VOID SHEET

TO: License Fee Management Branch

FROM: Wm. Adam

SUBJECT: VOIDED APPLICATION

Control Number: 3873007

Applicant: Troy Radiopharmacy

Date Voided: 8-4-89

Reason for Void: No response to deficiency ltr dtd 6-14-89.

W. J. Adam 8-7-89
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

☐ Refund Authorized and processed

☑ No Refund Due

☐ Fee Exempt or Fee Not Required

mcg 8/11

Comments: _____

Log completed ☑

Processed by: _____

11/27/90

AUG 0 8 1989

Troy Radiopharmacy, Inc.
ATTN: Mr. Mike Slugaj
Radiation Safety Officer
1555 W. Big Beaver Road
Troy, MI 48084

SUBJECT: REQUEST FOR AMENDMENT DATED APRIL 20, 1989 AND OUR DEFICIENCY LETTER DATED JUNE 14, 1989

Gentlemen:

We notified you in the above mentioned letter that we would void your request if you did not respond to our notice within 30 days.

You are hereby notified that we consider your application abandoned and have voided your request. This action is without prejudice to resubmission.

Sincerely,

Original Signed by
William J. Adam, Ph.D.
Materials Licensing Section

RIII
WJA
Adam/jl
08/7/89

JUN 14 1989

Troy Radiopharmacy, Inc.
ATTN: Mr. Mike Slugaj
Radiation Safety Officer
1555 W. Big Beaver Road
Troy, MI 48084

Gentlemen:

We have reviewed your letter dated April 20, 1989 requesting an amendment to NRC Byproduct Material License No. 21-24828-01MD and find that we will need additional information as follows:

1. With regard to the redistribution of iodine-125 and gadolinium-153 sealed sources, please submit the manufacturer's names and model numbers for each sealed source you wish to redistribute.

2. In order for us to authorize the additional forms and amounts of iodine-131 requested in Item 2 of your letter, we will need the following information:

   Since iodine-131 is already listed on your license under Subitem 6.C., we presume Item 2 of your letter basically represents a request to increase the possession limit for this material. If it was your intent to use this iodine-131 for purposes other than those listed in Subitem 9.C. of your current license, please so state and provide a detailed description of the additional uses you anticipate for this material. If it is your intent to use and dispense iodine-131 in liquid as well as capsule form, please review Item 10.10 of the enclosed Regulatory Guide and submit the precautions you will follow when handling liquid radioiodine in addition to the bioassay procedures you have already submitted.

3. The radioiodine handling precautions requested above will include the handling of this material under a properly functioning hood. Please outline the procedures and tests you will follow to assure that the radioiodine hood is functioning properly. These procedures should include, but not be limited to:

   a. Measurement of the hood face velocity at six-month intervals with a calibrated velometer.

   b. "Worst case" calculations demonstrating that 10 CFR Part 20 concentration limits for unrestricted areas will not be exceeded at the point of release for the hood.

c. Records of the results of all radioiodine hood tests. Please submit samples of such records.

d. If the hood employs an activated charcoal filter, the type and frequency of tests conducted to assure that the filter has sufficient adsorptive capacity to accommodate the maximum amount of volatile radioiodine that could be released.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 87307.

Upon failure to file an answer within the specified time, we will consider that you have abandoned your request and will void this action. This is without prejudice to resubmission of the application.

If you have any questions or require clarification on any of the information stated above, you may contact us at (312) 790-5625.

Sincerely,

Original Signed by
William J. Adam, Ph.D.
Materials Licensing Section

Enclosure: Nuclear Pharmacy
Regulatory Guide (Task FC 410-4)

RIII
wja
Adam/jl
06/14/89

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02500
STATUS CODE: 0
FEE CATEGORY: _____
EXP. DATE: 19900331
FEE COMMENTS: _____

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: TROY RADIOPHARMACY, INC.
RECEIVED DATE: 890428
DOCKET NO: 3029642
CONTROL NO.: 387307
LICENSE NO.: 21-24828-01MD
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: 230.00
CHECK NO.: 1351

3. COMMENTS

SIGNED _____
DATE 5/4/89

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 08 IS ENTERED /_/)

1. FEE CATEGORY AND AMOUNT: 3C $230

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT _____
RENEWAL _____
LICENSE _____

3. OTHER _____
_____

SIGNED _____
DATE 5/9/89

April 20, 1989

Troy Radiopharmacy
1555 W. Big Beaver Rd.
Building G
Troy, Michigan 48084

U.S. NUCLEAR REGULATORY COMMISSION
Material Licensing Section
Region III
799 Roosevelt Road
Glen Ellyn, Illinnis 60137

SUBJECT: Amendment to License No. 21-24828-01

Please find enclosed a check for ~~$150~~ 230.00 for two amendments to our NRC License (No. 21-24828-01).

1. We request NRC approval to redistribute the following 10 CFR 35.500 sealed sources obtained from a manufacturer authorized to distribute 10 CFR 35.500 sealed sources in accordance with a specific NRC license (10 CFR 32.74) or equivalent regulations of an Agreement State or Canada.

