



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
799 ROOSEVELT ROAD  
GLEN ELLYN, ILLINOIS 60137

INSPECTION REPORT NO. 7701  
Nuclear Diagnostic  
(Licensee name/address)  
575 Robbins Drive  
Troy, Michigan 48084  
Telephone No: 313-585-7600

Attached

- ( ) Appendix A  
( ) Appendix B  
( ) Appendix C  
( ) Memo

License No. 21-14161-02 Last amendment & date: 4, 9/24/78  
Docket No. 03010081  
Category: E & Priority: 4, as of last amendment.  
Inspection date(s): 11/17/77 Type of inspection: unannounced

SUMMARY OF FINDINGS AND ACTION

- (X) No noncompliance, clear 591 ( ) Noncompliance, 591 issued  
( ) Noncompliance, Appendix A ( ) Regional action ( ) Hq action  
( ) Action on previous n/c, App B ( ) Supplemental info, App C

RECOMMENDATIONS

See basis in Appendix C or attached memo.

- ( ) Change Category to: \_\_\_\_\_ ( ) Change Priority to: \_\_\_\_\_  
(X) Next inspection date: 11/80

PERSONS CONTACTED  
(NAME AND TITLE)

\* James Smart, Director of Technical Operations  
\* Walter N. Kesch, Consultant, RSO

\* Indicates those attending management meetings

Inspector: [Signature] 11/22/77  
(signature) (date signed)  
Approved: [Signature] 11/22/77  
(signature) (date signed)



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( ) Memo

License No. 21-14161-A6 Last amendment & date: 9, 4/6/77  
Docket No. 03007652  
Category: E & Priority: IV, as of last amendment.  
Inspection date(s): 11/17/77 Type of inspection: announced

SUMMARY OF FINDINGS AND ACTION

- (X) No noncompliance, clear 591 ( ) Noncompliance, 591 issued  
( ) Noncompliance, Appendix A ( ) Regional action ( ) Hq action  
( ) Action on previous n/c, App B ( ) Supplemental info, App C

RECOMMENDATIONS

See basis in Appendix C or attached memo.

- ( ) Change Category to: \_\_\_\_\_ ( ) Change Priority to: \_\_\_\_\_  
(X) Next inspection date: 11/80

PERSONS CONTACTED  
(NAME AND TITLE)

\* James Smart, Director of Technical Operations  
\* Walter Nicksch, Consultant, RSC

\* Indicates those attending management meetings

Inspector: J. T. [signature]

(signature)

11/22/77

(date signed)

Approved: James L. Pagliaro

(signature)

11/22/77

(date signed)

## PLANNING SHEET

Date: 11/17/27

Licensee: Nuclear Diagnostics Inc

License no: 21-14161016

Inspection Items	Scheduled for inspection	Post-inspection status	Module no.	766 Time Info
Management meeting - Entrance and Exit Interviews [REQUIRED]	✓	complete	30703B	
Initial Management Meeting			30800B	
Program requirements, MC 2B [REQUIRED]	✓	complete	7771013	
Licensee Event Followup			92700B	
Followup on Inspector-identified problems			92701B	
Followup on Noncompliance and Deviations			92702B	
IE Bulletin/Immediate Action Letter Followup			92703B	
Followup on Headquarters Requests			92704B	
Followup on Regional Requests			92705B	
Independent Inspection Effort [REQUIRED]	✓	complete	92706B	
Inspector Dispatched to Site			93700B	
Followup on Significant Event Occurring During Inspection			93701B	

## PLANNING SHEET

Date:

11/17/77

Licensee:

Nuclear Diagnostic Inc

License no:

21-14161-02

Inspection Items	Scheduled for inspection	Post-inspection status	Module no.	766 Time Info
Management meeting - Entrance and Exit Interviews [REQUIRED]	✓	complete	30703B	
Initial Management Meeting			30800B	
Program requirements, MC 28 [REQUIRED]	✓	complete	77710B	
Licensee Event Followup			92700B	
Followup on Inspector-identified problems			92701B	
Followup on Noncompliance and Deviations			92702B	
IE Bulletin/Immediate Action Letter Followup			92703B	
Followup on Headquarters Requests			92704B	
Followup on Regional Requests			92705B	
Independent Inspection Effort [REQUIRED]	✓	complete	92706B	
Inspector Dispatched to Site			93700B	
Followup on Significant Event Occurring During Inspection			93701B	

