UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	Byproduct Material
	)	License Nos. 29-13985-01
Diagnostic Isotopes, Incorporated	)	29-13985-04MD
225 Belleville Avenue	)	
Bloomfield, New Jersey 07003	)	

ORDER IMPOSING CIVIL MONETARY PENALTIES

I

Diagnostic Isotopes, Incorporated, 225 Belleville Avenue, Bloomfield, New Jersey ("the licensee"), is the holder of Byproduct Material License Nos. 29-13985-01 and 29-13985-04MD ("the licenses") issued by the Nuclear Regulatory Commission ("the Commission"). License No. 29-13985-01 authorizes production, quality control, radiopharmaceutical processing, research and development, and distribution to specifically licensed recipients in accordance with the conditions specified therein, and is due to expire on April 30, 1982. License No. 29-13985-04MD authorizes distribution to persons licensed pursuant to 10 CFR 35.14 and 10 CFR 35.100 for Group I and Group II as described in those sections, and is due to expire on August 31, 1982.

II

An inspection of the licensee's activities under License Nos. 29-13985-01 and 29-13985-04MD was conducted on August 2 and 3, 1979, at the licensee's facility in Bloomfield, New Jersey. As a result of this inspection, it appears that the licensee has not conducted its activities in full compliance with the conditions of its licenses and with the requirements of the Nuclear Regulatory Commission's "Standards for Protection Against Radiation," Part 20, Title 10, Code of Federal Regulations. Written Notices of Violation were served upon the licensee by letters dated October 15, 1979 and January 10, 1980, specifying the items of noncompliance, in accordance with 10 CFR 2.201. Notices of Proposed Imposition of Civil Penalties dated October 15, 1979 and January 10,

1980 were concurrently served 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, incorporating by reference the Notice of Violation, which stated the nature of the items of noncompliance and the provisions of Nuclear Regulatory Commission regulations and license conditions.

Answers dated November 5, 1979 and February 14, 1980, to the Notices of Violation and Proposed Imposition of Civil Penalties were received from the licensee.

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 Appendix A to this Order, the Director of the Office of Inspection and Enforcement has determined that the penalties proposed for the items of noncompliance designated in the Notices of Violation should be imposed, except for Item F.1, which is withdrawn.

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 Eight Thousand Dollars ($8,000) within twenty-five days of the date of this Order, by 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.

V

The licensee may, within twenty-five days of the date of this Order, request a hearing. If a hearing is requested, the Commission will issue an order designating the time and place of hearing. Upon failure of the licensee to request a hearing within twenty-five 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.

VI

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

(a) whether the licensee was in noncompliance with the Commission's regulations and the conditions of the licenses as set forth in the Notices of Violation referenced in Section III above; and,

(b) whether, on the basis of such items of noncompliance, this order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Victor Stello, Jr.
Director
Office of Inspection
and Enforcement

Dated this 15th day of May 1980
at Bethesda, Maryland

Attachment:
Appendix A, Evaluations
and Conclusions

MAY 15 1980

APPENDIX A

EVALUATIONS AND CONCLUSIONS

For each item of noncompliance and associated civil penalty identified in the Notices of Violation (dated October 15, 1979, and January 10, 1980) the original item of noncompliance is restated and the Office of Inspection and Enforcement's evaluation and conclusion regarding the licensee's responses to each item (dated November 5, 1979 and February 14, 1980) is presented.

Statement of Noncompliance

A. 10 CFR 20.101(a), "Exposure of individuals to radiation in restricted areas," limits the extremity dose that an individual working in a restricted area may receive to 18.75 rems per calendar quarter.

1. Contrary to this requirement, one individual working in your restricted area received a hand exposure of 19.9 rems during the first calendar quarter of 1979.

   This is an infraction. (Civil Penalty - $1,000)

2. Contrary to this requirement, one individual working in your restricted area received a hand exposure of 29.8 rems during the fourth calendar quarter of 1978.

