

LICENSE NO: 06-17718-01

DOCKET NO. (s) 030-13216

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ATTACHED

- Appendix A
- Appendix B
- Appendix C
- Memo

INSPECTION REPORT NO. 85-01

Nova Laboratories

LICENSEE CONTACT: Gregory Bidon RSG and Dr. Robert Starnes, usg Telephone No: 203-767-2401

LICENSE NO: 06-17718-01 CATEGORY F PRIORITY: 3 E11163

CATEGORY _____ PRIORITY: _____

CATEGORY _____ PRIORITY: _____

INSPECTION DATE (s): July 25, 1985

- TYPE OF INSPECTION:
- SPECIAL
 - ROUTINE
 - DAYSHIFT
 - OTHER
 - ANNOUNCED
 - UNANNOUNCED

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: _____
 NEXT INSPECTION DATE: 7/88

CHANGE PRIORITY TO: _____

PERSONS CONTACTED

Gregory Bidon, Industrial Hygienist, Regulatory Affairs

Dr. Robert Starnes, usg

Dr. Fordham Wray, Regulatory Affairs

INSPECTOR: Charles P. Starnes

APPROVED: John M. [Signature]

B/11
8/5/85

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 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 ITEMS	CRITERIA	FINDING
1. <u>Organization</u>	Lic Cond _____	<p>Mr. Robert Starnes user <i>Dr. Jos. Fordham</i> <i>Gregory Bidon</i> ^{R50} Industrial & Regulatory Affairs <i>Mr. Regulatory Affairs</i></p>
Management organization?		
Radiation Protection Organization?		
Scope of Operation?		
NOTES & REMARKS:	<p><i>Clinical Lab (RIA's) used at time of last inspection (1982) was discontinued in 1982. When use would be resumed it would be different. ONLY MATERIAL POSSESSED (storage only)</i></p>	<p><i>Dr. Robert Starnes user</i></p>
2. <u>Licensee Internal Audits</u>	Lic Cond _____	
Scope and frequency?		
Management controls?		
NOTES & REMARKS:	<p><i>~55 uL H-3 tagged HAD (previously used many years ago)</i> <i>* Sucrose H3 - 22.5 mCi</i> <i>Oleic Acid C-14 - 5 uCi (65%)</i> <i>(never removed from original containers in which received)</i></p>	
3. <u>Training and Instructions to Employees</u>		
Training program, scope and frequency, retraining?	Lic Cond _____	
Required tests administered; scores satisfactory?		<i>n/a</i>
Instructions to workers?	19.12	
NOTES & REMARKS:		
4. <u>Radiation Protection Procedures</u>		
Operating & emergency procedures implemented?	Lic Cond _____	
Security?	20.207	
NOTES & REMARKS:		<i>n/a</i>
5. <u>Materials, Facilities and Instruments</u>		
Authorized uses and quantities?	Lic Cond _____	
Restricted areas, posting requirements?	20.203	<i>n/a</i>
Survey instruments & dosimeters; operable, properly calibrated?		
NOTES & REMARKS:	<p><i>(New building at new location will be moved into when completed. probably ready for occupancy in a year.)</i> <i>Done. (Section) - (Switched to confirm clean)</i> <i>Building will include Lab Desimeter for ISOTOPE USE</i></p>	
<i>* Danbury, Conn</i>		

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	<i>none received</i>
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	<i>not needed</i>
Surveys conducted, adequate?	20.201	<i>Lab where RIA had been done was swiped → no contamination</i>
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	<i>n/a</i>
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
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9. Effluent Control, Waste Disposal

Release of effluents?

20.106

TS n/a

Waste disposal, proper packaging for shipment?

20.301, 20.303, 20.304, 20.305

none disposed

Procedures, records?

20.401, Lic Cond

(The small quantities

NOTES & REMARKS:

of 3 tagged compounds possessed are being held in storage)

10. Transportation

Management controls, audits?

Selection of packaging?

49 CFR 173.393-5; 10 CFR 71

Preparation of packages for shipment? Filling and loading, closing, liquids? Markings & labelling? Monitoring?

49 CFR 172.173
49 CFR 172.300
49 CFR 172.402, 403
49 CFR 173.393

*no diff
n/a*

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. Notifications and Reports

To individuals?

19.13

Overexposures, excessive levels and concentrations, incidents?

20.403, 20.405

none

Personnel exposures and monitoring, termination reports?

20.407, 20.408

TS n/a

Theft or loss of licensed materials?

20.402

none

NOTES & REMARKS:

AREAS INSPECTED AND FINDINGS

Licensee: _____ License No: _____ Amendment No: _____

INSPECTION ITEM	CRITERIA	FINDING
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12. Posting of Notices

Part 20, license & documents, procedures, notice of violations?

19.11(a)

NRC-3?

19.11(c)

NOTES & REMARKS:

*These were posted following previous inspections
— currently not needed*

13. Environmental Monitoring Program

Lic Cond _____ *n/a* _____

Implementation of program, scope and frequency as required?

Records maintained, reviewed by management?

NOTES & REMARKS:

14. Emergency Preparedness

Lic Cond _____ _____

Procedures available for incidents and accidents?

Training for personnel; coordination with supporting groups and agencies?

NOTES & REMARKS:

n/a

15. Other License Conditions

no ass

NOTES & REMARKS:

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	
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NOTES & REMARKS:

NRC Instrument: _____ Calibration due date: _____

17. Independent Inspection Effort

*Discussed procedures to follow for
 abandoning current building (and fee for
 licensing action for transferring use
 to a new address*

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 _____	<i>none</i>
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
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Report No: _____	Type n/c: <u>19.11(c)(1) d(6)</u>	Describe: <u>NAC Gather Documents</u>
Action taken:		OPEN <u>not posted</u>
<u>Documents posted following last inspection (currently not needed)</u>		<u>CLOSED</u>

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

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

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

(July 82)

INSPECTION REPORT NUMBER _____

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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