INDUSTRIAL - ACADEMIC INSPECTION REPORT

Licensee: Nuclear Diagnostics, Inc. Lic. No. 21-14161-02 Amendment No. 9  
 Date of Inspection: 11/17/77

1. INSPECTION HISTORY

- a. Items of noncompliance or safety items noted during last inspection

conducted on 7/72 (21-14161-016) Yes \_\_\_\_\_ No X

- b. Requirement

no previous inspection of 21-14161-02  
 Corrected \_\_\_\_\_ Not Corrected \_\_\_\_\_

- c. If any items of noncompliance or safety items noted during the last inspection were not corrected, explain: \_\_\_\_\_

2. ORGANIZATION

- a. Organizational structure as described in application or letter

Dated \_\_\_\_\_, Or \_\_\_\_\_

- b. List primary licensee contact:
- James Smart
- Telephone No.
- 313-585-7600

- c. Comment:
- President - Dr. Walter Di Giulio

James Smart, Director, Technical Operations

Dr. H. Lee, Director R & D

Dave Grawberg, Director, Manufacturing

Only 3 or 4 people actually involved in working with directly with radioactive material

3. SUMMARY OF LICENSED PROGRAM (Kind of program, number of people, rate of use or quantities on hand, places and frequency of use, type, quantity and use as authorized).

21-14161-016 10-15 m Ci of I-125 received monthly, - used to manufacture in vitro kits which are distributed to generally licensed customers. Includes calibration step every 3 weeks using 2-3 m Ci I-125 per calibration.

21-14161-02 On hand was 5 m Ci of Iron 59 which is used for product development. This program is not very active

Category and priority of this license is appropriate: Yes ☒ No ☐

If "No" state new Category \_\_\_\_\_ Priority \_\_\_\_\_.

4. INTERNAL AUDITS OR INSPECTIONS

a. Required by L/C or application: Yes \_\_\_\_\_ No ☒ If "Yes":

1) By whom \_\_\_\_\_

2) Frequency \_\_\_\_\_ Announced: \_\_\_\_\_ Unannounced: \_\_\_\_\_

3) Scope \_\_\_\_\_

4) Records maintained: Yes \_\_\_\_\_ No \_\_\_\_\_

5) Records reviewed: Yes \_\_\_\_\_ No \_\_\_\_\_

6) Period Reviewed: \_\_\_\_\_

b. Comment (responsibility of auditor or committee, management control): \_\_\_\_\_

by Walter Mikech monthly -



5. TRAINING RETRAINING AND INSTRUCTION TO WORKERS

a. Training program specified in L/C or application: Yes \_\_\_\_\_ No X

b. If training program is required, describe scope of program: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

c. Retraining required: Yes \_\_\_\_\_ No X

If "Yes" is retraining: Complete \_\_\_\_\_ Incomplete \_\_\_\_\_

1) Are tests and/or examinations required: Yes \_\_\_\_\_ No \_\_\_\_\_

2) If "Yes" are records available: Yes \_\_\_\_\_ No \_\_\_\_\_

3) Reviewed test results: Yes \_\_\_\_\_ No \_\_\_\_\_

4) Period reviewed: \_\_\_\_\_

5) Comment (per cent completed, test results, etc.): \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

d. Training provided, but not covered above: new employee - procedures and  
hazards and disorders. In house lectures given from time  
to time. College graduates & doctorate holders work  
with the radioactive materials

e. Instructions to workers in accord with 10CFR 19.12: Yes X No \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

6. RADIOLOGICAL PROTECTION PROCEDURES

a. Operating and emergency procedures

- 1) Required by L/C or application: Yes X No \_\_\_\_\_
- 2) Provided, but not required by L/C or application: Yes \_\_\_\_\_ No \_\_\_\_\_
- 3) Procedures reviewed: Yes X No \_\_\_\_\_
- 4) Appeared Adequate: Yes X No \_\_\_\_\_
- 5) Comments (personnel's understanding of procedures): \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

b. Changes in procedures since last inspection: Yes \_\_\_\_\_ No X

- 1) Were changes authorized: Yes \_\_\_\_\_ No \_\_\_\_\_

- 2) Comments: \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

7. INSTRUMENTATION

- a. Type(s) of radiation survey instruments on hand as per L/C, application or equivalent: Yes X No \_\_\_\_\_