   This is an infraction. (Civil Penalty - $1,000)

Evaluation of Licensee Response

A.1. The licensee denies this item of noncompliance and bases that denial on the assertion that there could be up to a 10% error in its film badge readings, thus reducing the possible dose below 18.75 rems. The intent of 10 CFR 20.101 is to prevent exposures in excess of the stated limits and not to authorize exposures up to the limit. It is recognized that the exposure is only slightly in excess of the limit. However, such cumulative exposures are preventable. The licensee is expected to predict the exposure for a given operation and thus ensure that an individual's exposure for a calendar quarter stays well below the limit. In addition, the licensee has not provided evaluations to establish that the error margin did in fact exist, and that it would show a higher reading than the actual exposure. Therefore, the exposure as determined by the dosimeter and associated records must be accepted as accurate.

A.2. The licensee admits this item and requests remission of the penalty based on the corrective action taken. Corrective action is always required and is therefore not a basis for mitigation. The licensee also maintains the time interval from its report of the overexposure in February 1979, and the proposed penalty make the penalty inappropriate. The fact that the overexposure of item A.1 occurred after this incident demonstrates the lack of effectiveness of the corrective action and the appropriateness of the penalty. Moreover, the licensee has had a history of exposures in excess of 10 CFR 20.101.

Conclusion

The item as stated is an item of noncompliance. The information presented by the licensee does not provide a basis for modification of this enforcement action. Items A.1 and A.2 are similar to items found in inspections 76-02 and 78-02.

Statement of Noncompliance

B. 10 CFR 20.405(a), "Reports of overexposures and excessive levels and concentrations," requires that you submit within 30 days, a report to the Commission concerning each exposure to radiation in excess of any applicable limit in Part 20 of your license.

Contrary to this requirement, as of August 2, 1979, you failed to report to the Commission the exposure described in item A.1 above.

This is a deficiency. (Civil Penalty - $250)

Evaluation of Licensee Response

B. The licensee denies this item for the reasons given in A.1.

Conclusion

The item as stated is an item of noncompliance. The information presented by the licensee does not provide a basis for modification of this enforcement action. Item C is similar to an item found in inspection 76-02.

Statement of Noncompliance

C. 10 CFR 20.201(b), "Surveys," requires that you make such surveys as may be necessary for you to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "Survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal or presence of radioactive materials or other sources of radiation under a specific set of conditions.

1. 10 CFR 20.101, "Exposure of individuals to radiation in restricted areas," limits radiation exposure to the extremities of individuals.

Contrary to this requirement, as of August 2, 1979, you failed to make such surveys as were necessary to assure compliance with 10 CFR 20.101. Specifically, you failed to evaluate the radiation dose to the right hand and fingers of an individual who used that hand to pick up vials and syringes containing millicurie quantities of technetium-99m without wearing a monitoring device on that hand.

This is an infraction. (Civil Penalty - $1,000)

2. 10 CFR 20.106, "Radioactivity in effluents to unrestricted areas," requires that you possess, use, or transfer licensed material in such a manner so as not to release licensed material to an unrestricted area in concentrations which exceed the limits specified in Appendix B, Table II, of Part 20.

   Section 4 of the March 17, 1977 application incorporated by reference in license condition 15 of License No. 29-13985-01 specified two specific methods to be used in evaluation (constant air monitoring and material balance) and also that the results be compared to determine the effluent released.

   Contrary to these requirements, you failed to make such surveys as were necessary to assure compliance with 10 CFR 20.106. Specifically, you failed to compare the results of the two methods of evaluation and hence failed to evaluate concentrations of xenon-133 released to an unrestricted area for the period January to August 1979.

   This is an infraction. (Civil Penalty - $750)

3. 10 CFR 20.105(b), "Permissible levels of radiation in unrestricted areas," requires that radiation levels in unrestricted areas be limited so that if an individual were continuously present in the area, he could not receive a dose in excess of two (2) millirems in any one hour or one hundred (100) millirems in any seven (7) consecutive days.

   Contrary to this requirement, on August 2, 1979, you failed to make such surveys as were necessary to assure compliance with 10 CFR 20.105(b). Specifically, radiation levels up to ten (10) milliroentgens per hour existed at a waste dumpster in an unrestricted area behind your facility.

   This is an infraction. (Civil Penalty - $750)

Evaluation of Licensee Response

C.1. The licensee denies this item based on data purporting to show an evaluation of the individual's exposure. The licensee's data displays ratios of right to left hand exposures, and he appears to argue that a film badge on the left hand is sufficient to evaluate exposure to the right hand. Four ratios, ranging from 1:1 to 2:1, are inadequate to show a proper evaluation, especially since the licensee's initial response stated the exposures to each hand were approximately equal. Had the licensee relied on these ratios for his evaluation, it would have been appropriate to require a right hand film badge in order to monitor the hand with the higher exposure.

