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January 6, 2005

Licensing Assistant Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406-1415
Attn: Bryan A. Parker

MAIL CONTROL NUMBER: 135741

03036157

SUBJECT: Radioactive Materials License Amendment Request (Lic. No. 29-30786-01)

Please find the enclosed resubmitted *Application for Amendment of Radioactive Materials License* for Pharmalogic P.E.T. Services of New Jersey (Pharmalogic). Pharmalogic currently operates a nuclear pharmacy at the facility under New Jersey State license NJBL-20779/01/003, but now wishes to add certain radiopharmaceuticals which are regulated by the NRC. Pharmalogic possesses a current NRC license (Lic. No. 29-30786-01) at the site for sealed sources.

Nature of Business: Pharmalogic PET Services is a nuclear pharmacy which also includes an on-site cyclotron for production of positron emitting radioisotopes.

If you have any questions or require any further information, please do not hesitate to contact myself at (518) 464-0871, or Mr. Gerard Strugala, Vice President of PET operations, at (732) 539-9395.

Sincerely,

Gregory S. Hisel, CHP
Corporate Physicist

136274

NMSS/RGNI MATERIALS-002

APPLICATION FOR MATERIAL LICENSE

Estimated burden per response to comply with this mandatory information collection request 7.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), 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, NE08-10202, (3150-0120), 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, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

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, PENNSYLVANIA,
RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

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

SAM NUNN ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
81 FORSYTH STREET, S.W., SUITE 23785
ATLANTA, GEORGIA 30303-8931

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS,
LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA,
OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH,
WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

03036157

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 JURISDICTIONS.

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

- A. NEW LICENSE
- B. AMENDMENT TO LICENSE NUMBER 29-30786-01
- C. RENEWAL OF LICENSE NUMBER _____

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

Pharmalogic P.E.T. Services of N.J.
60 H Commerce Way
Towaw, NJ 07512

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

60 H Commerce Way
Towaw, NJ 07512

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Gregory S. Hise, CHP

TELEPHONE NUMBER

518-464-0871

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 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 EXPERIENCE.

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

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, 36, 39 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

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

SIGNATURE

DATE

Gregory S. Hise, Corporate Physicist

[Signature]

1/6/05

FOR NRC USE ONLY

| TYPE OF FEE | FEE LOG | FEE CATEGORY | AMOUNT RECEIVED | CHECK NUMBER | COMMENTS |
|-------------|---------|--------------|-----------------|--------------|----------|
|-------------|---------|--------------|-----------------|--------------|----------|

\$

APPROVED BY

DATE

136274

ITEMS 5 & 6: RADIOACTIVE MATERIAL AND PURPOSES

See Tab 5 for table of isotopes, forms, and uses.

Pharmalogic will not perform compounding of radioiodine under this license.

Pharmalogic confirms that each sealed source, device, and source/device combination is registered as an approved sealed source or device by NRC or an agreement state.

Pharmalogic confirms that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an agreement state.

Pharmalogic confirms that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to 10 CFR 32.72.

Pharmalogic confirms that generators will be obtained from a manufacturer licensed pursuant to 10 CFR 32.72, or under equivalent Agreement state requirements.

Pharmalogic confirms that unused generators will be redistributed without opening or altering the manufacturer's packaging.

Pharmalogic will follow manufacturer's instructions for repackaging generators including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport.

Pharmalogic confirms that the manufacturer's packaging and labeling will not be altered.

Pharmalogic confirms that the generator will not be distributed beyond the expiration date shown on the generator label.

Pharmalogic confirms that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator.

Pharmalogic confirms that only generators used in accordance with the manufacturer's instructions will be redistributed.

Pharmalogic confirms that sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent Agreement State requirements.

Pharmalogic confirms that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package

insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

Pharmalogic confirms that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to 10 CFR 32.74 to initially distribute such sources.

Pharmalogic confirms that the prepackaged units for in vitro tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for in vitro tests in accordance with a specific license issued pursuant to 10 CFR 32.71 or under an equivalent license of an Agreement State.

Pharmalogic confirms that the manufacturer's packaging and labeling of the prepackaged units for in vitro tests will not be altered in any way.

Pharmalogic confirms that each distributed prepackaged unit for in vitro tests will be accompanied by the manufacturer-supplied package insert, leaflet, or other brochure that provides radiation safety instructions for general licenses.

Pharmalogic will continue to follow the sealed source handling procedures for reference and calibration in place under its current license.

Pharmalogic will not perform leak testing or instrument calibrations for customers under this license.

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

Radiation Safety Officer: Gregory S. Hisel, CHP will remain the radiation safety officer for the license with this amendment.

Authorized Users: Sealed Sources will only be used by or under the direct supervision of state certified nuclear pharmacists or the RSO.

Pharmalogic P.E.T. Services of NJ organizational chart is located in Tab 7. Training documentation for Michael Agnello, Vincent De Fedele, and Gerard Strugala are also included in Tab 7.

ITEM 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

All personnel entering restricted areas receive basic radiation safety training initially and annually under the current license. Orientation training for all Pharmalogic employees will be performed for each radiopharmaceutical obtained by Pharmalogic following this amendment to the license.

No change in company structure or employee positions will occur as a result of this amendment.

ITEM 9: FACILITIES AND EQUIPMENT

A copy of the State Board of Pharmacy license is included in Tab 9.

All licensed radiopharmaceuticals shall be stored and used in the Pharmacy and Manufacturing Rooms (see attached drawing in Tab 9). Generator and Fume Hood locations are shown on the attached drawing in Tab 9.

