NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 5-31-87

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [ ] A. NEW LICENSE
- [X] B. AMENDMENT TO LICENSE NUMBER #31-32-4
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Dr. Marcus A. Rothschild
VA Medical Center (630/115)
First Avenue at East 24th Street
New York, New York 10010

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

Veterans Administration Medical Center
First Avenue at East 24th Street
New York, New York 10010

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

DR. MARCUS A. ROTHSCHILD

TELEPHONE NUMBER: 212-686-7500 x663/405

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE

8604090600 851231
REG1 LIC30
31-00032-04 PDR

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY | AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE - CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
	MARCUS A. ROTHSCHILD, M.D.	Chief, Nuclear Medicine Service /115/	3/19/85

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] < $250K
- [ ] $250K – 500K
- [ ] $500K – 750K
- [ ] $750K – 1M
- [ ] $1M – 3.5M
- [ ] $3.5M – 7M
- [ ] $7M – 10M
- [ ] > $10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (DATA AND STATEMENTS) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial proprietary information furnished to the agency in confidence.)*
- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	APPROVED BY
AMOUNT RECEIVED	CHECK NUMBER		DATE

"OFFICIAL RECORD COPY"
04181
JUL 31 1985 ML10

PRIVACY ACT STATEMENT ON THE REVERSE

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY:** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S):** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954 as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES:** The information may be (a) provided to State health departments for their information and use; and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.

5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

APPLICATION FOR MATERIAL LICENSE

Item 5. Radioactive Material

a. Element and mass number (C-14)

b. Chemical and/or physical form (Aminopyrine) (diluted in H_2O)

c. Maximum amount which will be possessed at any one time (10mCi)

Item 6. Purpose(s) For Which Licenses Material Will Be Used.

Research - to establish aminopyrine breath test.

Item 7. Individual(s) Responsible For Radiation Safety Program And Their Training and Experience.

Dr. Marcus A. Rothschild

Item 8. Training For Individuals Working In Or Frequenting Restricted Areas.

On File License #31-32-4

Item 9. Facilities And Equipment.

On File License #31-32-4

Item 10. Radiation Safety Program.

On File License #31-32-4

Item 11. Waste Management.

On File License #31-32-4

EXHIBIT A

FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE -- MEDICAL	Approved: GAO R0557

INSTRUCTIONS - *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(Institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Dr. Marcus A. Rothschild
VA Medical Center (630/115)
First Avenue at East 24th Street
New York, New York 10010
TELEPHONE NO.: AREA CODE 212 686- 7500x663

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Dr. Marcus A. Rothschild

TELEPHONE NO.: AREA CODE ( ) _____ _____

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*

a. ☐ NEW LICENSE
b. XX AMENDMENT TO LICENSE NO. 31-32-4
c. ☐ RENEWAL OF LICENSE NO. _____

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

Dr. Marcus A. Rothschild and those users authorized by the Medical Isotopes Committee

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Dr. Marcus A. Rothschild

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 3[illegible], SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Carbon - 14	Aminopyrine	.002 per patient	To establish aminopyrine breath test for Hepatic function. -See appendix for 1) Research Plan and Methods 2) Dose Calculations 3) Subject Consent Forms

FORM NRC-313M
(8-78)

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. _____ Date: _____

All information is included within license #31-32-4
(VA Radiation Safety Guidelines or attached)

7. MEDICAL ISOTOPES COMMITTEE

- [X] Names and Specialties Attached; and
- [X] Duties as in Appendix B; or *(Check One)*
- [ ] Equivalent Duties Attached

8. TRAINING AND EXPERIENCE

- [ ] Supplements A & B Attached for Each Individual User; and
- [ ] Supplement A Attached for RSO.

