

December 15, 1981

MEMORANDUM FOR: Dudley Thompson, Director, Enforcement and Investigation Staff, IE

FROM: James G. Keppler, Administrator, Region III

SUBJECT: NUCLEAR DIAGNOSTICS, INC. - ORDER IMPOSING CIVIL PENALTY

We have reviewed the licensee's response dated November 5, 1981, and have concluded that one of the items of noncompliance should be withdrawn. However, no civil penalty was proposed for that item.

Attached is a draft Order Imposing Civil Monetary Penalties, a response to the licensee and the Appendix, Evaluations and Conclusions.

Original signed by
James G. Keppler

James G. Keppler
Regional Administrator

Attachments:

1. Draft ltr to licensee
2. Draft Order Imposing Civil Monetary Penalties w/attached Appendix, Evaluations and Conclusions

cc w/Attachments:

H. D. Thornburg, IE
J. Lieberman, ELD
Regional Enforcement Coordinators,
RI, RII, RIV, RV

A-8

RIII
CJM
Matson/so
12/10/81

RIII
Sreniawski
12/10/81

RIII
Greger
12/11

RIII
Schultz
12-15-81

RIII
Schultz
12-14-81

RIII
Warnick
12-14-81

RIII
Davis
12/14

RIII
Keppler
12/15/81

8507270064 850617
PDR FOIA
MCDERMAB5-322 PDR

Nuclear Diagnostics, Inc.

License No. 21-14161-01G

ATTN: Werner Wahl, Ph.D.

President

575 Robbins Drive

Troy, MI 48084

Gentlemen:

This will acknowledge receipt of your letter dated November 5, 1981, in response to the Notice of Violation and Proposed Imposition of Civil Penalties sent to you with our letter dated October 6, 1981. Our October 6, 1981, letter concerned violations found during our inspection conducted on June 4, 1981.

After careful consideration of your response, and for the reasons given in the enclosed Order and Appendix, we have concluded that with the exception of Item II C, the violations did occur as set forth in the Notice of Violation and Proposed Imposition of Civil Penalties. No adequate reasons have been stated as to why the penalties for Items I A and I B should not be imposed as proposed. Accordingly, we hereby serve the enclosed Order on Nuclear Diagnostics, Incorporated, imposing a civil penalty in the amount of One Thousand Dollars. As noted in the Appendix, we are withdrawing Item II C, based on additional information provided in your ^{NW 5-11-81} October 6, 1981, letter and November 20, 1981, telephone conversation. No civil penalty had been proposed for Item II C.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

In your letter dated November 6, 1981, you requested that certain confidential information be withheld from public disclosure. This request is being evaluated by our legal staff and you will be advised of their decision.

Sincerely,

Richard C. DeYoung, Director
Office of Inspection and Enforcement

Enclosure: Order Imposing
Civil Monetary Penalties

cc w/encl:

DMB/Document Control Desk (RIDS)

Appendix

EVALUATIONS AND CONCLUSIONS

For each item of noncompliance and associated civil penalty identified in the Notice of Violation, the original item of noncompliance is restated and the Office of Inspection and Enforcement's evaluation and conclusion regarding the licensee's response to each item contained in Nuclear Diagnostics, Inc.'s letter dated November 5, 1981, is presented.

1. STATEMENT OF NONCOMPLIANCE FOR ITEM 1A

10 CFR 20.201(b) requires that each licensee shall make or cause to be made such surveys as may be necessary for him to comply with the regulations in Part 20. A survey as defined in 20.201(a) is an evaluation of the radiation hazards incident to the use of radioactive material under a specific set of conditions.

Contrary to the above, the licensee failed to make such surveys or evaluations as were necessary to assure that an individual who handled significant quantities of iodine-125 did not receive an uptake exceeding the limits specified in 10 CFR 20.103. Specifically, surveys for contamination conducted as a result of iodinations and other uses of the licensed material were not adequate or commensurate

with the substantial increase in the amounts of iodine-125 used in iodinations (as high as 60 millicuries compared to 2-3 millicuries used in the past).

