

Nuclear Diagnostics, Inc.

Area Code 313

585-7600

575 Robbins Drive
Troy, Michigan 48084

July 25, 1978

21-14/61-17 ✓
11-111.1-2

U.S. Nuclear Regulatory Commission
Region 111
799 Roosevelt Road
Glen Ellyn, IL 60137

Gentlemen:

In accordance with 10 CFR 20.405 this letter represents our notification to the NRC of our receipt of a film badge report of an overexposure. Specifically, on June 27, 1978 we were notified via Telegram by R.S. Landauer, Jr. & Company that during the exposure period of 5-10-78 to 6-9-78 one film badge received an exposure of 3.22 REMS (energy in excess of 250 KEV). During this same period the ring badge ("TLD" - LiI crystal) worn by the same individual who wore the overexposed film badge received an exposure of 1.78 REMS. Further details of the individual's history are attached to this report.

Our own investigation is summarized as follows:

The individual involved was employed in the shipping and receiving department. The energy of the exposure indicated that Fe-59 was the source of radiation since the only other nuclide present during that period at time was I-125.

Upon questioning this individual, it was revealed that he had intentionally left his film badge and TLD ring in the storage area (cold room) positioned in close proximity to a 2 l solution containing about 0.2 mCi of Fe-59 for a continuous period of 5-7 days. It was also learned that the employee always kept his ring badge clipped to his film badge.

We believe that it was during the period that the badge and ring were left in the cold room that they received the reported exposures for the following reasons:

For the ring to receive an exposure of 1.78 REM, it would have to be in a field of radiation intensity of 10-11 mREM/hr for a continuous period of one week. Similarly, the film badge would have to be in a radiation field of 19-20 mREM/hr over the same time period to receive an exposure of 3.22 REMS. Measurements made on a similar solution of Fe-59 indicate that such a field is possible. Fields of 40 to 5 mREM/hr were obtained over a distance ranging from 3 inches to about 2 feet from the surface of the container. The discrepancy in the exposures registered by the film badge and TLD ring was discussed with J. MacDonald of Landauer. She indicated that such a discrepancy would be expected if the TLD ring was located behind the film badge (as when clipped to the film badge) placing the film badge between the radiation source and the TLD ring.

578

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PDR FOIA
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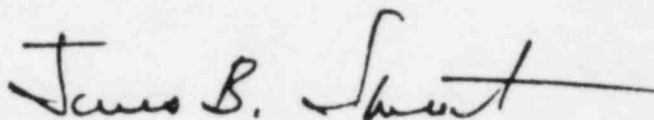
During the same period of time, lab and manufacturing personnel worked with larger amounts of Fe-59 over longer time intervals, than the individual in question, yet the maximum reported exposure was 30 mREM to one film badge.

In view of these facts it is our judgement that the reported overexposure was only to the film badge and not to the individual employee. It should also be noted that this person left our employ on 6-23-78 to accept a position in which there is no occupational exposure to radiation.

As a final comment, we are aware of the potential hazard of Fe-59, and, in anticipation of increased levels of this nuclide we have installed additional shielding (two inches of steel) in the storage area.

Communications regarding this report should be directed to the undersigned.

Sincerely,

A handwritten signature in dark ink, appearing to read "James B. Smart". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

James B. Smart, Ph.D.
Director of Technical Operations

JBS/dly

cc: W. Nikesh, Ph.D.

EXPOSURE HISTORY OF FILM BADGE AND TLD

RING ASSIGNED TO

NAME:

Social Security Number:

Exposure Period: 5-10-78 to 6-9-78

Film Badge Exposure: 3.22 REM

TLD Ring Exposure: 1.78 REM

Total Exposure Since Employment at NDI (November 1972):

Film Badge: 3.32 REM

TLD Ring: 1.78 REM

FEB 09 1982

*Mat. files
R. W. Warrin
Rep III*

License Nos. 21-14161-01G ✓
21-14161-02

EA 81-79

Nuclear Diagnostics, Inc
ATTN: Werner Wahl, Ph.D.
President
575 Robbins Drive
Troy, MI 48084

PRINCIPAL STAFF	
DIR	IS
D/D	AO
DO	
DE&TL	
DEPEOS	File

Gentlemen:

This will acknowledge receipt of your letter, dated January 28, 1982, with enclosed check in the amount of One Thousand Dollars in full payment of the civil penalty imposed by NRC Order, dated December 30, 1981.