9. INSTRUMENTATION *(Check One)*

- [ ] Appendix C Form Attached; or
- [ ] List by Name and Model Number

10. CALIBRATION OF INSTRUMENTS

- [ ] Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
- [ ] Equivalent Procedures Attached; and
- [ ] Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
- [ ] Equivalent Procedures Attached

11. FACILITIES AND EQUIPMENT

- [ ] Description and Diagram Attached Nuclear Med. Facilities - on file with License application

12. PERSONNEL TRAINING PROGRAM

- [ ] Description of Training Attached *See VA R.S. Guidelines

13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

- [ ] Detailed Information Attached *See VA R.S. Guidelines

14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*

- [ ] Appendix F Procedures Followed; or
- [ ] Equivalent Procedures Attached *

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*

- [ ] Appendix G Rules Followed; or *
- [ ] Equivalent Rules Attached *

16. EMERGENCY PROCEDURES *(Check One)*

- [ ] Appendix H Procedures Followed; or
- [ ] Equivalent Procedures Attached *

17. AREA SURVEY PROCEDURES *(Check One)*

- [ ] Appendix I Procedures Followed; or
- [ ] Equivalent Procedures Attached *

18. WASTE DISPOSAL *(Check One)*

- [ ] Appendix J Form Attached; or
- [ ] Equivalent Information Attached *

19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*

- [ ] Appendix K Procedures Followed; or
- [ ] Equivalent Procedures Attached

20. THERAPEUTIC USE OF SEALED SOURCES

- [ ] Detailed Information Attached; and
- [ ] Appendix L Procedures Followed; or *(Check One)*
- [ ] Equivalent Procedures Attached

21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)

- [ ] Detailed Information Attached

22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS

- [ ] Detailed Information Attached

23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b

- [ ] Detailed Information Attached

FORM NRC-313M
(8-78)

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM		
	X	TLD	EBERLINE DOSIMETRY SERVICES	MONTHLY
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	EBERLINE DOSIMETRY SERVICES	MONTHLY
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE
(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

(1) LICENSE FEE CATEGORY

(2) LICENSE FEE ENCLOSED: $

b. APPLICANT OR CERTIFYING OFFICIAL (Sign in ink)

(1) NAME (Type or Print)
MARCUS A. ROTHSCHILD, M.D.

(2) TITLE
Chief, Nuclear Medicine Service

c. DATE

FORM NRC-313M (8-78)

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on Form NRC-313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material licence or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

MINOPYRINE BREATH TEST/HEPATIC FUNCTION TEST

Objectives: To establish APBT in this Gastroenterology Laboratory.

Research Plan: Twenty-five patients without evidence of liver disease or COPD to be studied with APBT to establish values for normal controls to compare with patients with suspected or known liver disease.

Methods: 2.0 µCi (^{14}C) aminopyrine and 2 mg of unlabelled aminopyrine diluted with 1 ml of H_2O given orally to the fasting patient. Breath samples will be collected through Tygon tubing, over anhydrous calcium sulfate into scintillation vials containing a trapping solution (2 milliliter of 1 molar hyamine hydroxide and 2 milliliters of thymolphthalein solution 30 mg in 500 milliliters of absolute ethanol) trapping 1 milliliter of CO_2. Scintillation fluid is added and samples are collected in duplicate at baseline (time 0), 30, 60, 90 and 120 minutes. The percent dose excreted per hour is determined from each sample assuming a CO_2 production of 300 millimoles/m^2 body surface area per hour.

Dose Calculations - for 2μCi C-14 aminopyrine

1) Aminopyrine completely absorbed in GI tract
2) Aminopyrine is distributed in total body water, bound 29% to plasma proteins
3) Entirely metabolized by N-demathylation in hepatic smooths endoplasmic reticulum

metabolitis - CO_2 (C - 14)

4) Half-life (biological) of C-14 aminopyrine in body

a)	Normal controls	4.2 hours
b)	Patient with CHF	23.3 hours
c)	Patients with pleural effusion	110.7 hours

Source: Dr. Joel Goldfarb, Dr. Allan Wolkoff } Liver Research Center of Albert Einstein College Hospital

Using formula and constants from MIRD pamphlet No. 11 →

Dose W.B. = A_{WB} $S_{WB \leftarrow WB}$ (W.B. = Whole body)

