CITY OF PHILADELPHIA

DEPARTMENT OF PUBLIC HEALTH
1600 Arch Street, 7th Floor
Philadelphia, PA 19103

030-06186

ROBERT K. ROSS, M.D.
Commissioner

November 16, 1993

Charles W. Hehl, Director
Division of Radiation Safety & Safeguards
United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RE: NRC Confirmatory Action Letter No. 1-93-019 dated November 3, 1993
Docket No. 030-06186
License No. 37-08267-01 (Expired)

Dear Mr. Hehl:

Please be informed of the following actions which have been taken in response to the above letter:

1. The Air Management Services Laboratory has discontinued use of all radioactive materials. These materials are being kept in a secure location.

2. NRC Form 483, entitled "Registration Certificate in-vitro Testing With Byproduct Material Under General License" has been submitted and approved (copy attached). The possession limits specified in item 2 (no more than a total of 200 microcuries [uCi] of Iodine-125 for in-vitro kits not to exceed 10 uCi each for forensic medicine studies) are acceptable and will not be exceeded under any circumstances.

3. The license application for the Philadelphia Department of Public Health was submitted to Ms. Sheri A. Arredondo, NRC application containing additional information as per NRC request and the appropriate fees was forwarded to the NRC on November 3, 1993. The license application has been assigned NRC Mail Control Number 118933. The requested radiation safety program was sent to you by overnight delivery on November 9, 1993, with an advance copy having been faxed to Dr. Mohamed Shanbaky on November 9, 1993.

Thank you for your understanding and assistance in this matter. Please contact either me at 215-686-5171 or Mr. Barry Dickman, Executive Assistant, at 215-823-7450, if you require any additional information.

Sincerely yours,

Susan Pingree
Chief of Staff

SP:jg
Attachment

cc: Estelle B. Richman, Acting Health Commissioner
Haresh Mirchandani, Medical Examiner
John Domzalski, Deputy Health Commissioner
Robert Ostrowski, Director, Air Management Services
Barry Dickman, Executive Assistant, Medical Examiner's Office

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

DEPT. OF PUBLIC HEALTH
COMMISSIONER'S OFFICE

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Docket No. 030-06186
License No. 37-08267-01 (Expired)
CAL No. 1-93-019

City of Philadelphia
Department of Public Health
ATTN: Susan Pingree
Chief of Staff
1600 Arch Street, Seventh Floor
Philadelphia, PA 19103

Dear Ms. Pingree:

SUBJECT: CONFIRMATORY ACTION LETTER NO. 1-93-019

On November 2, 1993, Sheri A. Arredondo of this office conducted an inspection of your NRC licensed activities at 321 University Avenue, and 1501 E. Lycoming Avenue, Philadelphia, Pennsylvania. The inspector identified that The City of Philadelphia's NRC license to possess and use byproduct material had expired on August 31, 1993 and you did not apply for a license renewal or a new license. However, you continued the use of byproduct material without a valid NRC License. During this inspection, the inspector also identified that the Radiation Safety Officer retired and that there have been no authorized users at the 321 University Avenue location since January 1992. The inspector also verified that the radioactive materials were properly stored and used and no immediate safety issues existed. At the conclusion of the inspection, the inspector was given a letter dated November 2, 1993 requesting the renewal of their NRC license. Upon notification of the expired license, immediate action was initiated to curtail use of NRC licensed material and to obtain a valid NRC license.

Pursuant to a telephone conversation between Mr. Barry Dickman, Executive Assistant, of your staff and Dr. M. Shanbaky, of my staff, and the subsequent conversation between you and myself on November 3, 1993, it is our understanding that you have taken or will take the following actions (which will be completed by the dates specified):

1. Immediately discontinue use of all radioactive materials and keep it in a secure location.

2. Complete and submit NRC FORM 483, entitled "REGISTRATION CERTIFICATE-in vitro TESTING WITH BYPRODUCT MATERIAL UNDER GENERAL LICENSE", on November 3, 1993. After our approval of this form, you will be limited to the possession and use of no more than a total of 200 microcuries (uCi) of iodine-125 for in vitro kits not to exceed 10 uCi each for forensic medicine studies in accordance with 10 CFR 31.11.

3. Submit to the NRC Region I Office a request for a new NRC License for use of byproduct material by no later than November 12, 1993, including your radiation safety program and the appropriate fee.

Pursuant to Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, and 10 CFR 2.204, you are required to:

1. Notify me immediately if your understanding differs from that set forth above.

2. Notify me if for any reason you cannot complete the actions within the specified schedule and advise me in writing of your modified schedule in advance of the change.

3. Notify me in writing when you have completed the actions addressed in this Confirmatory Action Letter.

Issuance of this Confirmatory Action Letter does not preclude issuance of an Order formalizing the above commitments or requiring other actions on the part of the licensee. Nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this letter. In addition, failure to take the actions addressed in this Confirmatory Action Letter may result in enforcement action.

The response directed by this letter is not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

Sincerely,

Charles W. Hehl, Director
Division of Radiation Safety
and Safeguards

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Barry Dickman, Philadelphia Department
of Public Health
Commonwealth of Pennsylvania

NRC FORM 483

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

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: [illegible] FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE PAPERWORK REDUCTION PROJECT [illegible], OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC [illegible]

INSTRUCTIONS: TYPE OR PRINT (PRESS HARD — MULTIPLE COPIES)

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: (SEE ITEM 1.A.)

Dept. of Public Health
Medical Examiner c Office
321 University Ave.
Phila., PA 19104

TELEPHONE NUMBER: (215) 823-7450

2. APPLICATION

I hereby apply for a registration number pursuant to 10 CFR 31, Section 31.11, for use of byproduct materials for: *(Check one box only)*

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

1. INSTRUCTIONS:

A. In the address box above, print or type the name and address (including ZIP Code) 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.

B. Submit this form and the two yellow copies to:
Medical, Academic and Commercial Use Safety Branch (8412)
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555
(At NRC, a registration number will be assigned and a validated copy of NRC Form 483 will be returned.)

C. Retain the Registrant's Copy (white copy) for your files.

3. REGISTRATION

REGISTRATION NUMBER: 1481

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Carolyn Boyle
Carolyn Boyle

VALIDATED FOR THE U.S. NUCLEAR REGULATORY COMMISSION

November 4, 1993
DATE

(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 license, include your registration number.)

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

5. 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 Office 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
Barry Dickman, Exec. Asst.	Barry Dickman	11/3/93

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.

NRC FORM 483 [illegible]

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE, 10 CFR 31.11

§ 31.11 General license for use of byproduct material 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 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.

(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 americium-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, D.C. 20555, 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,[1] nor transfer the byproduct material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(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:[2]

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 materials 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 the "Registration Certificate—In Vitro Testing with Byproduct Material Under General License," NRC Form 483. The report shall be furnished within 30 days after the effective date of such change.[3]

(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 materials has been transferred by formal agreement, 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 validated 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, an "Application for Byproduct Material License," NRC Form 313 should be filed 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 (SHD), Division of Industrial and Medical Nuclear Safety, United States Nuclear Regulatory Commission, Washington, DC 20555.

TOTAL P.03

TOTAL P.03