NRC FORM 483 (3-93) U. S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0038
EXPIRES 3-31-96

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 7 MINUTES. THE VALIDATED REGISTRATION IS MANDATORY AND SERVES AS EVIDENCE TO SUPPLIERS OF BYPRODUCT MATERIAL THAT THE REGISTRANT IS ENTITLED TO RECEIVE THE BYPRODUCT MATERIAL. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0028), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

# REGISTRATION CERTIFICATE -- *in vitro* TESTING WITH BYPRODUCT MATERIAL UNDER GENERAL LICENSE

Section 31.11 of 10 CFR 31 establishes a general license authorizing physicians, clinical laboratories, hospitals, and veterinarians in the practice of veterinary medicine to possess certain small quantities of byproduct material for *in vitro* clinical or laboratory tests not involving the internal or external administration of the byproduct material or the radiation therefrom to human beings or animals. Possession of byproduct material under 10 CFR 31.11 is not authorized until the physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine, has filed NRC Form 483 and received from the Commission a validated copy of NRC Form 483 with a registration number.

**1. NAME AND ADDRESS OF APPLICANT** *(See Instruction 3.B. below)*

Winston Koo, M.D., M.B.B.S.
Department of Pediatrics
Hutzel Hospital
4707 St. Antoine Detroit, MI 48201

TELEPHONE NUMBER *(Include Area Code)*
313-745-7229

**2. APPLICATION** (Check one box only)

I hereby apply for a registration number pursuant to 10 CFR 31, Section 31.11, for use of byproduct materials for:

| | |
|---|---|
| X | A. Myself, a duly licensed physician authorized to dispense drugs in the practice of medicine. |
| | B. The above-named clinical laboratory. |
| | C. The above named hospital. |
| | D. Veterinarian in the practice of veterinary medicine. |

**3. INSTRUCTIONS:**

A. Submit this form in duplicate to:

Medical, Academic and Commercial Use
Safety Branch (6 H3)
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

(At NRC, a registration number will be assigned and a validated copy of NRC Form 483 will be returned.)

B. In the box above, print or type the name, address (including ZIP Code), and telephone number of the registrant physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine for whom or for which this registration form is filed.

**4. REGISTRATION**

REGISTRATION NUMBER:
9212

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Traci Kime

April 29, 2002

*(If this 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 license, include your registration number.)*

**5.** If place of use is different from address listed above, give complete address:

Neonatology Lab, 4th Floor, 4827 Brush Street, Detroit, MI 48201

**6. CERTIFICATION**

I hereby certify that:

A. All information in this registration certificate is true and complete.

B. The registrant has appropriate radiation measuring instruments to carry out the tests for which byproduct material will be used under the general license of 10 CFR 31.11. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the byproduct materials.

C. 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 effective date of such change.

D I have read and understand the provisions of Section 31.11 of NRC regulations 10 CFR 31 (reprinted on the reverse side of this form); and I understand that the registrant is required to comply with those provisions as to all byproduct material which he receives, acquires, possesses, uses, or transfers under the general license for which this Registration Certificate is filed with the U.S. Nuclear Regulatory Commission.

| PRINTED OR TYPED NAME AND TITLE OF APPLICANT | SIGNATURE OF APPLICANT | DATE |
|---|---|---|
| WINSTON KOO PROFESSOR OF PEDIATRICS | Koo | 4/8/02 |

**WARNING:** FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECTS. 18 U.S.C. SECTION 1001 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.

S. Laurie Gaspear, M.D., for material in 10 CFR 35.400 and 35.500.

T. Amr Aref, M.D., for material in 10 CFR 35.400 and 35.500.

U. David Donath, M.D., for material in 10 CFR 35.400 and 35.500.

V. Lawrence P. Davis, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.500.

W. James Fontanesi, M.D., for material in 10 CFR 35.400 and 35.500.

X. Michael P. Diamond, M.D., for material in 10 CFR 10 CFR 35.100.

Y. Winston W.K. Koo,, M.B.B.S., for hydrogen-3, iodine-125 and iodine-131 for in-vitro studies.

13. Pursuant to Title 10, Chapter 1, Code of Federal Regulations, Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material in the molybdenum-99/technetium-99m generators authorized by this license.

14. The licensee shall maintain records of information important to safe and effective decommissioning at 4707 St. Antoine, Detroit, Michigan per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

15. The licensee shall follow procedures contained in Appendix C, "Model Procedure For Calibrating Dose Calibration," Regulatory Guide 10.8, Revision 2, August 1987.

16. The licensee shall follow procedures contained in Appendix K, "Model Guidance For Ordering and Receiving Radioactive Materials," Regulatory Guide 10.8, Revision 2, August 1987.

17. The licensee shall maintain records of the individuals who have received training as described in application dated June 29, 1990, Item 8.1, "Personnel Training Program."

18. The licensee shall maintain the imaging room where xenon-133 is used at negative pressure.

19. As an exemption from Section 34.40(a), 10 CFR Part 35, the licensee may release patients from the medical institution while undergoing therapy with the Collaborative Ocular Melanoma Study Brachytherapy Plaques as describe in letter dated May 18, 1992.