- 1) If "No" list changes: \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_



b. Capability of radiation survey instruments adequate for program:

Yes X No \_\_\_\_\_

c. Calibration of instruments required: Yes X No \_\_\_\_\_

d. If "Yes" instruments calibrated in accord with requirements:

Yes X No \_\_\_\_\_

e. Comment: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

8. MATERIALS

a. Radioactive material secured to prevent unauthorized removal from:

1) Restricted area: Yes X No \_\_\_\_\_

2) Unrestricted area (20.207): Yes X No \_\_\_\_\_

b. Method of control appears adequate: Yes X No \_\_\_\_\_

c. Comment: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

9. FACILITIES

a. Facilities described in letter or application: Yes X No \_\_\_\_\_

b. Facilities inspected: Yes X No \_\_\_\_\_

c. Comment: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are approximately 20 lines visible. The paper appears to be from a notebook or a standard sheet of stationery. There is no handwriting or other markings on the page.

d. Records of receipt and transfer of material available (30.51(a); 40.61(a);

70.51(b)(1)): Yes X No \_\_\_\_\_

1) If "Yes" review of records was made by inspector: Yes X No \_\_\_\_\_

2) Period Reviewed: \_\_\_\_\_

3) Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

e. Packages on hand meet labelling requirements (49CFR 173.399):

Yes X No \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

f. Reports to commission required by L/C or regulation submitted:

Yes X No \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

12. PERSONNEL RADIATION PROTECTION - EXTERNAL

a. Film or TLD badge supplier RS Landauet

b. Badge exchange frequency Monthly

c. Reports reviewed by J. Smart & Walter

e. Records reviewed for period 10/10/72 to 10/9/77 by NRC inspector

f. NRC forms or equivalent

1) NRC-4 (20.102(b)): Yes \_\_\_\_\_ No X Complete: Yes \_\_\_\_\_ No \_\_\_\_\_

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

Maximum whole body quarterly exposure: 180 mrem (mostly Maximal)

Maximum extremity quarterly exposure: 200 mrem

3) Comment: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

g. Pocket dosimeters used: Yes \_\_\_\_\_ No ☒

1) Type used: \_\_\_\_\_  
2) Frequency of recharging: \_\_\_\_\_  
3) Frequency of reading: \_\_\_\_\_  
4) Comment: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

h. Direct radiation surveys of restricted and/or unrestricted areas being made:

Yes ☒ No \_\_\_\_\_

1) Records of surveys being maintained: Yes ☒ No \_\_\_\_\_

2) Records of surveys reviewed: Yes ☒ No \_\_\_\_\_

3) Period reviewed: \_\_\_\_\_

4) Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

13. PERSONNEL RADIATION PROTECTION - INTERNAL

a. Potential for exposure of individuals to airborne radioactive materials

exists: Yes ☒ No \_\_\_\_\_

1) If "Yes" does program for monitoring and control exist: Yes ☒ No \_\_\_\_\_

2) Program for monitoring and control appears adequate: Yes ☒ No \_\_\_\_\_

b. Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

c. Respiratory protection program required by L/C or application:

Yes \_\_\_\_\_ No \_\_\_\_\_

1) If "Yes" were respiratory protection procedures reviewed:

Yes \_\_\_\_\_ No \_\_\_\_\_

2) Respiratory protection procedures appear adequate: Yes \_\_\_\_\_ No \_\_\_\_\_

3) Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

d. Bioassay program required: Yes X No \_\_\_\_\_

1) If "Yes" was bioassay program reviewed: Yes X No \_\_\_\_\_

2) Bioassay program appear adequate: Yes X No \_\_\_\_\_

3) Comments: All lab employees checked monthly for I-125 thyroid  
burden. Individuals performing radiation checked 24 hours later.  
Highest burden was 0.06  $\mu$ Ci. (0.15  $\mu$ Ci <sup>approx</sup> is indicative  
of exposure to 40 MPC hours.)

e. Smears and air samples

1) Monitoring for airborne radioactivity is conducted (20.103):

