030-34940
MSIB
Q2

Nuclear Diagnostic Products Inc.

Suite 125
21 Pine Street
Rockaway, New Jersey 07866
Tel. 973-664-9696
Fax 973-664-9699

June 30, 1999

Sattar Lodhi, Ph.D.
Health Physicist
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety
Re: Docket No. 030-34940
Control No. 126497

License No. 29-30500-01MD

Dear Dr. Lodhi:

As per our discussion, I have addressed the items that need clarification on our license application. Attached you will find the following:

- The revised limited quantity shipments table
- Our policy for establishing beta correction factor for Sm-153 and Sr-89
- And a revision for page 49 that changes the cpm to dpm.

If you need to reach me call me at my home number [redacted]

Sincerely,

Rodney Prosser R.Ph.
President

136126
NMSS/RGNI MATERIALS-002

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Limited Quantity Shipment Limits

Radionuclide	Limited Quantity in mCi
57-Co	21.6
58-Co	2.7
51-Cr	81.1
67-Ga	16.2
123-I	16.2
125-I	5.41
131-I	1.35
111-IN	5.41
99-Mo	2
32-P	.811
75-Se	8.11
99m-Tc	21.6
201-Tl	27
133-Xe (Uncompressed)	541
169-Yb	8.11

The above values have been calculated using information from 49 CFR 173.423, Table7, and 49 CFR 173.435, Table of A-1 and A-2 values for radionuclides.

When shipping more than one type of radioactive material in the same package, the limit on the radioactivity that may be shipped is determined by the lowest curie quantity assigned for the items shipped.

Example:

If 99m-Tc and 123-I were being shipped in the same package only 16.2 mCi of total activity could be shipped.

Calibration Setting Procedure for Sm-153 and Sr-89

- **Perform your normal dose calibrator check (Note background if applicable).**
- **Using the manufactures calibrated activity and known decay factors, determine the activity of the vial. Document the calculated activity.**
- **Place the vial in the calibrator and determine the activity and document the measured activity.**
- **Remove the amount of activity that you would consider to be an average patient dose into a dispensing container (syringe or vial).**
- **Measure the dispensing container and document the measurement.**
- **Measure the amount of activity left in the original manufacture's container (residual activity).**
- **Calculate the percent accuracy utilizing the formula below.**

$$\frac{\text{Amount in syringe}}{\text{Amount in the original vial} - \text{residual activity}} = \text{the beta correction factor}$$

Item 10.15 Procedures for Packaging and Transporting Radioactive Drugs

Package Shipment Procedure

Purpose: It is required by the Nuclear Regulatory Commission, the State of New Jersey, and Nuclear Diagnostic Products, Inc. that only trained qualified individuals prepare packages for shipment. All packages must be packaged in accordance with NRC, State, and DOT regulations.

Guidelines:

1. Put on waterproof gloves.
2. Wipe test the containers of products that have been compounded on the premises of 21 Pine Street.
3. If the products are contaminated (above 6600 dpm per 300cm^2 or twice above background), then inform the authorized user in charge.
4. Place the product containers into the delivery box.
5. Confirm that the contents of the box matches that of the packing list.
6. Confirm that the contents of the box matches that of the deliver to address.
7. Close the delivery box and attach a security seal.
8. Wipe test the delivery box to insure that there is no removable contamination (less than 22 dpm/cm^2 or twice background).
9. With a survey meter, measure the amount of radiation at the surface of the delivery box and at one meter.
10. Apply the appropriate labels to the outside of the delivery box.

White Bar I:	< 0.5 mR/hr at the surface , T.I. is not applicable
Yellow Bar II	> 0.5 mR/hr but < 50 mR/hr at the surface, and < 1.0 mR/hr at one meter (T.I.).
Yellow Bar III	> 50 mR/hr but <200 mR/hr at the surface and < 10 mR/hr at 1 meter (T.I.).

11. Write the T.I. reading on the labels of the Bar II and Bar III labels.
12. Do not ship Yellow Bar III labeled boxes. They are to be reserved for authorized couriers.

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State of New Jersey

DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY STREET, 6TH FLOOR, NEWARK NJ

CHRISTINE TODD WHITMAN
Governor

PETER VERNIERO
Attorney General
MARK S. HERR
Director

In reply respond to:
P.O. Box 45013
Newark NJ 07101
(973) 504-6450

May 14, 1999

Rodney Prosser, RPIC
Nuclear Pharmacy
21 Pine Street, Suite #125
Rockaway, NJ 07866

Gentlemen:

This is to advise that your application for a permit to conduct a pharmacy at the above address has been approved.

Your permit number will be 5734

This letter, which will serve as your authority to conduct the pharmacy until the permit is issued, should be posted in the prescription department.

Yours truly,

H. Lee Gladstein, RP
Executive Director

HLG/gb

Permit approved at the Board meeting of 5-12-99

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JUN 15 1999

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