yes for RAM Users</i>	20.101, 20.202	
Exposure records (NRC-4 or 5) maintained? Available for employee review?	20.102(b), 20.401(a)	<i>One reported overexposure 1.8 RWBE 1.7 ext for 3/1-4/4/87. Was investigated by RPO staff. User suspended pending result. Determined to be result of storage of dosimetry in vicinity of P-32 for 2 wks, not a real error. Complete documentation</i>
Surveys conducted? Adequate? <i>Yes</i>	20.201	
Records of monitoring, surveys? <i>Yes</i>	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. Personnel Protection - Internal		
Airborne concentrations in restricted areas? (Xe-133, patients treated with I-131)	20.103	<i>No assay for C14 or H3</i>
Exposures to minors? <i>No minors</i>	20.104	<i>Reg. min sen I125 0.4 mCi I131 0.8 mCi</i>
Posting of airborne radioactivity areas?	20.203(d)	<i>Investigational 12 mCi 6 mCi</i>
Survey, monitoring bioassay adequate for airborne radioactivity, surface contamination? Records maintained?	20.201 20.401	
Procedures for use of Xe-133 followed? - <i>Closed Xe handling system checked weekly</i>		
NOTES & REMARKS: <i>Room under - pressure evaluated 6 m</i>		

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEM	CRITERIA	FINDING
<u>12. Effluent Controls, Waste Disposal</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:		
<hr/>		
<u>13. Notifications and Reports</u>		
To individuals? <i>None other than routine</i>	19.13	<i>System for notifying under when ALARA or investigational limits exceeded. Several interviewed individuals aware of prev investigations</i>
Overexposures, excessive levels & concentrations, incidents? <i>No</i>	20.403, 20.405	
Personnel exposures and monitoring, termination reports? <i>None required</i>	20.407, 20.408	
Theft or loss of licensed material? <i>No</i>	20.402	
Misadministrations? <i>yes as required see notes</i>	35.41-35.45	
NOTES & REMARKS:		
<hr/>		
<u>14. Posting of Notices</u>		
Part 20, license & documents, procedures, notice of violations posted?	19.11(a)	<i>Very numerous postings</i>
NRC-3 posted?	19.11(c)	
NOTES & REMARKS:		
<hr/>		
<u>15. Other License Conditions</u>		

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEMS	CRITERIA	FINDING
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16. Confirmatory Measurements

NRC Instrument: ^{L-16} L-142 Calibration Due Date: _____
 L-16 28000 cpm w/Std

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

(July 82)

INSPECTION REPORT NUMBER _____

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APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

Licensee: _____

License No: _____

Reference	Basis for noncompliance
Report item _____ 10 CFR <u>20.205(b)(c) & 20.401(a)</u> Lic Cond _____ Type n/c _____	
Report item _____ 10 CFR _____ Lic Cond <u>20</u> 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 _____	

(July 82)

INSPECTION REPORT NUMBER _____

Page _____ of _____

APPENDIX B - LICENSEE ACTION ON PREVIOUS INSPECTION FINDINGS

Licensee: _____

License No: _____

Identification and summary of action taken	Status
<p>Report No: <u>86-01</u> Type n/c: <u>10 CFR 20.201</u> Describe: <u>Failure to perform Adequate survey RAM in trash</u> Action taken: _____</p>	<p>OPEN <input checked="" type="radio"/> CLOSED</p>
<p>Report No: <u>86-01</u> Type n/c: <u>10 CFR 20.201</u> Describe: <u>Failure to perform adequate survey for No F.B. for run</u> Action taken: _____</p>	<p>OPEN <input checked="" type="radio"/> CLOSED</p>
<p>Report No: <u>86-01</u> Type n/c: <u>10 CFR 20.201</u> Describe: <u>Failure to perform adequate survey No cut down for P-32 use</u> Action taken: _____</p>	<p>OPEN <input checked="" type="radio"/> CLOSED</p>
<p>Report No: <u>86-01</u> Type n/c: <u>Tedown cond.</u> Describe: <u>No lab coats in nuc med lab</u> Action taken: <u>Observed 3 different techs wearing lab coats</u></p>	<p>OPEN <input checked="" type="radio"/> CLOSED</p>
<p>Report No: <u>86-01</u> Type n/c: <u>Tedown cond</u> Describe: <u>Failure to wear assigned dosm</u> Action taken: _____</p>	<p>OPEN <input checked="" type="radio"/> CLOSED</p>
<p>Report No: <u>86-01</u> Type n/c: <u>Tedown cond.</u> Describe: <u>Failure to use syringe shield</u> Action taken: <u>Observed</u></p>	<p>OPEN <input checked="" type="radio"/> CLOSED</p>

