30-29932
NLHL23679

NRC FORM 313
(9-86)
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

(Grandfathered human use 10 CFR 35.31 general license that expired March 31, 1987)

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 HAMPSHIRE, NEW JERSEY, NEW YORK, PENNEYLVANIA, 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)*

[X] A. NEW LICENSE
[ ] B. AMENDMENT TO LICENSE NUMBER _____
[ ] C. RENEWAL OF LICENSE NUMBER _____

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

PRIMARY CARE MEDICAL CENTER
7531 East Eight Mile Road
WARREN, MICHIGAN 48091
VINOD KHOLI, MD

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

PRIMARY CARE MEDICAL CENTER
7531 East Eight Mile Road
Warren, Michigan 48091

RECEIVED
MAR 31 1987
REGION III

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

VINOD KHOLI, M.D. Vinod K. Kholi MD

TELEPHONE NUMBER: 313 759 6300

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. see ATT 5.

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

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

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

9. FACILITIES AND EQUIPMENT. see ATT 9.

10. RADIATION SAFETY PROGRAM. see ATT 10.

11. WASTE MANAGEMENT. see ATT 11.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY: exempt
AMOUNT ENCLOSED: $0.00

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

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 *(Dollar and/or staff hours)* 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	COMMENTS	APPROVED BY
A03	90016		FEE EXEMPT 3537	CP
AMOUNT RECEIVED	CHECK NUMBER			DATE 4/20/87

8711300231 871130
REG3 LIC30
PDR

postmarked 3/31/87

32047

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

FEB 19 1987

TO ALL PHYSICIANS WHO USE A GENERAL LICENSE ISSUED PURSUANT TO 10 CFR 35.31

The Nuclear Regulatory Commission (NRC) recently published a revision of 10 CFR Part 35, its regulations that apply to the medical use of byproduct material. In the revision, the general license that allows physicians to conduct six in vivo clinical procedures (use of iodine-131 for measuring thyroid uptake and blood volume, iodine-125 for measuring blood volume, cobalt-58 and cobalt-60 for measuring intestinal absorption of cyanocobalamin, and chromium-51 for measuring red blood cell volume and survival time) has been eliminated. In the future, these clinical procedures will only be authorized by specific license.

If you want to continue performing just the clinical procedures authorized by the general license, you must complete items 2., 3., 4., and 13. of the attached application and submit it to the address indicated on the form by March 31, 1987. The NRC will issue you a specific license that has all the features of the general license. If you are currently authorized under a specific license to perform the clinical procedures listed in 10 CFR 35.100(a) (Group I, use of prepared radiopharmaceuticals for measuring uptake, dilution, and excretion), you probably do not need a separate specific license to continue the generally licensed activities, and need not return the application.

The general license in section 31.11 that allows the in vitro use of byproduct material in radioimmunoassay kits was not affected by the revision of 10 CFR Part 35. NRC Forms-483, "Registration Certificate-In Vitro Testing with Byproduct Material Under General License," are valid and will continue to be issued in the future.

Sincerely,

Handy L. Miller

Handy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosures
1. 10 CFR 35.31
2. Preprinted Application for a specific license to perform certain in vivo clinical procedures

8705290118 4p

cals which are under the general license in this paragraph to include the following statement in the label affixed to the container or in the leaflet or brochure which accompanies the radiopharmaceutical:

This radioactive drug may be received, possessed and used only by physicians licensed to disperse drugs in the practice of medicine. Its receipt, possession, use, and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of manufacturer)

(b) No physician shall receive, possess, use, or transfer byproduct material pursuant to the general license established by paragraph (a) of this section until he has filed Form NRC-482, "Registration Certificate—Medical Use of Byproduct Material Under General License" with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and received from the Commission a validated copy of the Form NRC-482 with registration number assigned. The registrant shall furnish on Form NRC-482 the following information and such other information as may be required by that form:

(1) Name and address of the registrant;

(2) A statement that the registrant is a duly licensed physician authorized to dispense drugs in the practice of medicine, and specifying the license number and the State in which such license is valid; and

(3) A statement that the registrant has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use byproduct material under the general license of § 35.31 of this part and that he is competent in the use of such instruments.

(c) A physician who receives, possesses, or uses a pharmaceutical containing byproduct material pursuant to the general license established by paragraph (a) of this section shall comply with the following:

(1) He shall not possess at any one time, pursuant to the general license in paragraph (a) of this section, more than:

(i) 200 microcuries of iodine-131,

(ii) 200 microcuries of iodine-125,

(iii) 5 microcuries of cobalt-58,

(iv) 5 microcuries of cobalt-60, and

(v) 200 microcuries of chromium-51.