Sealed Sources shall be stored in the manufacturing room within the facility. Access to restricted areas is controlled via doors with combination locks. Only authorized personnel have access to the combinations. Sealed Sources will be purchased with accompanying shielded containers and shall remain in the shielded containers when not in use.

Areas of Use: Sealed sources shall be used for reference checks on instrumentation at various locations throughout the restricted area.

NOTE: Pharmalogic will not be compounding iodine. Pharmalogic intends only to redistribute capsules of radioiodine.

Air Concentrations of Xenon-133 for Unrestricted Areas

- All Xenon-133 gas will be stored in a fume hood.
- The maximum amount of activity on hand at any one time per week is 1000 mCi.
- We use an estimated maximum loss factor of 0.05% per day from the dose vials, and a fume hood flow rate of 450 cfm to obtain an estimated worst case concentration in unrestricted areas:

$$\frac{(1,000 \text{ mCi} \times 0.0005/\text{dy}) \times (1,000 \text{ uCi/mCi})}{(24 \text{ hrs/dy}) \times (60 \text{ min/hr}) \times (450 \text{ ft}^3/\text{min}) \times (12 \text{ in/ft})^3 \times (2.54 \text{ cm/in})^3 \times (1 \text{ ml/cm}^3)}$$
$$= 2.7 \times 10^{-8} \text{ uCi/ml}$$

Compare to the maximum allowed concentration: $5 \times 10^{-7} \text{ uCi/ml}$

ITEM 10: RADIATION SAFETY PROGRAM

Annual ALARA Audit and Radiation Safety Committee: Pharmalogic shall continue quarterly RSC meetings and modify annual audit checklists to include new radiopharmaceuticals to reflect inventories.

Pharmalogic will use equipment that meets the radiation monitoring instrument specifications and implement the model survey meter calibration program published in Appendix J to NUREG-1556, Vol. 13.

Pharmalogic has developed, and will implement and maintain written procedures for safely opening packages that meet the requirements in 10 CFR 20.1906, and will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months.

Pharmalogic has developed, and will implement and maintain written procedures for licensed material accountability and control to ensure that license possession limits are not exceeded, licensed material in storage is secured from unauthorized access or removal, licensed material not in storage is maintained under constant surveillance and control, and records of receipt, transfer, and disposal of licensed material are maintained.

Pharmalogic has developed and will implement and maintain written procedures for monitoring occupational dose that meet requirements in 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.1202, 10 CFR 20.1202, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, AND 10 CFR 20.2106, as applicable.

Pharmalogic has developed and will implement and maintain written procedures for the safe use of radioactive materials that address facility and personnel radioactive contamination minimization, detection, and control, performing molybdenum-99 breakthrough measurements on all generator elutions used to prepare radioactive drugs for human medical use, and use of protective equipment by personnel that meet the requirements in 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 30.34(g), AND 10 CFR 19.11(a)(3), as applicable.

Pharmalogic has developed and will implement and maintain written procedures for identifying and responding to emergencies involving radioactive material including the following:

- Lost, stolen, or missing licensed material
- Exposures to personnel and the public in excess of NRC regulatory limits
- Releases of licensed materials in effluents and the sanitary sewer in excess of NRC regulatory limits
- Excessive radiation levels or radioactive materials concentrations in restricted or unrestricted areas
- Radioactive spills and contamination
- Fires, explosions, and other disasters with the potential for the loss of containment of licensed material, and
- Routine contacts with local fire departments

that meet the requirements in 10 CFR 20.1101, 10 CFR 20.2201-2203, AND 10 CFR 30.50, as applicable.

Pharmalogic has developed and will implement and maintain written procedures for a survey program that specifies the performance of radiation and contamination level surveys in

restricted and unrestricted areas, personnel contamination monitoring, action levels, and the frequencies and records maintenance of those surveys and monitoring that meet the requirements in 10 CFR 53, 10 CFR 20.1501, AND 10 CFR 20.2103 as applicable.

Pharmalogic will employ a Capintec CRC-15 dose calibrator at the facility.

Pharmalogic has developed and will implement and maintain a written procedure for the performance of dosage measurement system checks and tests that meet the requirements in 10 CFR 32.72(c).

A sample of the labels used by Pharmalogic is included in Tab 10. Radioactive materials labels are black and yellow or yellow and magenta. Individual doses and dose containers are labeled.

Pharmalogic has developed and will implement and maintain written procedures for leak testing that meet the requirements in 10 CFR 30.53, 10 CFR 20.1501, AND 10 CFR 20.2103.

ITEM 11: WASTE MANAGEMENT

Pharmalogic has developed and will implement and maintain written procedures for waste management that meet the requirements in 10 CFR 20.2001(a), 10 CFR 20.2003, 10 CFR 20.2006, 10 CFR 20.2108, 10 CFR 30.51, as applicable.

Pharmalogic has developed and will implement and maintain written procedures for customer return of pharmacy supplied syringes and vials and their contents which specify that only pharmacy supplied syringes and vials and their contents may be returned to the pharmacy, instructions will be provided to radiopharmacy, and instructions will be provided to pharmacy staff for the pick-up, receipt and disposal of the returned radioactive waste that meet the requirements in 10CFR 20.2001(a), 10 CFR 30.33, AND 10 CFR 71.5, as applicable.