Yes \_\_\_\_\_ No X

a. Records of monitoring reviewed: Yes \_\_\_\_\_ No \_\_\_\_\_

b. Period reviewed: \_\_\_\_\_

c. Records of monitoring appears adequate: Yes \_\_\_\_\_ No \_\_\_\_\_

2) Smear surveys being conducted (20.201, b): Yes X No \_\_\_\_\_

a. Records of smear surveys reviewed: Yes X No \_\_\_\_\_

b. Period reviewed: 1/1/75 to 11/17/77

c. Records appeared adequate: Yes ✓ No \_\_\_\_\_

3) Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

14. LEAK TESTS

- a. Leak tests required: Yes \_\_\_\_\_ No X
- b. If "Yes" leak tests conducted: Yes \_\_\_\_\_ No \_\_\_\_\_
- c. Records of leak tests maintained: Yes \_\_\_\_\_ No \_\_\_\_\_
- d. Leak tests records reviewed: Yes \_\_\_\_\_ No \_\_\_\_\_
- e. Period reviewed: \_\_\_\_\_
- f. Records of leak tests appear adequate: Yes \_\_\_\_\_ No \_\_\_\_\_
- g. Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

15. RADIOACTIVE EFFLUENT CONTROL AND WASTE DISPOSAL

- a. Byproduct material released to atmosphere and/or sewer (20.106 and 20.303):  
Yes X No \_\_\_\_\_
- b. Records of releases or radioactive effluents maintained (20.401):  
Yes X No \_\_\_\_\_
- 1) Period reviewed: limit 150  $\mu$ g/day use 100  $\mu$ g/day as control  
in hot lab - 20  $\mu$ g/day
- 2) Records appear adequate: Yes X No \_\_\_\_\_ X 80  $\mu$ g/day  
max.  
 $\sim \frac{1}{3}$  the limit
- c. Solid waste disposal method: Neco
- 1) Records of disposal maintained (30.51): Yes X No \_\_\_\_\_
- 2) Surveys of waste prior to disposal made (20.201): Yes X No \_\_\_\_\_
- 3) Period reviewed: 1/1/75 to 11/12/77
- 4) Records of surveys appear adequate (20.401): Yes X No \_\_\_\_\_
- d. Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_



16. SHIPPING INCIDENTS

- a. Have any shipping incidents occurred since (date) none
- 1) Was incident documented: Yes \_\_\_\_\_ No \_\_\_\_\_
- 2) If "Yes" documentation appears adequate: Yes \_\_\_\_\_ No \_\_\_\_\_
- b. Comments (reports to DOT, etc.): \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

17. NOTIFICATIONS AND REPORTS

- a. Licensee in compliance with 10CFR 19.13 (reports to individuals):  
Yes ✓ No \_\_\_\_\_
- b. Licensee in compliance with 10CFR 20.405 (over exposures):  
Yes ✓ No \_\_\_\_\_
- c. Licensee in compliance with 10CFR 20.403 (incidents):  
Yes ✓ No \_\_\_\_\_
- d. Licensee in compliance with 10CFR 20.402 (theft or loss):  
Yes ✓ No \_\_\_\_\_
- e. Comments: \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

18. POSTING OF NOTICES

- a. Licensee in compliance with 10CFR 19.11(a) or (b): Yes ☒ No ☐
- b. Licensee in compliance with 10CFR 19.11(c): Yes ☒ No ☐
- c. Comments: \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

19. ENVIRONMENTAL MONITORING PROGRAM

- a. Environmental Monitoring Program required: Yes \_\_\_\_\_ No ☒
- b. If "Yes" records reviewed: Yes \_\_\_\_\_ No \_\_\_\_\_
- c. Period reviewed: \_\_\_\_\_
- d. Records appeared adequate: Yes \_\_\_\_\_ No \_\_\_\_\_
- e. If Environmental Program is not required, briefly describe any existing program: \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

20. CONFIRMATORY MEASUREMENTS

- a. Independent measurements made by inspector: Yes ☒ No ☐
- b. Comments (describe type, results, comparison with licensee results): \_\_\_\_\_
- using the licensee's GM survey meter, verification*
- surveys were made in the laboratories. NO*
- problems were identified*
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

21. INDEPENDENT INSPECTION EFFORT

- a. Comment on type of independent inspection effort conducted: The inspector  
took the facility to observe use equipment, storage, security,  
of material, control of restricted areas, and posting. NO  
problems were identified

22. CONTINUATION FROM PREVIOUS PARAGRAPHS - USE BACK OF PAGE IF NECESSARY

none.