The corrective measures that you have taken will be reviewed during future inspections at your facility.

Sincerely,

James Lieberman, Acting Director
of Enforcement
Office of Inspection and Enforcement

Distribution:

PDR
NSIC
TIC
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CA
VStello, DED/ROGR
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JCummings, OIA
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TWBrockett, IE

IE Files
Central Files
CP Book

State of Michigan
Department of Public Health
ATTN: Donald E. Van Farowe, Chief
Division of Radiological Health
3500 North Logan Street
Lansing, MI 48909

Enforcement Coordinators,
RI, RII, RIII, RIV, RV

ES:IE *jh*
JRMetzger/jh
02/9/82

ES:DL
JLieberman
02/9/82

~~8207250376 PDR~~
LP

FEB 11 1982

A-9

21-14161-01

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MAK 12 1985

Nuclear Diagnostics, Inc.
ATTN: James Smart, Ph.D.
Director of Operations
575 Robbins Drive
Troy, Michigan 48084

License No. 21-14161-02 430-2008
License No. 21-14161-01G 430-4765

Gentlemen:

This refers to the routine safety inspection conducted by Mr. W. J. Slawinski of this office on February 26, 1985, of activities authorized by NRC Byproduct Material Licenses No. 21-14161-02 and No. 21-14161-01G and to the discussion of our findings with you at the conclusion of the inspection.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel.

In addition to the above areas, the inspector examined actions described in your letter dated November 5, 1981, regarding apparent items of noncompliance found during our June 4, 1981 inspection. It appears that your proposed corrective actions have not been fully implemented. Specifically, corrective actions for Item IA included the performance of swipe tests in your hot lab after each iodination. This was to be implemented by November 30, 1981. Contrary to this commitment, it was determined during this inspection that hot lab wipe tests are not performed after each iodination.

In November-December 1982, two individuals who performed iodinations received thyroid uptakes exceeding the Commission's 40 hour control measure (i.e., 40 MPC-hours). Your investigation revealed that improper personnel and area monitoring contributed to these uptakes.

In addition to our concern regarding your failure to perform hot lab wipe tests after each iodination, we are also concerned that individuals who perform these iodinations typically do not monitor themselves immediately afterwards, before leaving the hot lab. Please address these concerns, including why your proposed corrective actions will be more effective than the actions proposed in your November 5, 1981 letter.

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21-14161-01 PDR

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Nuclear Diagnostics, Inc.

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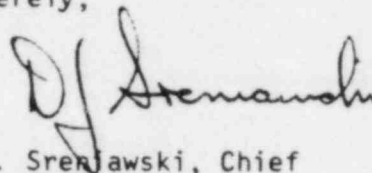
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No items of noncompliance with NRC requirements were identified during the course of this inspection.

The responses directed by this letter are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

We will gladly discuss any questions you have concerning this inspection.

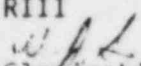
Sincerely,



D. J. Sreniawski, Chief
Nuclear Materials Safety
Section 2


cc: DMB/Document Control Desk (RIDS)

RIII


Slawinski/ld
03/07/85

3/11/85

RIII


Sreniawski

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

REGION III

Reports No. 30-7652/81-01; 30-10081/81-01

Docket Nos. 03007652; 03010081

Licenses No. 21-14161-01G; 21-14161-02

Licensee: Nuclear Diagnostics, Inc.
575 Robbins Drive
Troy, Michigan 48084

Inspection At: Nuclear Diagnostics, Inc., Troy, Michigan

Inspection Date: June 4, 1981

Inspector: Evelyn R. Matson

E. J. Sreniawski for

9/4/81

Approved By: D. J. Sreniawski, Chief
Materials Radiation Protection
Section 2

D. J. Sreniawski

9/4/81

Inspection Summary

Inspection on June 4, 1981 (Reports No. 03007652/81-01; 03010081/81-01)

Areas Inspected: Routine, announced inspection of activities conducted under Licenses No. 21-14161-01G and No. 21-14161-02 including licensed program inspection history, organization, internal audits, training, re-training and instruction to workers, radiological protection procedures, facilities, instrumentation, security of material, posting and labeling, surveys, waste disposal, personnel monitoring - external, personnel monitoring - internal, notification and reports, receipt and transfer, transportation, and confirmatory measurements. The inspection involved seven inspector-hours onsite and 11 hours at the Region III office.