APPENDIX D

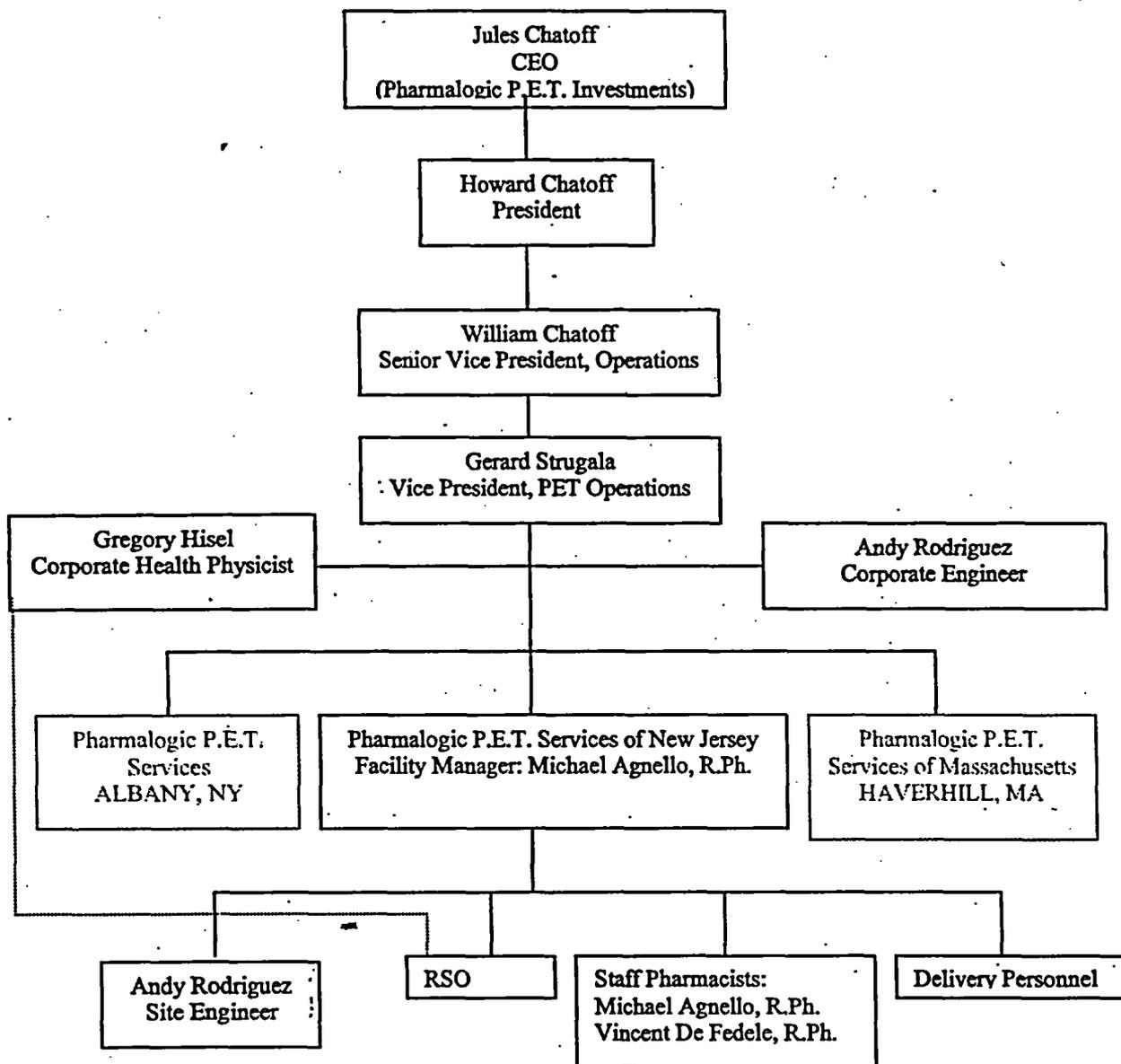
D.5 ITEMS 5 & 6: MATERIALS TO BE POSSESSED AND PROPOSED USES

| Yes | No | Radioisotope | Form or Mfg/Model No. | Quantity | Purpose of Use | Specify Other Uses Not Listed on SSD Certificate |
|-----|----|---|---|--|-------------------------------|--|
| ✓ | | Byproduct Materials with Atomic No. 1-83 | Any | <u>100</u> millicuries per nuclide, 1 curie total possession, except as noted: | 10 CFR 32.72 and 10 CFR 30.41 | [] Not applicable [] Uses are: |
| ✓ | | Molybdenum-99 | Any | <u>100</u> curies | 10 CFR 32.72 and 10 CFR 30.41 | [] Not applicable [] Uses are: |
| ✓ | | Technetium-99m | Any | <u>100</u> curies | 10 CFR 32.72 and 10 CFR 30.41 | [] Not applicable [] Uses are: |
| ✓ | | Iodine-131 | Any | <u>2,000</u> millicuries | 10 CFR 32.72 and 10 CFR 30.41 | [] Not applicable [] Uses are: |
| ✓ | | Xenon-133 | Any | <u>1.0</u> curies | 10 CFR 32.72 and 10 CFR 30.41 | [] Not applicable [] Uses are: |
| ✓ | | Any Byproduct Material in a Brachytherapy Source, as listed in 10 CFR 35.400 | Sealed Sources | <u>500</u> millicuries | 10 CFR 32.74 and 10 CFR 30.41 | [] Not applicable [] Uses are: |
| ✓ | | Any Byproduct Material in a sealed source for diagnosis, as listed in 10 CFR 35.500 | Sealed Sources | <u>1.5</u> curies per source and <u>5.5</u> curies total | 10 CFR 32.74 and 10 CFR 30.41 | [] Not applicable [] Uses are: |
| ✓ | | Any byproduct material listed in 10 CFR 3111(a) | Prepackaged units for in vitro diagnostic tests | <u>50</u> millicuries | 10 CFR 31.11 | [] Not applicable [] Uses are: |