C.2. The licensee denies this item and has provided dates on which surveys of the air monitoring system were performed by his production manager.

This individual has stated to the NRC inspector that he did not follow the procedures for evaluating total activity and concentrations in the effluent as required by the license. The licensee has provided no data or calculations to demonstrate compliance with the methods specified in the license.

C.3. The licensee denies this item based on the observations of his employee that the activity at the waste dumpster was approximately 2 mr/hr. The NRC inspector measured radiation levels up to 10 mr/hr at the dumpster which was in an unrestricted area. The levels were measured using an Eberline Geiger-Mueller Survey Meter, Model E-120, calibrated on June 20, 1979. Following the inspection, the survey meter was satisfactorily checked against a reference source to verify calibration.

Conclusion

The item as stated is an item of noncompliance. The information presented by the licensee does not provide a basis for modification of this enforcement action. Item C.1 is similar to items found in inspections 76-01 and 77-02. Item C.2 is similar to items found in inspections 76-01 and 76-02, and is of the same requirement as cited in 76-01 and 76-02, however, in this case the adequacy of the evaluation and not the failure to perform any evaluation was cited. Item C.3 is similar to an item cited in inspection 76-02, and in both instances byproduct material was found in a waste dumpster.

Statement of Noncompliance

D. Condition 12 of License No. 29-13985-04MD requires licensed material be used by, or under the supervision of, a named individual.

Contrary to this requirement, as of August 2, 1979, and for a period of approximately one month prior, licensed materials were dispensed and distributed to Group II licensees by and under the supervision of individuals other than the individual named on the license.

This is an infraction. (Civil Penalty - $500)

Evaluation of Licensee Response

D. The licensee denies this item. He states the named supervisor was present at the facility from July 12 through July 20, 1979, but had not been seen by the midnight to 8 a.m. shift personnel for approximately one month. The intent of the license condition is that the named supervisor be readily available to contact, observe, instruct or otherwise assure that licensed operations are conducted safely and within the limits of NRC requirements.

Conclusion

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

Statement of Noncompliance

E. Condition 15 of License No. 29-13985-01 requires that licensed materials be possessed and used in accordance with the statements, representations, and procedures contained in your application dated March 17, 1977, letter dated March 24, 1977; application dated July 29, 1977, as amended September 19, 1977, and application dated February 13, 1978.

1. Items A-4, A-14 and B-3 of your "Radiation Safety Manual," attached to your application dated March 17, 1977, requires that individuals wear protective gloves when working with radioactive material, avoid unnecessary exposure to radiation or radioactive materials, and wear laboratory coats before beginning any duties in the restricted area.

   Contrary to this requirement, on August 2, 1979, an individual working with millicurie quantities of radioactive materials did not wear protective gloves, did not in all cases use remote handling tools (tongs) or vial and syringe shields to avoid unnecessary exposure to radiation and, in one case, failed to wear a laboratory coat when dispensing millicurie quantities of radioactive materials in your restricted Radiopharmacy area.

   This is an infraction. (Civil Penalty - $750)

2. Section 5, "Training Program" of your "Radiation Protection Program," attached to your application dated March 17, 1977, requires that any person whose job requires admittance to the restricted area complete your training program for laboratory personnel.

   Contrary to this requirement, on August 2, 1979, truck drivers who entered your restricted area to pick up and deliver packages had not received the required instruction.

   This is an infraction. (Civil Penalty - $500)

3. Item B-2 of your "Radiation Safety Manual" attached to your application dated March 17, 1977, requires that personnel monitoring equipment (TLD badge plus one dosimeter) shall be worn by all authorized personnel entering the restricted area.

   Contrary to this requirement, on August 2, 1979, truck drivers who entered your restricted areas had not received the required personnel monitoring equipment.

   This is an infraction. (Civil Penalty - $500)

Evaluation of Licensee Response

E.1. The licensee admits this item, but argues the presence of NRC inspectors contributed to the noncompliance. Routine, unannounced inspections are standard procedure to ensure licensee compliance. A licensee consents to

reasonable inspections by accepting his license. A licensee is expected to follow basic radiation safety practices whether or not there are NRC inspectors present.