Results: Of the 18 areas inspected, five items of noncompliance were identified against License No. 21-14161-01G. *now is*
(1) 10 CFR 20.103 - thyroid exposure in excess of authorized limits (Paragraph 15); (2) 10 CFR 20.405(a) - failure to report exposure to NRC (Paragraph 16); (3) 10 CFR 19.13(d) - failure to provide written report of exposure to individual (Paragraph 16); (4) 10 CFR 20.201(b) - failure to make adequate evaluation of iodine-125 contamination (Paragraph 12); (5) 10 CFR 20.203(f) - waste drums not labelled as required (Paragraph 11). No items of noncompliance were identified for License No. 21-14161-02.

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DETAILS

1. Persons Contacted

Warner Wahl, Ph.D., President

*James B. Smart, Ph.D., Director of Operations

*Ronald Krammer, Director of Manufacturing

*Attended exit interview on June 4, 1981.

2. Licensed Program

NRC Byproduct Material License No. 21-14161-02 is an industrial Type E, Priority IV license issued February 7, 1974. It currently authorizes the possession and use of any byproduct material with atomic numbers three through 83 for product development. NRC Byproduct Material License No. 21-14161-01G, issued August 13, 1971, currently authorizes the possession and use of iodine-125 and iron-59 in any chemical or physical form for the manufacture of in vitro kits and distribution to persons generally licensed pursuant to 10 CFR 31.11.

Licensed activities include research and development of products using dilute solutions (approximately .1 microcurie/ml) of I-125 and Fe-59. Larger quantities of these isotopes are used for preparing in vitro diagnostic kits which contain less than 10 microcuries of I-125 or less than 20 microcuries of Fe-59. Kit preparation includes the use of 45 to 60 millicuries of radioactive NaI during iodinations which are performed once or twice a month. Included also, are large volume dilutions, packing and distribution of the kits.

No violations were identified.

3. Inspection History

A. Inspection July 20, 1972

Results: No items of noncompliance.
Clear NRC Form 591 issued.

Comments: Small program, no iodination done.

B. Telephone Contact March 24, 1975

Results: Licensee moved to new location. No licensed activities being conducted.

C. Inspection July 25, 1978

Results: No items of noncompliance.
Clear NRC Form 591 issued.

Comments:	Licensee now doing iodination with 2 or 3 millicuries of I-125.
D. Incident	July 25, 1978
Description:	Licensee reported an overexposure of 3.22 rem to whole body and 1.78 rem to extremity.
E. Special Inspection:	August 22, 1978
NRC Actions:	An NRC inspector was onsite to determine cause of overexposure and identify any related problems.
Results:	(1) NRC inspector concluded exposures were to the badges only. (2) No personnel overexposure occurred. (3) No items of noncompliance identified.
F. Inspection	June 4, 1981
Comments:	Much larger program than before. The licensee is now using 45 to 60 millicuries of I-125 for iodinations.
Results:	See Appendix

4. Organization

The President of Nuclear Diagnostics, Inc., is Warner Wahl, Ph.D., James B. Smart, Ph.D., is the Director of Operations. The consulting physicist and Radiation Safety Officer is Walter Nikesch, Ph. D., from St. John Hospital in Detroit.

No violations were identified.

5. Internal Audits or Inspections

The license contains no specific requirements for internal inspections. The physicist and R.S.O., Walter Nikesch, however, visits the facility at least monthly. During these visits he reviews film badge records, swipe test results, bioassay results, survey meter calibrations, posting, and does a radiation survey. He makes recommendations pertinent to radiation safety and informs the licensee of current regulations. He provides a written report of his review, findings and recommendations.

No violations were identified.