A_{WB} = 1.44 x 2μCi x $T_{\frac{1}{2}}$ hours

= 2.88 x $T_{\frac{1}{2}}$ μCi - hours

WHERE

$S_{WB \leftarrow WB}$ = 1.5×10^{-6} Rads/μCi hour for C-14

Dose $_{WB}$ = 2.88 $T_{\frac{1}{2}}$ x 1.5 x 10^{-6} Rad

= 4.32 $T_{\frac{1}{2}}$ x 10^{-6} Rad

a) Normal Controls - Dose $_{WB}$ = $4.32 \times 4.2 \times 10^{-6}$ R

= 0.018 mR

b) Patients with CHF Dose $_{WB}$ = $4.32 \times 23.3 \times 10^{-3}$ R

= 0.10 mR

c) Patients with Pleural Effusion Dose $_{WB}$ = $4.32 \times 110.7 \times 10^{-6}$ R

= 0.48 mR

Radiation Protection Guidelines -
General Population: permissible whole body dose = 500 mR/year

PART I-AGREEMENT TO PARTICIPATE IN RESEARCH BY OR UNDER THE DIRECTION OF THE VETERANS ADMINISTRATION

DATE

1. I, _____ (Type or print subject's name) voluntarily consent to participate as a subject in the investigation entitled AMINOPYRINE BREATH TEST (Title of study)

2. I have signed one or more information sheets with this title to show that I have read the description including the purpose and nature of the investigation, the procedures to be used, the risks, inconveniences, side effects and benefits to be expected, as well as other courses of action open to me and my right to withdraw from the investigation at any time. Each of these items has been explained to me by the investigator in the presence of a witness. The investigator has answered my questions concerning the investigation and I believe I understand what is intended.

3. I understand that no guarantees or assurances have been given me since the results and risks of an investigation are not always known beforehand. I have been told that this investigation has been carefully planned, that the plan has been reviewed by knowledgeable people, and that every reasonable precaution will be taken to protect my well-being.

4. In the event I sustain physical injury as a result of participation in this investigation, if I am eligible for medical care as a veteran, all necessary and appropriate care will be provided. If I am not eligible for medical care as a veteran, humanitarian emergency care will nevertheless be provided.

5. I realize I have not released this institution from liability for negligence. Compensation may or may not be payable, in the event of physical injury arising from such research, under applicable federal laws.

6. I understand that all information obtained about me during the course of this study will be made available only to doctors who are taking care of me and to qualified investigators and their assistants where their access to this information is appropriate and authorized. They will be bound by the same requirements to maintain my privacy and anonymity as apply to all medical personnel within the Veterans Administration.

7. I further understand that, where required by law, the appropriate federal officer or agency will have free access to information obtained in this study should it become necessary. Generally, I may expect the same respect for my privacy and anonymity from these agencies as is afforded by the Veterans Administration and its employees. The provisions of the Privacy Act apply to all agencies.

8. In the event that research in which I participate involves certain new drugs, information concerning my response to the drug(s) will be supplied to the sponsoring pharmaceutical house(s) that made the drug(s) available. This information will be given to them in such a way that I cannot be identified.

I _____
NAME OF VOLUNTEER

HAVE READ THIS CONSENT FORM. ALL MY QUESTIONS HAVE BEEN ANSWERED, AND I FREELY AND VOLUNTARILY CHOOSE TO PARTICIPATE. I UNDERSTAND THAT MY RIGHTS AND PRIVACY WILL BE MAINTAINED. I AGREE TO PARTICIPATE AS A VOLUNTEER IN THIS PROGRAM.

9. Nevertheless, I wish to limit my participation in the investigation as follows:

VA FACILITY VA MEDICAL CENTER NEW YORK, NEW YORK 10010	SUBJECT'S SIGNATURE
WITNESS'S NAME AND ADDRESS (Print or type)	WITNESS'S SIGNATURE
INVESTIGATOR'S NAME (Print or type)	INVESTIGATOR'S SIGNATURE

☐ Signed information sheets attached. ☐ Signed information sheets available at:

SUBJECT'S IDENTIFICATION (I.D. plate or give name + last, first, middle)

SUBJECT'S I.D. NO. | WARD

AGREEMENT TO PARTICIPATE IN RESEARCH BY OR UNDER THE DIRECTION OF THE VETERANS ADMINISTRATION

VA FORM 10-1086 SEP 1979

SUPERSEDES VA FORM 10-1086 JUN 1975, WHICH WILL NOT BE USED.