APPENDIX D

| Yes | No | Radioisotope | Form or Mfg/Model No. | Quantity | Purpose of Use | Specify Other Uses Not Listed on SSD Certificate |
|-----|----|---|---|---|---|---|
| ✓ | | Any byproduct material authorized under 10 CFR 35.57(a) | Sealed Sources | 50 millicuries | Calibration and checking of the licensees instruments and 10 CFR 32.74 and 10 CFR 30.41 | <input type="checkbox"/> Not applicable <input type="checkbox"/> Uses are: |
| ✓ | | Depleted Uranium | Metal | 600 kilograms | shielding for molybdenum-99/technetium-99m generators | <input type="checkbox"/> Not applicable <input type="checkbox"/> Uses are: |
| ✓ | | Cesium-137 | Sealed sources in compatible device as specified in Sealed Source and Device Registration Sheet | Not to exceed maximum activity per source as specified in Sealed Source and Device Registration Sheet | Instrument calibration | <input type="checkbox"/> Not applicable <input type="checkbox"/> Uses are: |
| ✓ | | Other (specify) Sm-153 | Any except Sealed Source | 600 mCi | 10 CFR 32.72 and 10 CFR 30.41 | |
| ✓ | | Y-90 | Any except Sealed Source | 400 mCi | 10 CFR 32.72 and 10 CFR 30.41 | |

PHARMALOGIC P.E.T. SERVICES OF NJ ORGANIZATION CHART



Pharmalogic P.E.T. Services of New Jersey, LLC is wholly owned by Pharmalogic P.E.T. Investments, LLC.

Pharmalogic P.E.T. Investments, LLC Ownership:

| | |
|------------------------------|--------|
| Pelican Holdings, LLC | 51% |
| Positron Partners NY, LLC | 26.79% |
| Venture Partners, LLC | 8.08% |
| Alan Cadkin TTE | 4.04% |
| Ilene Cadkin | 2.02% |
| Syracuse Investment Club, LC | 8.08% |

GERARD ANTHONY STRUGALA
R.Ph., B.C.N.P.

CURRICULUM VITAE

PLACE OF BIRTH

[REDACTED]

DATE OF BIRTH

[REDACTED]

FAMILY

[REDACTED]

LICENSURE

Massachusetts, Number 18455, Pharmacist
New York, Number 041881-1, Pharmacist
New Jersey, Number RI 26584, Pharmacist

CERTIFICATION

Board of Pharmaceutical Specialties
Certified Nuclear Pharmacist, 8 April 1989
Re-Certified March 1996
Certified in Advanced Cardiac Life Support (ACLS)

ACADEMIC AND PROFESSIONAL EDUCATION

| INSTITUTION | DEGREE | GRADUATION |
|-------------------------------|---|-------------------|
| Northeastern University | Bachelor of Science-Pharmacy | June 1981 |
| Letterman Army Medical Center | Nuclear Pharmacy Residency | June 1986 |
| June 2002 | 49 th Annual Meeting Society of Nuclear Medicine (SNM) Los Angeles, California | |
| March 2002 | 149 th Annual Meeting & Exposition American Pharmaceutical Association (APhA) Philadelphia, Pennsylvania | |
| March 2001 | 148 th Annual Meeting & Exposition American Pharmaceutical Association (APhA) San Francisco, California | |
| June 2000 | 47 th Annual Meeting Society of Nuclear Medicine (SNM) St. Louis, Missouri | |
| March 2000 | 147 th Annual Meeting & Exposition American Pharmaceutical Association (APhA) Washington, District of Columbia | |
| October 1999 | 11 th Annual Meeting Institute of Clinical P.E.T. (ICP) Vancouver, British Columbia | |

**PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.**

PROFESSIONAL EXPERIENCE

AUGUST 2000 - VICE PRESIDENT, OPERATIONS
PRESENT PharmaLogic P.E.T. Group, LLC

As an experienced P.E.T. nuclear pharmacist and corporate officer initiated and managed nation-wide cyclotron and pharmacy operations in the United States involving the distribution of P.E.T. radiopharmaceuticals. Responsibilities include:

- designed twelve prospective P.E.T. Cyclotron and Pharmacies in the United States over a 3 year period;
- responsible for construction project oversight of all P.E.T. facilities;
- evaluated equipment and technological advances; empowered with purchasing authority for all manufacturing, analytical and dispensing equipment at each facility, established supply contracts with vendors for recurring expendable goods;
- responsible for budgetary conduct at each facility, monitored the cost of goods, capital expenditures and construction variances;
- supervised all PharmaLogic P.E.T. Cyclotron and Pharmacy operations;
- established staffing criteria for all facilities, established minimal requirements for each position, established job descriptions and responsibilities, hired and trained cyclotron operators, pharmacists, engineers and couriers;
- compiled P.E.T. cyclotron and pharmacy licensing applications to include State Radioactive Material, Environmental Protection and Pharmacy licenses;
- initiated compliance with FDA Regulations on the manufacture of P.E.T. radiopharmaceuticals;
- composed and installed standard operating procedures covering cyclotron operations, drug manufacturing, quality control testing and pharmaceutical dispensing;
- pending regulatory approval as radiation safety officer at the Albany, New York facility;
- managed the sales and marketing section and the customer service activities of each facility.