Sealed Source	Maximum Permissible Activity
Iodine-125	0.750 Curies
Gadolinium-153	4.5 Curies

The sealed sources will be redistributed to NRC approved licensees. The manufacturer's packaging, labelling, and shielding will not be altered. The sources will be redistributed with the manufacturer-supplied package insert that provides radiation safety instructions for handling and storing these sources.

2. Please amend our license to add I-131 (sodium iodide) in liquid and or capsule form with a maximum possession limit of 300 millicuries. See the attached procedures for Thyroid Uptake Bioassay Procedure and Precautions in Handling and Transporting I-131.

Thank you for your consideration. Please contact me if you have any questions about this amendment request (telephone no. 313-649-3682).

Sincerely,

MIKE SLUJAG
Radiation Safety Officer

May 1 1989
$230.00
and
5/1/89

CONTROL NO. 87307

RECEIVED
APR 27 1989
REGION III

APR 27 1989

THYROID UPTAKE BIOASSAY PROCEDURE

POLICY:

1) The radiopharmacist shall routinely handle unsealed I-131 within a glovebox that is closed.

2) Radiopharmacists who handle more than 100 mCi of liquid NaI-131 at any one time or cumulatively over a three (3) month period in a glovebox shall have a thyroid uptake bioassay performed within 24 to 72 hours after, not to exceed one bioassay per week. If more than 10 mCi of liquid NaI-131 is handled in the fume hood, then thyroid uptake bioassay shall be performed 24 to 72 hours after.

EQUIPMENT: Nuker Spectrascaler and Uptake Probe System, I-131 Lucite Neck Phantom and B Filter to count background.

PROCEDURE:

a) Place the I-131 standard in the neck phantom and position the phantom in exactly the same position the employee's neck will assume for thyroid uptake.

b) Calibrate the uptake probe system by setting a range of 1.0; LLD = 314 and ULD = 414, and adjusting the high voltage such that the photopeak of I-131 is centered properly in the window. Record the high voltage setting and date.

c) Immediately before performing the bioassay take one count of the standard for 10 minutes.

d) Take one count of room background for 10 minutes.

e) Position individual with their neck extended with the probe-measuring bar half-way between crichoid cartilage and suprasternal notch. Obtain a 10 minute count.

f) Complete the I-131 Bioassay Report Form.

g) Notify the Radiation Safety Officer whenever the thyroid burden exceeds 0.04 uCi of I-131. Actions equivalent to those specified in Regulatory Guide 8.20 shall be taken.

h) The statistical accuracy shall be verified on a periodic basis to determine the minimum detectable activity and sensitivity of the uptake probe system.

/nd
2bio

I-125 AND I-131 BIOASSAY PROCEDURE

NAME _____

Department _____

I-125 or I-131 _____ Standard Lot #: _____ Standard Total Activity _____

Standard Counts _____ Standard Count Time 10 min.

(Standard Counts / 10 minutes) _____

Room Counts/10 Minutes _____ Subjects Counts/10 Minutes _____

Compute:

$$\frac{(\text{Subject counts/10 min.}) - (\text{Room counts/10 min.})}{(\text{Standard count /10 min.}) - (\text{Room counts/10 min.})} \times (\text{Total Standard Activity}) = \underline{\quad X \quad} \text{ uCi}$$

(in microcuries)

$$\frac{(\quad\quad) - (\quad\quad)}{(\quad\quad) - (\quad\quad)} \times (\quad\quad \text{uCi}) = \_\_\_\_\_ \text{uCi}$$

☐ Bioassay negative

☐ Medical Physics Contacted

For I-125

If X < 0.12 uCi, bioassay is negative

If X > 0.12 uCi, contact Medical Physics

For I-131

If X < 0.04 uCi, bioassay is negative

If X > 0.04 uCi, contact Medical Physics

If X > than stated values, a repeat measurement may be required (including a 10 minute count over patient's thigh to measure patient background).

CONTROL NO. 87307

PRECAUTIONS FOR HANDLING AND TRANSPORTING I-131

1. Liquid NaI-131 in activities greater than 1 millicurie shall be handled only in the Nuaire glove box or fume hood.

2. Therapeutic amounts of I-131 should not be handled directly with the hands. Use a remote device, pipet the aliquot of I-131 into a prepared container in a lead vial shield.

3. Assay the activity using long forceps.

4. Carefully dispose of the contaminated pipette tip and other contaminated waste in the longer lived lead storage area.

5. The I-131 shall be stored in the original shipping vial and shielding containers or the equivalent behind lead bricks in the fume hood or glove box.

6. I-131 shall be transported for commercial distribution in the original shipping materials whenever possible. In the event that more than one dose is to be drawn from the original shipping vial, equivalent lead shielding (from old doses of I-131) shall be used. The I-131 will be packed in DOT approved shipping containers and labelled according to NRC/DOT regulations.

7. The drivers shall be carefully instructed about the delivery of I-131 to designated, locked areas only, and emergency procedures.