6. Training, Retraining and Instruction to Workers

The licensee's training program consists of periodic lectures by Walter Nikesch and occasionally a guest lecturer. Licensee representative stated all new people are given lectures on radiation safety, laboratory safety, regulations and the license. The latest lecture was given on November 28, 1980, and is documented. The requirements of 10 CFR 19.12 appear to have been met.

No violations were identified.

7. Radiological Protection Procedures

Procedures are provided for the safe receipt, disposal and transfer of radioactive materials. Also available are emergency and laboratory safety procedures.

No violations were identified.

8. Facilities

Nuclear Diagnostics, Inc., facility is an industrial office suite consisting of rooms for offices, counting equipment, general lab, hot lab, quality control lab, manufacturing lab, kit assembly, cold storage, general storage, loading dock, and shipping and receiving.

The hot lab contains an enclosed overhead fume hood, hot sink, storage safe, cabinets and counter tops.

No violations were identified.

9. Instrumentation

The instrumentation specified in License Condition No. 13, referenced in letters dated March 21, 1977, and July 28, 1976, and referenced in License Condition No. 13 was available.

Survey instruments available in the hot lab are a Victoreen-493 G-M meter and a Nuclear Chicago Model 1620A area monitor.

Counting equipment consists of two Nuclear Chicago auto-gamma counters and a Nuclear Chicago manual well counter.

The instrument used for performing routine bioassays consists of the Nuclear Chicago well counter Model 8725 in conjunction with an Eberline Model PG-1 (plutonium gamma) hand held probe which contains a NaI (TL) crystal.

No violations were identified.

10. Security of Material

In the areas inspected, all licensed material was secured against unauthorized removal. When the office is open, the laboratories are

constantly attended and during off hours the office is locked and properly secured.

No violations were identified.

11. Posting and Labeling

Posting of radioactive caution and warning signs in isotope use and storage areas appeared to be adequate. Posting of notices as required by 19.11 appeared to be adequate.

Labeling of storage containers, however, was not adequate. 10 CFR 20.203(f) requires that each container with greater than exempt quantities (one microcurie of I-125 and 10 microcuries of Fe-59) shall bear the radiation caution symbol and "Caution, Radioactive Material" statement. Several drums used for storage and shipment of radioactive waste which were stored in a rear storage room were not labelled. Based on licensee estimates at least one of these drums contained millicurie quantities of I-125 and another contained greater than 10 microcuries of Fe-59. In addition, an independent survey conducted by the inspector with the instrument described in Confirmatory Measurements revealed readings on the surface of one of the higher level I-125 barrels of 1.1 mR/hr to 3 mR/hr. A barrel containing Fe-59 read 11.4 to 16.2 mR/hr at the surface.

Contrary to 10 CFR 20.203(f) requirements these barrels were not labeled.

10 CFR 32.71(c)(1) requires that each prepackaged unit of I-125 bear a durable label indicating that the amount of radioactivity does not exceed 10 microcuries. A review of the labels currently used revealed they do not conform with this requirement. Specifically, the I-125 kit label states the total activity is approximately 10 microcuries.

One violation was identified.

12. Surveys

The application dated July 26, 1976, specifies swipes of laboratory and surrounding areas be performed monthly and the results recorded. The action level for decontamination is .005 microcuries.

A review of a sampling of swipe test records show several areas in the hot lab are frequently contaminated above the action level of .005 microcuries. These areas include the I-125 fractionating column, hot sink, and hood. Corrective actions including decontamination and rewipes were noted in the survey records. There is a potential for these contamination sites to contribute to airborne I-125.

In addition to swipe tests, the R.S.O. performs G-M surveys monthly in use and storage areas. A sampling of these records were reviewed. Occasional high readings have been noted and corrective action taken to reduce them.

Procedures and frequencies of personnel and laboratory contamination surveys, as well as evaluations of airborne I-125 potential, have failed to remain commensurate with the increasing radiological hazards associated with a marked increase in the quantity of I-125 used. Specifically, the latest evaluation of the fume hood exhaust rate and potential I-125 air concentrations were performed several years ago when only one or two millicuries of I-125 were used per iodination. Currently from 45 to 60 millicuries are used per iodination. In addition, contamination swipe tests are still performed once a month.