SEPTEMBER 1999 - VICE PRESIDENT, OPERATIONS
AUGUST 2000 Advanced Isotope Corporation, LLC

As an experienced P.E.T. nuclear pharmacist and corporate officer initiated P.E.T. cyclotron and pharmacy operations in Florida involving the distribution of P.E.T. radiopharmaceuticals. Responsibilities included:

- designed P.E.T. Nuclear Pharmacies in Orlando and Ft. Lauderdale, Florida;
- responsible for oversight of construction phase of both facilities;
- completed the radioactive material and pharmacy manufacturing applications and obtained appropriate licensing for both facilities;
- equipped facilities with manufacturing, analytical and dispensing equipment;
- established the training program and trained pharmacists and cyclotron operators involved in all operational aspects;
- composed and installed standard operating procedures covering cyclotron operations, drug manufacturing, quality control testing and pharmaceutical dispensing;
- served as the radiation safety officer for the Ft. Lauderdale P.E.T. Manufacturing Center.

MAY 1998 - REGIONAL MANAGER, NORTHEAST
SEPTEMBER 1999 - P.E.T.Net Pharmaceutical Services, LLC

As an experienced P.E.T. nuclear pharmacist managed pharmacy operations in the northeastern region of the United States involving distribution of P.E.T. radiopharmaceuticals:

- evaluated, implemented and qualified new P.E.T. radiopharmaceutical synthesis programs;
- developed an efficient operation at New York under adverse physical and operational demands that allowed it to become the site with the greatest number of doses dispensed internally and externally and generated the highest amount of revenue;
- trained a nuclear pharmacist as a facility manager;
- performed budget compilation and review for the New York pharmacy;
- monitored radiation exposure of the New York personnel and generated several equipment proposals and operational procedures to reduce personnel risk and increase regulatory compliance;
- designed and equipped new pharmacies in Boston and Columbus, Ohio;
- organized sales and marketing efforts in the New York, Boston and Baltimore metropolitan areas;
- established pricing schedules for the Northeast Region, resulting in pricing tiers for customers based on sales volume and logistic expenses;
- lectured as a nuclear pharmacy consultant in seminars on metabolic imaging;
- continued training and operations support at the New York pharmacy.

JANUARY 1993 - FACILITY MANAGER, P.E.T. NUCLEAR PHARMACY
MAY 1998 - P.E.T.Net Pharmaceutical Services, LLC
COLUMBIA-PRESBYTERIAN MEDICAL CENTER
NEW YORK, NEW YORK

Board certified nuclear pharmacist responsible for the operational and personnel management of the P.E.T.Net Pharmaceutical Services Positron Emission Tomography (P.E.T.) Nuclear Pharmacy located at Columbia-Presbyterian Medical Center. Responsibilities include the following:

- coordinated PETNet goals with those of the Medical Center, their Directors and Committees to achieve the desired results involving the operation of the P.E.T. Nuclear Pharmacy. Maintains accounts with external customers and incorporates their clinical needs into the production/synthesis cycle of this pharmacy;
- developed and monitored compliance of the policies and procedures addressing the operation of the Nuclear Pharmacy. The overall scope of which involves the preparation and quality control of positron emitting pharmaceuticals, isotope quantification, dispensing, containment and handling;
- prepared chemical synthesis units, and compounded chemical precursors and radiopharmaceuticals (F-18 FDG, N-13 Ammonia, O-15 Water) in parenteral form. Developed and completed analytical testing to insure product quality and safety using High Pressure Liquid Chromatography, Gas Chromatography, Thin Layer Chromatography, and sterility and pyrogen testing;
- developed patient monitoring modules for each new radiopharmaceutical developed;
- conducted teaching seminars with physician and technical staff on the chemistry, quality control and biodistribution of these diagnostic agents;
- maintained the required accountability and recordkeeping of radioisotopes and radiopharmaceuticals in accordance with the State Board of Pharmacy, and the City Bureau of Radiological Health;

FACILITY MANAGER, P.E.T. NUCLEAR PHARMACY (con't)

- assembled a radiation safety program within the cyclotron and P.E.T. Nuclear Pharmacy; responsible for operational compliance of the facility personnel with radiation safety procedures; conducts semi-annual audits of the radiation safety program within the facility; conducted inspections with the City of New York Bureau of Radiological Health.

NOVEMBER 1988 - COORDINATOR, NUCLEAR PHARMACY
JANUARY 1993 HARPER HOSPITAL
DETROIT, MICHIGAN

Board certified nuclear pharmacist responsible for the operational and personnel management of the Harper Nuclear Pharmacy. Responsibilities included the following:

- operated under the auspices of a broad scope radioactive materials license in the preparation of diagnostic and therapeutic doses in support of the Harper Nuclear Medicine Service and the off campus Grace Hospital Nuclear Medicine Service;
- served as clinical coordinator for the immune globulin G, prostate carcinoma monoclonal antibody, and the strontium-89 therapy research protocols;
- initiated policies and procedures specifically addressing the preparation and quality control of radiolabelled pharmaceuticals, in vitro radiolabelling of blood components, and isotope quantification;
- introduced procedures for newly approved and investigational radiopharmaceuticals; techniques initiated for immune globulin G radiolabelling, improved leukocyte separation and prostate carcinoma monoclonal antibody isotope labelling;
- monitored the radiation safety standards and their application in the handling of all radioactive material throughout all clinical and research settings in Harper Hospital and Wayne State University;
- served as faculty member to the residency programs within the Departments of Pharmacy and Diagnostic Imaging;
- prepared the application for renewal of a broad scope radioactive materials license and amended license as required;
- insured compliance with the Nuclear Regulatory Commission and the Department of Transportation Regulations and Guidelines;
- maintained the required accountability and recordkeeping as dictated by state and federal regulations;
- developed criteria for the application of low osmolality contrast media; presented semi-annual evaluations of new agents, and advances in the use of contrast media; and conducted drug utilization reviews for these diagnostics.

