

UNITED STATES
ATOMIC ENERGY COMMISSION
DIRECTORATE OF REGULATORY OPERATIONS
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

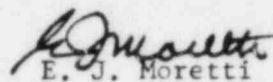
TELEPHONE
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July 20, 1972

James M. Allan, Acting Chief,
Radiological and Environmental Protection Branch

HEALTH PHYSICS ANALYSIS, NUCLEAR DIAGNOSTICS, INC.
GROSSE POINTE WOODS, MICHIGAN, LICENSE NO. 21-14161-1G

This small business group makes diagnostic kits containing 10 microcuries of I-125 or less for distribution to persons generally licensed pursuant to 10 CFR 31.11. No processing is done, only dilution of the $\frac{1}{2}$ to 1 mCi I-125 labeled compound as received from supplier with solvent solution to prepare the test kits. This program appears to be adequately supervised by competent personnel and conducted with due regard to radiation safety, AEC regulations and license conditions. Adequate records of receipt, transfers and inventory are maintained. Distribution to customers are limited to sales of 10 microcurie I-125 units or less, and if more than these quantities are requested the customer is requested to furnish his specific AEC license. Personnel monitoring records reveal minimal exposures accrued by licensee personnel. It is the opinion of the inspector that this program is being supervised by competent licensee personnel and conducted by them with due regards to health and safety of the employees and general public.


E. J. Moretti

Radiation Specialist

U. S. ATOMIC ENERGY COMMISSION
DIVISION OF COMPLIANCE

REGION III

EXPANDED FIELD NOTES

CO Inspection Report No.: _____

Subject: Nuclear Diagnostics, Inc.

754 Priescliff Drive

License No.(s) 21-14161-14

Location: Grosse Pointe Woods, Michigan

Priority III

48286

Category E

Type of Licensee: Manufacture-Distributor - GENERAL LICENSED ITEMS

Type of Inspection: Initial - announced.

Date(s) of Inspection: July 20, 1972

Date(s) of Previous Inspection: N/A

Principal Inspector: E. J. Marlette

Accompanying Inspector(s): none

Other Accompanying Personnel: none

Report Prepared By: E. J. Marlette

Report Reviewed By: J. M. Allan

7/26/72
(Date)

7-28-72
(Date)

Proprietary Information: none

List of Documents Attached: none

Licensee Nuclear Diagnostics, Inc.

A. Participants

Dr. Walter Di Giulio, M.D., President; Walter J. Robinson,
Radiological Health Physicist, and David Shwaberg, Technician.
State of Michigan notified of scheduled visit - inspection is accompanied

B. Scope of License Program

Byproduct material is used to make in vitro kits containing
D-T₃ for distribution to persons generally licensed pursuant
to 10 CFR 31.11. No processing is done, only dilution of
solutions, ²²³procured from suppliers.

C. Organization

Walter Di Giulio, M.D., President
Walter J. Robinson, M.S., Radiological Safety Officer.
David Shwaberg, Registered Technician, NMT
Sueet Sui, Biochemist
Ken Lombardi, Technician

D. Administrative Control

Dr. Di Giulio has overall responsibility for the
administrative control and radiological safety
program of this licensed activity. Mr. Robinson serves
as RSO.

E. Use of Material

Iodine 125, as Liothyronine and L-Thyronine, is procured
from Abbotts in 1/2 MCi to 1 MCi amounts which are
diluted with buffer and serum solution and packaged
for distribution to persons generally licensed pursuant to
10 CFR 31.11 for in vitro clinical and laboratory testing.
This program was initiated in Sept. 1971, and about 1 1/2 MCi to
3 MCi per month are procured to satisfy customer needs. No processing
of byproduct material takes place.

Licensee Nuclear Diagnostics, Inc.

F. Facilities

The isotope division laboratory facilities located at 21420 Mack Avenue, St. Clair Shores, Michigan were noted to be as described in the license application. Keys to these facilities are in custody of Mr. DeHunder and Mr. Robinson. Plans are being made to move to new location several blocks north of present location - maybe in Sept 1972 - license is to be amended for this new location in June.

G. Equipment

The licensee's radiation detection and measurement equipment on hand is as described in license application. Remote handling and supporting equipment available for use in this program. Also, a Victor 740B survey instrument is used for area monitoring.

H. Radiological Safety Procedures

Written and verbal instructions and procedures are employed in this program. Mr. Robinson, makes monthly audits of the radiological safety aspects of this program. Form REC-3, "Notice to Employees" posted in isotope laboratory.

I. Personnel Monitoring and Exposure to External Radiation

Individual film badge service provided on monthly basis. A review of the film badge records through June 1972 revealed that personnel doses were all recorded as being minimal.

J. Exposure of Employees to Concentrations of Radioactive Materials

none

Licensee Nuclear Diagnostics, Inc.

K. Effluents to Unrestricted Areas

none

L. Disposals

One transfer of waste to date - on 6/28/72 - To Nuclear Energy -
Sheffield. Most waste stored for decay, then disposed to licensed
agent. In future unusual amounts, if any, are disposed to
Sanitary Sewerage System.

M. Miscellaneous Surveys, Evaluations, and Records

Records of receipts, deliveries to customers, waste disposal,
personnel monitoring, calibration surveys & analysis, inventory
are being maintained. To date - 25 customers - 18 REC licensed and 7 - REC-493
licensees. Monthly smear surveys made by Mr. Robinson - records
reveal no unusual contamination problems above background. Distribution
records show that 225 units transfer do not exceed 10 microcuries
each when sent to authorized REC recipients.

N. Special License Conditions

License Conditions reviewed with Dr. D. H. Miller and Mr.
Robinson, no discrepancies were noted. Cond #10 through
an omission the DML should have included the licensee's 21240
Main Ave., St. Clair Shores, Michigan address in license. On
July 13, 1972, Borsini advised that license would be amended accordingly.

O. Posting and Labeling

Posting & labeling was observed to be in accordance with provisions
of 10 CFR 20.203. Also, it was noted that packages of waste were
labeled in accordance with provisions of 10 CFR 32.71(c), and (d) and (e)
have and repeat information or data for general license items. Files
and records were noted to be as described in license application.
for licensee's Th-Std T3 and Tetr-Std T4 (9125) test kits.

Licensee Nuclear Diagnostics, Inc.

P. Independent Measurements

none

Q. Operations Observed

none

R. Incidents, Overexposures, Theft or Loss, Equipment Malfunction

none

S. Other Information or Continuation from Previous Paragraphs

none

Licensee Nuclear Diagnostics, Inc.

Summary

S125, as Iothalamate and I-Thyronine, is prepared at 1/2 to 1 mCi lots from Abbotts for manufacture of an extract for distribution to generally licensed persons pursuant to 10 CFR 31.11. There is no processing, but children of stock solution received and transfer to prepackaged kits for distribution to the unlicensed recipients.

Noncompliance and Safety Items

none

Unusual Occurrences

none

Status of Previously Reported Noncompliance or Safety Items

none

Management Interview

With Dr. Walter Di Bello, M.D., President, and Mr. Walter Roman, RSO, who were advised no items of noncompliance noted. A Class I NRC-551 was issued upon conclusion of inspection.