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

Open item from prev. inspection (cont)

Report 86-01 Failure to conduct bioassay of individual using ≥ 1 mCi I-125

CLOSED

*Open item (LER) Diagnostic Misadministration - misadmin of Tc 99m-O₄ instead of prescribed Tc 99m MD
Due to "loose" SOP Separate partition used to separate pharmaceuticals. Failed to return O₄ to partition.
Then drew dose. Briefed tech staff on procedures. Developed alternate procedures to identify Tc 99m
using different size vials. Reviewed during inspection; preventative & corrective actions appear
complete Item closed for this inspection*

Major General Lewis A
C.O. Mologne ~~MC~~

James E. Haslinga

Radiation Control Committee - Deputy Commander Clinical Services, WRAMC

Walter Connock Health Physics Officer

WRAMC
5000 military emp
5000 civilian emp

Health Physics Officers

Operations
day to day operations
inspections labs
reactive
brachy support
therapy support
wipes collected

Tech Services
ALARA
dosimetry
dosimetry eval
Monitoring instr.
wipes counted
Training

Radiation Material Control
Receipt & distribution of RAM
Confirming authorization
6 month audits of program

Initial Training 16 hours

Recurrent training Annual frequency

COL Jay Anderson Chief of Nuclear Medicine

COL Nasser Ghacol Chief of Dept of Radiology

On site police & fire services

Int Dietrich

Billy G Bass Director of Decontamination (202) 576-

Cs 137

- small animal

350 used per year

Co 60

- small animal

FX2

List of authorized users Bass will operate system for ocean & new users

No transfer receipt or disposal of RAM

Watal Mc Nell

Minton

Glaser & Doe

Bill Beakwith RRO

Hazard Biologicals

H3 C14 S35 I125 In III

All animal no human use

30-40 auth users ~~100-150~~ 100-150 people work w/ RAM Lx-ray

5 authorizations including 1 for irradiation - 1 principle user

Institutional RSC for program → non-human use → RCO

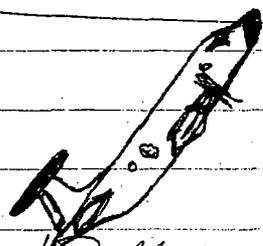
Order RAM receipt survey

116 labs

Lab surveys perf. monthly

Steve Tobery

Iod ↔ Broussey



I said it was good for me.

Bioassay Tolery Procedure 3/4/86
5/5/86

Bioassay 3/12/86
5/6/86

Merril @

4/22/88
4/19/88
4/15/88
4/12/88
3/14/88
2/19/88
1/13/88

prob
after bioassay

~~Bioassay 4/26/88~~

4/12/88
3/8/88
2/9/88
1/26/88

Rommelburg No bioassay since 1/24/88

No records for receipt surveys

Peter Petrosia

Ex 6

2 NEN containers

5 iododeoxydridine 500 μ Ci I-125 ^{cont # NEX 072 031698 Day 127} assay date 8/4/78

Sodium iodide 2 mCi NEZ 0331 8/4/78 027256 day 123

Previous owner was chemist for local cancer treatment group

Current owner been in home for 4 years

Survey w/ L-14C & L-16 analysis all background readings

L-16 checked w/ mock iodine 125 source

Advised that disposal as normal trash would be appropriate

LICENSE NO: _____

DOCKET NO. (s) _____

PAGE _____ OF _____

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INSPECTION REPORT NO. _____

Walter Reed Army Medical Center
Department of The Army
Washington, DC 20012

LICENSEE CONTACT: _____ Telephone No: _____

LICENSE NO: _____ CATEGORY _____ PRIORITY: _____

_____ CATEGORY _____ PRIORITY: _____

_____ CATEGORY _____ PRIORITY: _____

INSPECTION DATE (s): _____ 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
- ACTION ON PREVIOUS NONCOMPLIANCE, APPENDIX B
- NONCOMPLIANCE, 591 ISSUED
- SUPPLEMENTAL INFO, APPENDIX C

RECOMMENDATIONS
SEE BASIS IN APPENDIX C

- CHANGE CATEGORY TO: _____
- CHANGE PRIORITY TO: _____
- NEXT INSPECTION DATE: _____

PERSONS CONTACTED

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

INSPECTOR: *John Pelchit*

APPROVED: *John S. Hill*

INSPECTION PLAN AND REPORT NUMBER _____ Page _____ of _____

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 2850 (Required)			77710B
Followup on Noncompliance and Deviations			92702B
Independent Inspection Effort (Required)			92706B
Transportation			86740B