Based on the above information and the excessive thyroid uptake described in the section Radiation Protection - Internal, the licensee has failed to make adequate surveys or evaluations as required and defined by 10 CFR 20.201(a) and (b).

One violation was identified.

13. Waste Disposal

Radioactive waste consists of I-125 and Fe-59 which is disposed by sewerage dilution or shipped by the commercial disposal company, U.S. Ecology (formerly Nuclear Engineering Company).

Licensee has made calculations based on sewerage volume of the maximum permissible amounts of Fe-59 and I-125 that can be disposed daily. A record review indicated sewerage releases appear to be in accordance with applicable regulations.

For details on waste shipments see the section Transportation.

No violations were identified.

14. Personnel Monitoring - External

Evaluations of whole body and extremity exposures are performed using film badges and TLD ring dosimeters supplied monthly by R. S. Landauer, Jr., Company. All persons working in the vicinity of radioactive material are supplied with whole body badges. In addition, ring dosimeters are issued to the individuals working in the isotope hot laboratory.

The inspector reviewed film badge reports from 1977 through May 1981. With the exception of the May 1978 report, the maximum whole body quarterly exposure was noted to be 680 mrem. The maximum quarterly extremity exposure was 120 mrem. For the period May 10, 1978, to June 9, 1978, a whole body reading of 3.220 rem and a ring badge reading of 1.780 rem was recorded. These exposures were reported

to the NRC on July 25, 1978. An NRC investigation on August 22, 1978, verified the licensee's conclusion that these exposures were to the badges only.

No violations were identified.

15. Personnel Monitoring - Internal

The licensee's internal monitoring program consists of performing routine bioassays of employees' thyroid glands for I-125 content. Monitored are all persons working with I-125 and occasionally other office personnel. The licensee is required by License Condition No. 13, referencing the letter dated March 21, 1977, to perform bioassays monthly. Bioassay result records were reviewed from July 1978 to June 1981.

The bioassay results (Attachment 1) show that for the period from March 10, 1981, to April 24, 1981, an individual had an iodine-125 thyroid burden. The highest burden of 2.11 microcuries was recorded on March 16, 1981, and is the equivalent of about 3 times the 40 hours per week for 13 weeks (520 MPC-hours) limit expressed in 10 CFR 20.103(a)(1).

Further investigation into this matter revealed the following information:

- A. The individual performed an iodination on or about February 27, 1981.
- B. On March 8, 1981, the individual was pooling radioactive NaI waste from a purification into a waste bottle in the hood. He handled nine to ten test tubes with 1 to 2 millicuries per test tube, totaling 10 to 20 mCi I-125.
- C. On March 9, 1981, a routine bioassay was performed. The results were high which initiated an investigation by the licensee. At this time it was discovered the individual's hands, lab coat, pockets, and pants were contaminated. Cleanup procedures included decontaminating his hands, removing the lab coat and changing clothes. A resurvey showed the cleanup was successful. The licensee sought to determine the cause of the incident but the individual stated he did not know how he became contaminated. At this time, the individual was suspended from the hot lab because of the high readings and as of June 11, 1981, is still suspended.
- D. On March 9, 1981, a routine wipe test showed significant (.33 uCi/100cm² I-125) contamination on the hot lab hood sash. Other areas of the hot lab were also contaminated.
- E. The hot lab was decontaminated on March 10, 1981, or March 11, 1981. A resurvey showed the cleanup was successful.

The counting system used for bioassays consists of a Nuclear Chicago manual well counter Model 8725 with an Eberline Model PG-1 hand held probe. The system is calibrated using a single hole, plastic neck phantom and a secondary NBS traceable, .0736 microcurie, mock-iodine (Am-241/I-129) source.

The phantom is counted with the probe held in front in contact with the surface. A 30 second count is made.

Personnel are counted by holding the probe up to each lobe of the thyroid, on contact with the skin. A 30 second count is taken on the right side and then on the left side. The two numbers are sometimes averaged and at other times the highest activity may be used for calculation purposes. Results are recorded in units of microcuries.

One violation was identified.

16. Notifications and Reports

10 CFR 20.405(a) requires a written report of each exposure of an individual to radioactive material in excess of the limits in 10 CFR 20.103(a)(1). As of June 4, 1981, the licensee had not submitted a written report to the NRC of the thyroid overexposure discovered on March 9, 1981.