MAY 1981 - PHARMACY OFFICER
PRESENT UNITED STATES ARMY / ARMY RESERVE

U.S. Army

Graduated as a Distinguished Military Graduate and commissioned as an Regular U.S. Army Pharmacist in 1981. Served as a Pharmacy Officer in ascending positions of responsibility throughout an 8 year active duty career.

- Chief of Outpatient Pharmacy providing outpatient pharmaceutical services at a health care clinic in Yuma Proving Grounds, Arizona.
- Chief of Pharmacy Support Section providing logistical support and budgetary oversight of a 2.4 million dollar pharmaceutical formulary at Fitzsimons Army Medical Center, Colorado.
- Chief of Nuclear Pharmacy at Madigan Army Medical Center.

U.S. Army Reserve

Served as assistant chief of Pharmacy Services for the 323rd Combat Support Hospital. Activated during Desert Storm and assigned as assistant chief of inpatient pharmacy services in a 600 bed tertiary care facility.

- Managed oral unit dose and intravenous product preparation for inpatient and home care use.
- Conducted research on extemporaneously compounded ophthalmic preparations; resulting in new product formulations verified to be stable and safe for ophthalmic use.
- Instituted automated supply functions within the inpatient pharmacy.
- Coordinated efforts with the Department of Nursing to standardize inpatient dosing regimens and ward pharmaceutical supplies.

Served as Chief, Pharmacy Service and Special Operations Officer for the 343rd Combat Support Hospital.

- as Operations and Intelligence Officer organized combat service support missions to Panama, Ecuador, Honduras and Guatemala.
- commanded 35 personnel on overseas missions of 21 day duration to Honduras and Guatemala. Completed medical missions successfully, evaluated above standard and returned all personnel home safely in both missions.

**AUGUST 1986 -
OCTOBER 1988**

**CHIEF, NUCLEAR PHARMACY
MADIGAN ARMY MEDICAL CENTER
TACOMA, WASHINGTON**

Board eligible nuclear pharmacist responsible for the administration and daily operations of the nuclear pharmacy. Responsibilities included the following:

- functioned under a broad scope license in support of the medical center's nuclear medicine service;
- advanced the nuclear pharmacy assets evidenced by an increase in the computer capabilities, an increase in the qualitative and quantitative detection capabilities, and an increase in the biological/radiological safety equipment employed. Designed, justified and equipped the proposed nuclear pharmacy encompassing twice the area of the existing facility;
- served as a clinical specialist; functioned as a faculty member for the nuclear medicine technologists in-training, the pediatric dental residency, and the nuclear pharmacy orientation program;
- implemented new diagnostic imaging procedures involving specialized cell labelling techniques, alternative lung ventilation studies and single photon emission computed tomography studies;
- interpreted Federal and Army Regulations with the subsequent establishment and evaluation of radiation health physics practices. Completed and compiled necessary paperwork for the renewal of a NRC broad scope license for this facility. Responsible for changes in Army regulations which created prescribing capabilities for qualified nuclear pharmacists.

JUNE 1985 -
JULY 1986

**NUCLEAR PHARMACY RESIDENT
LETTERMAN ARMY MEDICAL CENTER
PRESIDIO OF SAN FRANCISCO, CALIFORNIA**

Completed a 2000 hour residency program encompassing the nine primary objectives set forth in the American Society of Hospital Pharmacist Accreditation Standards. Functioned as a nuclear pharmacist with responsibilities in the following areas:

- managed the daily operation of the nuclear pharmacy and the actions of two nuclear medicine technologists;
- performed the procurement, dispensing, quality control, recordkeeping and cost effective utilization of diagnostic and therapeutic radiopharmaceuticals;
- compounded ligands for future radiolabelling under the guidelines established by the Current Good Manufacturing Practices; to include stability and sterility tests completed for each lot;
- insured compliance with federal regulatory agencies;
- provided training for physicians (residents and fellows) and technologists in radiopharmaceutical chemistry and pharmacology;
- supported protocols for investigational use;
- assumed the functions as Director, Nuclear Pharmacy during his absence.

PRESENTATIONS

"Positron Emission Tomography (PET) Radiopharmacy"

Yale University Metabolic Imaging Seminar
New Haven, Connecticut, (1998 / 1999)

**"Positron Emission Tomography (PET) Radiopharmaceuticals:
Applications in Oncology and Cardiology"**

4th Annual Nuclear Pharmacy Lecture Series, Florida Pharmacy Association,
Boca Raton, Florida, (June 1995)

"Conventional and P.E.T. Radiopharmaceuticals Lecture Series"

Columbia University, School of Public Health, New York, New York,
(February-March 1994, 1995, 1996)

"F-18 Fludeoxyglucose - Synthesis and Quality Control"

Columbia University, School of Public Health, New York, New York, (February 1993)

"The Utilization of Low Osmolality Contrast Agents - A Summary of a National Survey"

Detroit Medical Corporation Non-Ionic Task Force, Detroit, Michigan, (June 1992)

"The Practice of Nuclear Pharmacy"

Harper Hospital, Detroit, Michigan, (February 1990)

"Nuclear Pharmacy Services at Harper - Grace Hospitals"

24th Annual ASHP Midyear Clinical Meeting, Atlanta, Georgia, (December 1989)

"Nuclear Pharmacy Instrumentation"

20th & 21st Annual Tri-services Nuclear Pharmacy Orientation Course
Presidio of San Francisco, California, (March 1988 & March 1987)

"Technetium-99m Red Blood Cell Labelling Techniques"

20th & 21st Annual Tri-services Nuclear Pharmacy Orientation Course
Presidio of San Francisco, California, (March 1988 & March 1987)

**"Madigan Army Medical Center Pediatric Dental Residency Pharmacologic/Pharmacokinetic
Lecture Series"**

Tacoma, Washington (June 1987)