Standard Form 507
(Revised August 1954)
Bureau of the Budget
Circular A-32

APPENDIX D

U.S. GOVERNMENT PRINTING OFFICE 1961 O-587679

CLINICAL RECORD

Dr. Elizabeth Weinshel

Report on _____

or

Continuation of S. F. VA Form 10-1086

(Strike out one line) (Specify type of examination or data)

(Sign and date)

INFORMATION ABOUT THE AMINOPYRINE BREATH TEST

The aminopyrine breath test is a sensitive test of liver function. It is used to distinguish patients with liver disease from those who have normal liver function. You have been determined to have impaired liver function. We will be using this test to determine the degree of liver impairment. The test involves the ingestion of a small amount of labelled aminopyrine and collection of breath samples over a two hour period. The amount of radiation is extremely small (0.1-0.5 mREM). This dose is about 1/100 to 1/20 the dose received in a chest x-ray. This test has been done in thousands of people throughout the world without any side effects reported and it is commonly used as a liver function test in many other hospitals.

A potential benefit of your participation in this study is a knowledge about the functional capacity of your liver.

You may not benefit directly from the result of this study but it is hoped that the information generated by this study would help us to understand liver disease in other patients.

You need not agree to participate in this study and if you do agree, you may withdraw your consent and discontinue participation in this project at any time, for whatever reason. Such withdrawal will not jeopardize your future treatment.

If you agree to participate, we would like to sign this form indicating that you understand the purposes, risks and benefits of the study, plus VA Form 10-1086 which is your consent to participate in the study.

We will be available for answering any further inquiries at 686-7500, ext 393 or 424.

_____ _____

Subject's Signature Date

_____ _____

Witness' Signature Date

_____ _____

Investigator's Signature Date

(Continue on reverse side)

PATIENT'S IDENTIFICATION (If a typed or written entries give: Name—last, first, middle; grade; date; hospital or medical facility)

REGISTER NO.

WARD NO.

REPORT ON or CONTINUATION OF

APPENDIX E

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CLINICAL RECORD

Dr. Elizabeth Weinshel

Report on _____
or
Continuation of S. F. VA Form 10-1086
(Strike out one line) (Specify type of examination or data)

(Sign and date)

INFORMATION ABOUT THE AMINOPYRINE BREATH TEST (CONTROLS)

The aminopyrine breath test is a sensitive test of liver function. It is used to distinguish patients with liver disease from those who have normal liver function. You have been determined to have normal liver function. We would like to use this test at the NYVA but must establish normal values to compare with those patients felt to have liver disease. The test involves the ingestion of a small amount of labelled aminopyrine and collection of breath samples over a two hour period. The amount of radiation is extremely small (0.1-0.5 mREM). This dose is about 1/100 to 1/20 the dose received in a chest x-ray. This test has been done in thousands of people throughout the world without any side effects reported and it is commonly used as a liver function test in many other hospitals.

A potential benefit of your participation in this study is a knowledge about the functional capacity of your liver.

You may not benefit directly from the result of this study but it is hoped that the information generated by this study would help us to understand liver disease in other patients.

You need not agree to participate in this study and if you do agree, you may withdraw your consent and discontinue participation in this project at any time, for whatever reason. Such withdrawal will not jeopardize your future treatment.

If you agree to participate, we would like you to sign this form indicating that you understand the purposes, risks and benefits of the study, plus VA Form 10-1086 which is your consent to participate in the study.

We will be available for answering any further inquiries at 686-7500, ext. 393 of 424.

_____ _____
Subject's Signature Date

_____ _____
Witness' Signature Date

_____ _____
Investigator's Signature Date

(Continue on reverse side)