In addition, 10 CFR 19.13(d) requires the licensee to notify in writing the individual exposed. As of June 4, 1981, a written report of the exposure described in Personnel Monitoring - Internal was not submitted to the individual exposed.

Two violations were identified.

17. Receipt and Transfer

Byproduct Material received consists of 60 millicuries of I-125 from AECL, and 5 millicuries of Fe-59 once a month. When packages containing these materials arrive, they are taken immediately to the hot lab, surveyed with a G-M survey meter and wipe tested for contamination. Receipt and survey records were reviewed from November 1977, to May 28, 1981, and appear adequate.

Byproduct Material is transferred in three ways; as I-125 solutions to Diagnostic Corporation of America, as in vitro clinical laboratory test kits to general licensees, and as waste to U.S. Ecology.

Records of transfers of kits to general licensees and the I-125 solutions appear to be in compliance with 10 CFR 30.41.

For transfer of waste see Transportation.

No violations were identified.

18. Transportation

The licensee transfers I-125 and Fe-59 solid waste in 55 gallon drums to U.S. Ecology (formerly Nuclear Engineering Co.). The licensee responded to IE Bulletin No. 79-19 in a letter dated October 8, 1979. A review of applicable documents and records indicated the procedures described in that letter appear to be implemented.

The inspector opened and examined the contents of one barrel.

No violations were identified.

19. Confirmatory Measurements

The inspector made independent measurements during the inspection using a Xetex 305B, NRC Serial No. 007852, calibrated on March 20, 1981.

The results were as follows:

A. Hot lab;

1. hot sink, 1.2 mR/hr
2. fraction collector, 1.0 mR/hr
3. Fe-59 storage safe, surface, .4 mR/hr
4. Face of hood, 2.5 mR/hr
5. a lead brick inside fume hood, 54 mR/hr

B. Production room; .2 mR/hr

C. Cold room; .1 mR/hr

1. I-125 research solution, 15.5 mR/hr

D. Waste drums;

1. I-125 drum, 1.1 mR/hr
2. Fe-59 drum, 16.2 mR/hr

E. Fe-59 storage area; 6.5 mR/hr

No violations were identified.

20. Exit Interview

On June 4, 1981, an exit interview was held at the conclusion of the inspection with the licensee representatives identified in Section 1. The apparent items of noncompliance were reviewed.

21. Enforcement Conference

An enforcement conference was held in the Region III office on July 30, 1981. The meeting was attended by Drs. Warner Wahl and Walter Nikesch of Nuclear Diagnostics, Inc. and Messrs. A. B. Davis, L. R. Greger, D. J. Sreniawski and Ms. E. R. Matson of the Region III staff. During the meeting the NRC enforcement policy and the five items of noncompliance were discussed. Also discussed were causes of, and corrective actions taken as a result of, the excessive thyroid uptake.

Attachment: As Stated

Attachment A

Attachment A							
		Body	Head	1st Individual	2nd Individual		
2-8-80	18	96	337	55 56	514	0.0077	.25
2-6-81	101	162	165	118 191	400	0.0077	
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3-9-81	40	300/825	225	5135 4060	600	0.62	←
3-10-81	101	179/107	1277	5200/1000	618	0.82	.25
3-11-81	101	105/107	105	1000/1000	100	1.25	.25
3-12-81	100	115/107	141	1000/1000	100	1.63	.3
3-13-81	157	106/97	143	1000/1000	785	1.44	.19
3-14-81	107	135/81	110	1237/1427	623	2.11	.19
3-17-81	86	114/98	112	1000/1000	580	1.75	.19
3-18-81	100	106/90	122	1000/15132	580	2.10	.17
3-19-81	120	159/142	128	1150/1000	625	1.85	.21
3-20-81	119	390/115	141	1279/15000	740	1.30	.15
3-21-81	100	200/1250	260	1000/1000	140	1.68	.14
3-22-81	100	342/415	210	1229/2000	1105	1.54	.15
3-25-81	105	254/103	212	1570/18000	1015	1.40	.15
3-26-81	100	167/123	142	1000/1000	735	1.68	.1
3-27-81	100	161/66	129	1000/1717	725	1.38	.1
3-31-81	70	129/103	59	1000/1000	740	1.12	.15
4-1-81	80	55/103	70	1000/1000	690	1.18	.1
4-3-81	80	100/27	10	1000/1000	705	1.00	.0
4-5-81					1140		
4-16-81	10	91/35	101	1000/1000	1000	0.97	.0
4-24-81	100	100/100	100	1000/1000	1000	0.81	
5-29-81	105	95/112	143	3500/5694	864	0.44	.0
6/11						0.39	