"Letterman Army Medical Center Nuclear Pharmacy Residency"

Annual Ralph D. Arnold Pharmaceutical Service Course, Aurora, Colorado, (May 1986)

"Distribution and Localization of Radiopharmaceuticals"

Safe Use and Handling of Radioisotopes Course, Presidio of San Francisco, California, (April 1986)

PROFESSIONAL SOCIETY MEMBERSHIPS

Institute of Clinical P.E.T.
Society of Nuclear Medicine
American Pharmaceutical Association
American Society of Health System Pharmacists



Gerard A. Strugala, RPh, BCNP
1 September 2002

Certification in Nuclear Pharmacy



Board of Pharmaceutical Specialties

attests that

Gerard Anthony Strugala

*having fulfilled all requirements, and having been recommended
by the Specialty Council on Nuclear Pharmacy, is CERTIFIED
in the specialty of Nuclear Pharmacy.*

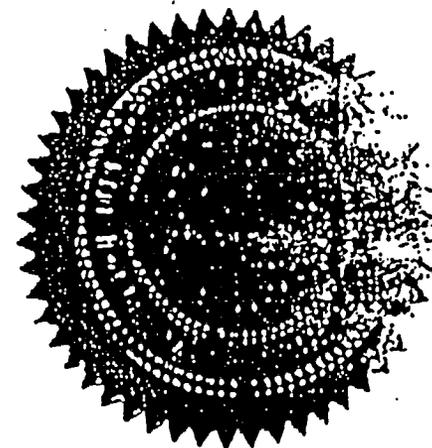
Chairman

Ray L. Meltz

Secretary

D. P. Gorman

Date July 17, 1989



American Pharmaceutical Association

GA-8

000030

U. S. Army Medical Department

Graduation Certificate

This is to certify that

Captain Gerard A. Strugala, MS

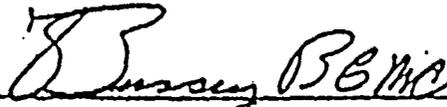
has successfully completed the

Nuclear Pharmacy Residency

from 1 July 1985 *to* 30 June 1986

given at Letterman Army Medical Center, Presidio of San Francisco, California

this 30th day of June 19 86


Frederick H. Bussey, MA
Brigadier General, MC
Commanding

GA-9

000029

GA-13

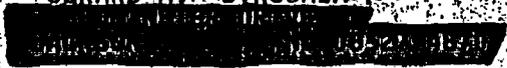
THE FACE OF THIS DOCUMENT HAS A MULTI-COLORED BACKGROUND AND MULTIPLE SECURITY FEATURES

State Of New Jersey
Department Of Law and Public Safety
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
BOARD OF PHARMACY

HAS LICENSED

GERARD A. STRUGALA



FOR PRACTICE IN NEW JERSEY AS A(N) PHARMACIST

05/01/01 TO 04/30/03

VALID

SIGNATURE OF REGISTRANT

RI 26584

LICENSE/REGISTRATION/CERTIFICATION #

DIRECTOR

STATE OF NEW JERSEY DIVISION OF CONSUMER AFFAIRS

THIS IS TO CERTIFY THAT

BOARD OF PHARMACY
HAS LICENSED
GERARD A. STRUGALA
PHARMACIST

05/01/01 TO 04/30/03

VALID

RI 26584

LICENSE NO.



SIGNATOR

DIRECTOR

PLEASE DETACH HERE

IF YOUR LICENSE/ID CARD
IS LOST PLEASE NOTIFY:

BOARD OF PHARMACY
PO BOX 45013
NEWARK NJ 07101

PLEASE DETACH HERE

PERSONAL INFORMATION WAS REMOVED
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COLLEGE OF PHARMACY*Office of the Dean*

4301 West Markham, Slot 522
Little Rock, Arkansas 72205-7122
501/686-5557
501/686-8315 (fax)

Departments:

Biopharmaceutical Sciences
(501) 686-5937
(501) 686-6057 (fax)

Pharmaceutics
(501) 686-6280

Pharmacy Practice
(501) 686-6390

Services:

Arkansas Poison & Drug
Information Center
(501) 686-5540
(800) 3 POISON
(501) 686-7357 (fax)

Continuing Education
(501) 686-5396



April 19, 2004

Vincent De Fedele
Pharmalogic
80-H Commerce Way
Totowa, NJ 07512

Dear Vincent,

Congratulations on your completion of Nuclear Education Online program for nuclear pharmacy training. We hope that you have gained the fundamental knowledge of the profession on which to build experience and expertise in this specialty area of pharmacy.

The faculty would also like to congratulate you for your outstanding performance. You earned the distinction of the NEO "Honor Roll" with a course performance score greater than 90%.

We appreciate your participation in the program and wish you the best in your career.

Best regards,

Nicki Hilliard, Pharm.D, MHSA, BCNP, FAPhA
Associate Professor of Nuclear Pharmacy
University of Arkansas for Medical Sciences

cc: Mike Agnello



CERTIFICATION OF CONTINUING PHARMACEUTICAL
EDUCATION PROGRAM - STATEMENT OF CREDIT

NAME University of Arkansas for Medical Sciences

PROGRAM INFORMATION

| | | | | |
|---------------------|--|-----------|---|----|
| 004-039-04-200-H-01 | Nuclear Education Online Program - Nuclear Instrumentation | 3/23/2004 | 3 | 30 |
|---------------------|--|-----------|---|----|