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEM	CRITERIA	FINDING
6. <u>Receipt and Transfer of Materials</u>		
Procedures implemented, adequate?	20.205, 71.51	
Transfer of byproduct material?	30.41	
Control of source material,	40.51, 40.64, 70.42, 70.51, 70.53, 70.54	
Labeling and packaging?	71.5, 49CFR 170-189	
Records of receipt, transfer, storage, survey, and monitoring?	30.51	
Procedures for pickup, receipt, monitoring of packages?	20.205(b)&(c)	
NOTES & REMARKS:		
7. <u>Personnel Protection - External</u>		
Personnel monitoring control; minimize exposures, control of accumulated dose?	20:101, 201.102, 20.202	
Surveys conducted, adequate?	20.201	
Records of monitoring, surveys, disposals?	20.401, Lic Cond _____	
Levels in unrestricted areas?	20.1, 20.105	
NOTES & REMARKS:		
8. <u>Personnel Protection - Internal</u>		
Airborne concentrations in restricted areas?	20.103	
Exposure of minors?	20.104	
Posting of airborne radioactivity areas?	20.203	
Survey, monitoring bioassay requirements; records?	20.201, 20.401	
Leak tests of sealed sources?	Lic Cond _____	
NOTES & REMARKS:		

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEM	CRITERIA	FINDING
9. <u>Effluent Control; Waste Disposal</u>		
Release of effluents?	20.106	_____
Waste disposal, proper packaging for shipment?	20.301, 20.303, 20.304, 20.305	
Procedures, records?	20.401, Lic Cond _____	
NOTES & REMARKS:		
10. <u>Transportation</u>		
Management controls, audits?		_____
Selection of packaging?	49 CFR 173.393-5; 10 CFR 71	
Preparation of packages for shipment? Filling and loading, closing, liquids?	49 CFR 172.173	
Markings & labelling?	49 CFR 172.300	
Monitoring?	49 CFR 172.402, 403	
	49 CFR 173.393	
Shipping papers, loading and placarding of vehicles?	49 CFR 172.200	
Reports of incidents?	49 CFR 171.15, 171.16	
Training program?		
Examination of packages?		
NOTES & REMARKS:		
11. <u>Notifications and Reports</u>		
To individuals?	19.13	_____
Overexposures, excessive levels and concentrations, incidents?	20.403, 20.405	
Personnel exposures and monitoring, termination reports?	20.407, 20.408	
Theft or loss of licensed materials?	20.402	
NOTES & REMARKS:		

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEM	CRITERIA	FINDING
12. <u>Posting of Notices</u>		
Part 20, license & documents, procedures, notice of violations?	19.11(a)	
NRC-3?	19.11(c)	
NOTES & REMARKS:		
13. <u>Environmental Monitoring Program</u>		
	Lic Cond _____	
Implementation of program, scope and frequency as required?		<i>Sewer sampled once per year</i>
Records maintained, reviewed by management?		
NOTES & REMARKS:		
14. <u>Emergency Preparedness</u>		
	Lic Cond _____	
Procedures available for incidents and accidents?		
Training for personnel; coordination with supporting groups and agencies?		
NOTES & REMARKS:		
15. <u>Other License Conditions</u>		
NOTES & REMARKS:		

INSPECTION REPORT NUMBER _____

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777108 - Industrial - Academic

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEM	CRITERIA	FINDING
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16. Confirmatory Measurements _____

Licensee's surveys verified on sampling basis? 201.105, 20.201

NOTES & REMARKS:

NRC Instrument: _____ Calibration due date: _____

17. Independent Inspection Effort _____

NOTES & REMARKS:

INSPECTION REPORT NUMBER _____

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APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

Licensee: _____

License No: _____

Reference	Basis for noncompliance
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 _____	
Report item _____ 10 CFR _____ Lic Cond _____ Type n/c _____	

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

INSPECTION REPORT NUMBER _____

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APPENDIX C - SUPPLEMENTARY INFORMATION

Licensee: _____ License No: _____

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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 | |
-

Adminstrations - 2 mCi/vial
1 mCi/use

I 125 Procedure performed 4/26/88 1 mCi
Breassay not performed til 5/3

200,000 apm @ head face

SP Olson - collect & segregate waste org & ~~ty~~ acq lig
long & short t-1/2 solids

~~Audits~~

~~Survey Records~~

Daily Nuc Med Surveys

Quarterly Radiation Control Committee

Adequate representation of depts on committee