(2) He shall store the pharmaceutical until administered in the original shipping container or a container providing equivalent radiation protection.

(3) He shall use the pharmaceutical only for the uses authorized by paragraph (a) of this section.

(4) He shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age.

(5) He shall not transfer the byproduct material to a person who is not authorized to receive it pursuant to a license issued by the Commission or an Agreement State, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

(d) The registrant possessing or using byproduct material under the general license of paragraph (a) shall report in duplicate to the Director of Licensing, any changes in the information furnished by him in the "Registration Certificate—Medical Use of Byproduct Material Under General License," Form NRC-482. The report shall be submitted within 30 days after the effective date of such change.

(e) Any person using byproduct material pursuant to the general license of paragraph (a) of this section is exempt from the requirements of Parts 19, 20, and 21 of this chapter with respect to the byproduct materials covered by the general license.

[35 FR 6200, June 26, 1958, as amended at 38 FR 1572, Jan. 11, 1973; 38 FR 19201, July 19, 1973; 42 FR 28896, June 6, 1977.]

ATT 5.

A. Iodine-131	A. Sodium iodide	A. and B. 200 microcuries
B. Iodine-131	B. Iodinated human serum albumin	
C. Iodine-125	C. Iodinated human serum albumin	C. 200 microcuries
D. Cobalt-58	D. Cyanocobalamin	D. 5 microcuries
E. Cobalt-60	E. Cyanocobalamin	E. 5 microcuries
F. Chromium-51	F. Sodium chromate	F. 200 microcuries

ATT 6.

A. Measurement of thyroid uptake
B. Determinations of blood and blood plasma volume
C. Determinations of blood and blood plasma volume
D. Measurement of intestional absorption of cyanocobalamin
E. Measurement of intestional absorption of cyanocobalamin
F. Determination of red blood cell volumes and studies of red blood cell survival time.

ATT 7. I will be personally responsible for the radiation safety program. I am a licensed physician authorized to dispense drugs in the practice of medicine, and have had training and experience in the use of the instruments that will be used to perform clinical procedures.

ATT 8. Not applicable

ATT 9. I have on hand the appropriate radiation measuring instruments needed to carry out the clinical procedures that will be performed under this license.

ATT 10. Not applicable

ATT 11. Not applicable.

10 CFR 35

REGISTRATION CERTIFICATE–MEDICAL USE OF BYPRODUCT MATERIAL UNDER GENERAL LICENSE

3150-0022
Expires 12-31-84

Section 35.31 of 10 CFR 35 establishes a general license authorizing physicians to possess certain small quantities of I 125, I 131, Co 58, Co 60, and Cr 51 for specified diagnostic uses. Possession of byproduct material under 10 CFR 35.31 is not authorized until the physician has filed NRC Form 482 and received from the Commission a validated copy of NRC Form 482 with registration number assigned.

INSTRUCTIONS

Submit this Form in triplicate to: Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, United States Nuclear Regulatory Commission, Washington, D.C. 20555. *A registration number will be assigned and a validated copy of NRC Form 482 will be returned. Please print or type your name and address* (including ZIP code), *within and below the two dots. Limit the address to 4 lines.*

Address

Primary Care Medical Center
7531 East Eight Mile
Warren, Michigan 48091

Registration number: 1259

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

ELOISE E. BARRY — SEPTEMBER 15, 1986

(If this is an initial registration, leave this space blank — number to be assigned by NRC. If this is a change of information from a previously registered general licensee, include your registration number.)

I am a duly licensed physician authorized to dispense drugs in the practice of medicine. My license(s) is (are) valid under the laws of:

STATE(S) OF LICENSURE	LICENSE NUMBER(S)
MICHIGAN	40989
MARYLAND	D22510
NORTH CAROLINA	037370

CERTIFICATE

I hereby certify that:

1. All information in this registration certificate is true and complete.
2. I have appropriate radiation measuring instruments to carry out the diagnostic procedures for which I will use byproduct material under the general license of 10 CFR 35.31 and I am competent in the use of such instruments.
3. I understand that Commission regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Director of Nuclear Material Safety and Safeguards, within 30 days from the date of such change.
4. I have read and understand the provisions of Section 35.31 of NRC regulations (10 CFR 35) reprinted on the reverse side of this form; and I understand that I am required to comply with those provisions as to all byproduct material which I receive, possess, use, or transfer under the general license for which this Registration Certificate is filed with the Nuclear Regulatory Commission.

Date September 8, 1986

Ueinod K. Edwards
(Signature of Registrant)

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.