NRC FORM 483 (7-1999)

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0038 EXPIRES: 07/31/2002

Estimated burden per response to comply with this mandatory collection request: 7 minutes. The validated registration serves as evidence to suppliers of byproduct material that the registrant is entitled to receive the byproduct material. Send comments regarding burden estimate to the Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0038), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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)*

Quest Diagnostics Clinical Laboratory
900 Business Center Drive
Horsham, PA 19044
Linda Dickson

TELEPHONE NUMBER (Include Area Code):
215-442-7656

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:

- ☐ Myself, a duly licensed physician authorized to disperse drugs in the practice of medicine.
- ☒ The above-named clinical laboratory.
- ☐ The above named hospital.
- ☐ Veterinarian in the practice of veterinary medicine.

INSRUCTIONS

A. Submit this form in duplicate to:

Materials Safety Branch (T-8 F5)
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.)

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:

2219

FOR THE NUCLEAR REGULATORY COMMISSION

Traci Kime 4/5/2001

(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.)

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

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	DATE
LINDA DICKSON	Linda Dickson	3/28/01

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. 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.

PRINTED ON RECYCLED PAPER

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 10 CFR 31.11

§31.11 General license for use of byproduct materials for certain *in vitro* clinical or laboratory testing.

(a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs (b), (c), (d), (e), and (f) of this section, the following byproduct materials in prepackaged units:

(1) Iodine-125, in units not exceeding 10 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(2) Iodine-131, in units no exceeding 10 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(3) Carbon-14, in units not exceeding 10 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(4) Hydrogen 3 (tritium), in units not exceeding 50 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(5) Iron 59, in units not exceeding 20 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(6) Selenium-75, in units not exceeding 10 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(7) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americum-241 each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(b) A person shall not receive, acquire, possess, use or transfer byproduct material under the general license established by paragraph (a) of this section unless that person:

(1) Has filed NRC Form 483, "Registration Certificate - in vitro Testing with Byproduct Material Under General License," with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and received from the Commission a validated copy of NRC Form 483 with registration number assigned; or

(2) Has a license that authorizes the medical use of byproduct material that was issued under Part 35 of this chapter.

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

(1) The general licensee shall not possess, at any one time, pursuant to the general license in paragraph (a) of this section, at any one location of storage or use, a total amount of iodine 125, iodine 131, selenium-75, and/or iron 59 in excess of 200 microcuries.

(2) The general licensee shall store the byproduct material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(3) The general licensee shall use the byproduct material only for the uses authorized by paragraph (a) of this section.

(4) The general licensee shall not transfer the byproduct material, except by transfer to a person authorized to receive it by a license pursuant to this chapter or from an Agreement State, nor transfer the byproduct material in any manner other than in the unopened, labeled shipping container as required by §20.301 of this chapter.

(5) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in paragraph (a)(7) of this section, as required by §20.301 of this chapter.

(d) The general licensee shall not receive, acquire, possess, or use byproduct material pursuant to paragraph (a) of this section:

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of §32.71 of this chapter or in accordance with the provisions of a specific license issued by an Agreement State that authorizes manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59 or Mock Iodine-125 for distribution to persons generally licensed by the Agreement State.

(2) Unless the following statement or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. 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

(e) The registrant possessing or using byproduct material under the general license of paragraph (a) of this section shall report in writing to the Director of Nuclear Material Safety and Safeguards any changes in the information furnished by him in NRC Form 241, "Registration Certificate - in vitro Testing with Byproduct Material Under General License." The report shall be furnished within 30 days after the effective date of such change.

(f) 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 byproduct materials covered by that general license, except that such persons using the Mock Iodine-125 described in paragraph (a)(7) of this section shall comply with the provisions of §20.301, 20.402, and 20.403 of this chapter.

NOTES

[1] A State to which certain regulatory authority over radioactive material has been transferred [illegible], pursuant to section 274 of the Atomic Energy Act of 1954, as amended.

[2] Material generally licensed under this section prior to January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

[3] A new triplicate set of this Registration Certificate, NRC Form 483, may be used to report any change of information furnished by a registrant as required by §31.11(e).

If larger quantities or other forms of byproduct material than those specified in the general license of 10 CFR 31.11 are required, file NRC Form 313, "Application for Byproduct Material License," to obtain a specific byproduct material license. Copies of application and registration forms may be obtained from the Medical, Academic and commercial Use Safety Branch (O-6 H3), Division of Industrial and Medical Nuclear Safety, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.