September 30, 1981

OFFICE OF INSPECTION AND ENFORCEMENT
NOTIFICATION OF SIGNIFICANT ENFORCEMENT ACTION

EN 81-36

Licensee: Nuclear Diagnostics, Incorporated, Troy, Michigan
License No. 21-14161-01G

Lic. File
(Correspondence)

Subject: PROPOSED IMPOSITION OF CIVIL PENALTIES - \$1,000

This is to inform the Commission that a Notice of Violation and Proposed Imposition of Civil Penalties in the amount of One Thousand Dollars will be issued on or about October 6, 1981, to Nuclear Diagnostics, Incorporated. This action is based on alleged violations involving failure to perform adequate surveys that resulted in an uptake by an employee into the body of iodine-125 in excess of NRC limits. Three other violations not related to the excessive internal exposure occurrence were also found. The nature and significance of those items were such that civil penalties would not be warranted. A news release has been prepared and will be issued five days following mailing of the Notice. The State of Michigan will be notified.

It should be noted that the licensee has not been specifically informed of the enforcement action. The schedule of issuance and notification is:

Action Signed	September 30, 1981
Mailing of Notice	October 6, 1981
Telephone Notification of Licensee	October 6, 1981

The licensee has 30 days from the date of the Notice in which to respond. Following NRC staff evaluation of the response, the civil penalties may be remitted, mitigated or imposed by Order.

Contacts: J. Metzger, IE 24941 R. Wessman, IE 24900 D. Thompson, IE 24909

Distribution:
Chairman Palladino
Commissioner Gilinsky
Commissioner Bradford

Transmitted H St. 3:48
Commissioner Ahearne
Commissioner Roberts
S. J. Chilk, SECY

C. C. Kammerer, CA
F. J. Remick, PE
ACRS

MNBB: 3:50
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C. Michelson, AEOD
J. J. Fouchard, PA
H. S. Bassett, MPA
H. K. Shapar, ELD

Phillips: 3:46
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R. H. Vollmer, NRR
T. E. Murley, NRR
D. Eisenhut, NRR
R. Mattson, NRR
S. H. Hanauer, NRR

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J. J. Cummings, OIA

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G. W. Kerr, OSP

Regional Directors: RI

RII _____
RIII _____
RIV _____
RV _____

Willste: 3:52
J. G. Davis, NMSS
R. Minogue, RES

Mail
Document Mgt. Br. (PDR)
S. Ebbin, NSOC

PRELIMINARY INFORMATION - NOT FOR PUBLIC DISCLOSURE UNTIL October 6, 1981

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3:00

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JUL 13 1981

Nuclear Diagnostics, Inc.
ATTN: Warner Wahl, Ph.D.
President
575 Robbins Drive
Troy, MI 48080

License No. 21-14161-01G

Gentlemen:

This refers to the telephone conversation between Dr. J. Smart of your organization and Ms. E. Matson of this office on June 30, 1981, regarding arrangements for a meeting between members of our respective organizations. This meeting is scheduled for 2:00 p.m., July 22, 1981, at the Region III Office in Glen Ellyn, Illinois.

The purpose of this meeting is to discuss the items of noncompliance identified during a recent inspection, your corrective actions, and possible NRC enforcement actions.

If you have any questions related to this meeting, please contact Evelyn Matson or Don Sreniawski at 312-932-2500.

Sincerely,

James G. Keppler
Director

cc: DMB/Document Control Desk (RIDS)

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RIII
W/D
Matson/jp
7/7/81

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Sreniawski
7/7/81

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Gregor

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Streeter

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Nurellaus
7/8/81

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Davis

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Keppler
7/12/81