E.2. The licensee denies this item based on the employee drivers' previous training and experience gained while working for other companies in this industry. Previous experience or training by other companies does not suffice to assure that the individuals are knowledgeable about the licensee's radiation safety requirements, procedures, or facility.

E.3. The licensee denies this item on the basis that item B-2. of the Radiation Safety Manual only refers to employees and that a badged escort is sufficient. Item B-2. refers to all "authorized personnel," not just employees. Escorted visitors are authorized personnel and are required to wear personnel monitoring equipment.

Conclusion

The item as stated is an item of noncompliance. The information presented by the licensee does not provide a basis for modification of this enforcement action. Item E.1 is similar to an item cited in inspection 76-01. In both instances, required protective clothing was not worn.

Statement of Noncompliance

F. Condition 14 of License No. 29-13985-04MD requires that licensed material be used in accordance with the statements, representations, and procedures contained in your application dated May 27, 1977, and in letters dated July 19, 1977 and August 10, 1977.

1. Item 2.a of the supplement of your application dated May 27, 1977, requires that you check each batch of generator eluate for molybdenum-99 breakthrough and alumina content.

   Contrary to this requirement, on August 2, 1979, you failed to check each batch of generator eluate for molybdenum content.

   This is an infraction. (Civil Penalty - $500)

2. Item 2.c of this supplement requires that your dose calibrator be checked daily using cesium-137 and cobalt-57 standards as specified in Appendix E, item c of your application dated March 17, 1977.

   Contrary to this requirement, you had failed to check your dose calibrator with cesium-137 and cobalt-57 standards during the period July 26, to August 2, 1979.

   This is an infraction. (Civil Penalty - $500)

Evaluation of Licensee Response

F.1 The licensee denies this item on the basis that each batch of generator eluate was checked for molybdenum-99 breakthrough and alumina content. THis item is unresolved and the records of August 2, 1979, showing the checks of each batch will be reviewed during the next inspection.

F.2. The licensee admits this item but argues that his checks on Monday, Wednesday and Friday were sufficient. He states that an overwhelming body of data supports the reproducibility of his checks on the Monday through Friday performance. In a facility of this sort, with numerous patient doses prepared each day, a daily check is essential. This view is supported by the American National Standards Institute standard N42, 13-1978, which requires a calibration check on each work shift during which the instrument is used.

Conclusion

F.1. The licensee's response, if verified, forms a basis for remitting the civil penalty. Accordingly, this item is withdrawn pending a future inspection.

F.2. This item as stated is an item of noncompliance. The information presented by the licensee does not provide a basis for modification of this enforcement action.

Statement of Noncompliance

G. Condition 14 of License No. 29-13985-04MD requires that licensed material be used in accordance with the statements, representations, and procedures contained in your application dated May 27, 1977, and in letters dated July 19, 1977, and August 10, 1977.

Item 3.b of the supplement to your application dated May 27, 1977, requires that you distribute radiopharmaceuticals in compliance with all applicable federal and state regulations. Item 1 of your letter dated July 19, 1977, assigns to your Radiopharmacy responsibility to assure that reports from the customer are submitted to the sponsor.

Contrary to this requirement, as of August 3, 1979, you failed to obtain the reports required by the United States Food and Drug Administration under your Notice of Claimed Investigational Exemption of a New Drug (IND) from your customers who received technetium-99m as pertechnetate eluted from your technetium-99m generating system, the "Union Carbide Master Milker."

This is an infraction. (Civil Penalty - $500)

Evaluation of Licensee Response

G. The licensee denies this item on the basis that patient reports are not required for drugs dispensed under prescription and whose monographs appear in the United States Pharmacopoeia (U.S.P.). It has been the FDA's consistent position that all radioactive drugs are new drugs and must be dispensed under an IND or New Drug Application. There is nothing in FDA regulations that suggests a USP monograph exempts a holder of an IND from the duty of obtaining patient reports, whether the drug is dispensed under prescription or not.

Conclusion

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

DATES OF INSPECTION

76-01	March 19, 1976
76-02	December 29, 1976 and January 2, 1977
77-01	April 28-29, 1977
77-02	October 28, 1977
78-01	May 25, 1978
78-02	August 8, 1978