This is a Severity Level III violation (Supplement IV).

(Civil Penalty - \$650).

EVALUATION OF LICENSEE'S RESPONSE TO ITEM 1A

The licensee admits the violation, but states there is an error in the violation in that NDI has never used more than 30 millicuries of iodine-125 per iodination. This information does not alter the significance of the violation in-as-much as it still represents a substantial increase in the amount of iodine-125 handled in the laboratory.

CONCLUSION

The item, as stated, is a violation. The information presented by the licensee does not provide a basis for modification of the enforcement action.

2. STATEMENT OF NONCOMPLIANCE FOR ITEM IB

10 CFR 20.103(a)(1) states no licensee shall possess, use, or transfer licensed material in such a manner as to permit an individual in a restricted area to inhale a quantity of radioactive material which would result from inhalation for 40 hours per week for 13 weeks at uniform concentrations of radioactive material in air specified in Appendix B, Table 1, Column 1.

If the radioactive material is of such form that intake by absorption through the skin is likely, individual exposures to radioactive material shall be controlled so that the uptake of radioactive material by any organ from either inhalation or absorption or both routes of intake in any calendar quarter does not exceed that which would result from inhaling such radioactive material for 40 hours per week for 13 weeks at uniform concentrations specified in Appendix B, Table 1, Column 1.

Significant intake by ingestion or injection must be evaluated and accounted for by techniques and procedures as may be appropriate to the circumstances of the occurrence. Exposures so evaluated shall be included in determining whether the limitation on individual exposures in 10 CFR 20.103(a)(1) has been exceeded.

Contrary to the above, the licensee's bioassay records showed that an individual working in a restricted area during the first quarter of 1981 had an uptake of iodine-125 that resulted from an intake greater than the equivalent of inhaling iodine-125 for 40 hours per week for 13 weeks at the uniform concentration specified in 10 CFR 20, Appendix B, Table 1, Column 1. Specifically, a bioassay conducted on March 16, 1981, showed the individual's uptake of iodine-125 was about three times the 13 week limit.

This is a Severity Level III violation (Supplement IV).

(Civil Penalty - \$350).

EVALUATION OF LICENSEE'S RESPONSE TO ITEM IB

The licensee denies the violation on the basis that the thyroid exposure was within ICRP, NCRP, and 10 CFR 20.101 guidelines and that the NRC regulations are vague and subject to interpretation. The licensee states as evidence of the vagueness of the regulations that it took NRC Region III almost a month to conclude there may have been a violation. However, the licensee states they now understand how the NRC determined there was a violation.

Simply because an exposure is within ICRP and NCRP guidelines does not negate the necessity of complying with NRC regulations. The applicable limits for iodine-125 intake are addressed in 10 CFR 20.103. 10 CFR 20.101 defines the exposure limits for whole body, head and trunk, active blood forming organs, et cetera. Although these limits must not be exceeded either, they do not apply to the thyroid burden accrued in this case.

The NRC (Region III) interpretation and use of 10 CFR 20.103 follows ICRP and NCRP guidelines for uptake and retention of iodine-125 by the thyroid and has precedence in previous NRC enforcement actions. The licensee's lack of familiarity with the guidelines and the significance of the actual radiation exposure relative to ICRP and NCRP guidelines were considered when determining the amount of the civil penalty. For the sake of clarity, it should be noted that the licensee was informed that the thyroid uptake was an apparent violation of NRC regulations on the day of the inspection, June 4, 1981.

CONCLUSION

The item, as stated, is a violation. The information presented by the licensee does not provide a basis for modification of this enforcement action.

3. STATEMENT OF NONCOMPLIANCE FOR ITEM IIC

10 CFR 20.203(f) requires that each container of licensed material in excess of 1 microcurie of iodine-125 and 10 microcuries of iron-59 shall bear a durable, clearly visible label identifying the radioactive contents. The label shall bear the radiation caution symbol and the words, "Caution - Radioactive Material."

Contrary to the above, on June 4, 1981, the inspector observed waste storage drums containing millicurie quantities of iodine-125 and 20 millicuries of iron-59 that were not labeled as required.

This is a Severity Level VI violation (Supplement IV).

EVALUATION OF LICENSEE'S RESPONSE TO ITEM IIC

The licensee denies the violation on the basis that the storage barrels are stored in a restricted area and, therefore, exempt from labeling under 10 CFR 20.203(f)(3)(vi). The licensee also stated during a telephone conversation on November 20, 1981, that a written record of the barrel contents are available to individuals who have access to the barrels. Based on the additional information supplied, we agree this item does not constitute a violation and it will be deleted from our records.

CONCLUSION

The item is not a violation. The information presented by the licensee provides a basis for deleting the item. No civil penalty was proposed for this item.

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

In the Matter of:)	
)	
Nuclear Diagnostics, Inc.)	License No. 21-14161-01G
575 Robbins Drive)	EA 81-79
Troy, MI 48084)	

ORDER IMPOSING CIVIL MONETARY PENALTIES

I

Nuclear Diagnostics, Inc., Troy, Michigan (the "licensee") is the holder of Byproduct Material License No. 21-14161-01G (the "license") issued by the Nuclear Regulatory Commission (the "Commission") which authorizes the licensee to manufacture in vitro kits and to distribute these kits to persons generally licensed pursuant to 31.11 of 10 CFR Part 31. The license was issued on August 13, 1971, and a timely renewal application has been submitted.

II

A routine inspection was conducted of licensed activities under the license on June 4, 1981. As a result of this inspection it appears that the licensee has not conducted its activities in full compliance with the conditions of the license and with the requirements of the Nuclear Regulatory Commission's "Notices, Instructions and Reports to Workers; Inspections," Part 19 and "Standards for Protection Against Radiation," Part 20, Title 10, Code of Federal Regulations. A written Notice of Violation was served upon the licensee by letter dated October 6, 1981, specifying the items of noncompliance in accordance with 10 CFR 2.201. A Notice of Proposed Imposition of Civil Penalties was served concurrently upon the licensee in accordance with Section 234 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2282), and 10 CFR 2.205, which incorporates by reference the Notice of Violation. The licensee responded to the Notice of Violation and Proposed Imposition of Civil Penalties by letter dated November 5, 1981.

III

Upon consideration of the answers received and the statements of fact, explanation, and argument for deferral, compromise, mitigation, or cancellation contained therein, as set forth in the Appendix to this Order, the Director of the Office of Inspection and Enforcement has determined that the penalties proposed for Items I.A and I.B should be imposed. No penalty was proposed for Items II.A, II.B and II.C.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2282), and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The licensee pay civil penalties in the total amount of One Thousand Dollars within thirty days of the date of this Order, by ~~X~~ check, draft, or money order payable to the Treasurer of the United States and mailed to the Director of the Office of Inspection and Enforcement.

The licensee may, within thirty days of the date of this Order, request a hearing. A request for a hearing shall be addressed to the Director, Office of Inspection and Enforcement, U.S.N.R.C., Washington, D.C. 20555. A copy of the hearing request shall also be sent to the Executive Legal Director, U.S.N.R.C., Washington, D.C. 20555. If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. Upon failure of the licensee to request a hearing within thirty days of the date of this Order, the provisions of this Order shall be effective without further proceedings and, if payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the licensee requests a hearing as provided above, the issues to be considered at such a hearing shall be:

- a. whether the licensee was in noncompliance with the Commission's regulations and the conditions of the license in the respects set forth in the Notice of Violation (Items I.A and I.B) and
- b. whether on the basis of such items of noncompliance the Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Richard C. DeYoung, Director
Office of Inspection and Enforcement

Dated at Bethesda, Maryland

this _____ day of _____ 1981

Attachment: Appendix,
Evaluation and Conclusion