PARTICIPANT INFORMATION

LICENSE NO.(S)
NJ 28R10162000

NAME Vincent De Fede

ADDRESS Pharmalogic
60-H Commerce Way

CITY, STATE, ZIP Totowa, NJ 07512-

TOTAL CREDITS ISSUED 3 CEU'S
OR 30 CONTACT HOURS

4/7/2004

DATE

Charles Stone

AUTHORIZED SIGNATURE



**CERTIFICATION OF CONTINUING PHARMACEUTICAL
EDUCATION PROGRAM - STATEMENT OF CREDIT**

NAME University of Arkansas for Medical Sciences

PROGRAM INFORMATION

| | | | | |
|---------------------|--|-----------|---|----|
| 004-039-04-201-H-01 | Nuclear Education Online - Nuclear Physics for Radiopharmacy | 3/23/2004 | 8 | 80 |
|---------------------|--|-----------|---|----|

PARTICIPANT INFORMATION

LICENSE NO.(S)
NJ 28R10162000

TOTAL CREDITS ISSUED 8 **CEU'S**
OR 80 **CONTACT HOURS**

NAME Vincent De Fedele

4/7/2004

ADDRESS Phamalogic
60-H Commerce Way

DATE

CITY, STATE, ZIP Totowa, NJ 07512-

Greg Stone

AUTHORIZED SIGNATURE



CERTIFICATION OF CONTINUING PHARMACEUTICAL
EDUCATION PROGRAM - STATEMENT OF CREDIT

NAME University of Arkansas for Medical Sciences

PROGRAM INFORMATION

| | | | | |
|---------------------|---|-----------|---|----|
| 004-039-04-202-H-01 | Nuclear Education Online - Radiation Biology | 3/23/2004 | 2 | 20 |
|---------------------|---|-----------|---|----|

PARTICIPANT INFORMATION

LICENSE NO.(S)
NJ 28R10162000

TOTAL CREDITS ISSUED 2 CEU'S
OR 20 CONTACT HOURS

NAME Vincent De Fedele

ADDRESS Pharmacologic
60-H Commerce Way

CITY, STATE, ZIP Totowa, NJ 07812-

4/7/2004

DATE

Greg Stone

AUTHORIZED SIGNATURE



**CERTIFICATION OF CONTINUING PHARMACEUTICAL
EDUCATION PROGRAM - STATEMENT OF CREDIT**

NAME University of Arkansas for Medical Sciences

PROGRAM INFORMATION

| | | | | |
|---------------------|--|-----------|---|----|
| 004-039-04-203-H-01 | Nuclear Education Online - Radiation Safety | 3/23/2004 | 3 | 30 |
|---------------------|--|-----------|---|----|

PARTICIPANT INFORMATION

LICENSE NO.(S)
NJ 28R10162000

NAME Vincent De Fedele

ADDRESS Pharmalogic
60-H Commerce Way

CITY, STATE, ZIP Totowa, NJ 07512-

TOTAL CREDITS ISSUED 3 **CEU'S**
OR 30 **CONTACT HOURS**

4/7/2004

DATE

Carol Stone

AUTHORIZED SIGNATURE



CERTIFICATION OF CONTINUING PHARMACEUTICAL
EDUCATION PROGRAM - STATEMENT OF CREDIT

NAME University of Arkansas for Medical Sciences

PROGRAM INFORMATION

| | | | | |
|---------------------|--|-----------|---|----|
| 004-039-04-204-H-01 | Nuclear Education Online - Radiopharmacy | 3/23/2004 | 4 | 40 |
|---------------------|--|-----------|---|----|

PARTICIPANT INFORMATION

LICENSE NO.(S)
NJ 28R10162000

TOTAL CREDITS ISSUED 4 CEU'S
OR 40 CONTACT HOURS

NAME Vincent De Fedele

ADDRESS Pharmalogic
60-H Commerce Way

CITY, STATE, ZIP Totowa, NJ 07512-

4/7/2004

DATE

Greg Stone

AUTHORIZED SIGNATURE

Michael J. Agnello Rph., BCNP
Pharmalogic P.E.T.
60 H Commerce Way
Totowa, NJ 07512
973-785-2242/fax 973-785-2248
April 14, 2004

Ms. Joanne Boyer
Executive Director
Board of Pharmacy
PO Box 45013
Newark, NJ 07101

Dear Ms. Boyer,

As of this letter dated April 14, 2004, Vincent DeFedele Rph has successfully completed 800 hours of contact training in the area of nuclear pharmacy with extensive training in the radiopharmaceutical production of FDG (fluoro-deoxy-glucose) via cyclotron. As his preceptor, I have supervised his training and found him to be competent in the area of nuclear pharmacy. Thank you for your time.

Sincerely,


Michael J. Agnello Rph., BCNP

Michael J. Agnello Rph., BCNP

University of Arkansas for Medical Sciences
and
University of New Mexico Health Science Center

Nuclear Pharmacist Education

Vincent De Fedele

P. 1

5052724721

| Nuclear Pharmacy Courses & Training | Nuclear Physics | Instrumentation | Radiation Safety | Radiation Biology | Radiopharmacy | Total |
|-------------------------------------|---------------------|---------------------|---------------------|---------------------|---------------------|-------|
| | 004-039-01-201-H-01 | 004-039-01-200-H-01 | 004-039-01-203-H-01 | 004-039-01-202-H-01 | 004-039-01-204-H-01 | |
| Radiation Physics & Instrumentation | 75 | 25 | | | | 100 |
| Radiation Protection | | | 30 | | | 30 |
| Math & Measure of Radioactivity | 5 | 5 | | | 10 | 20 |
| Radiation Biology | | | | 20 | | 20 |
| Radiopharmaceutical Chemistry | | | | | 30 | 30 |
| Clinical Radiopharmacy | | | | | 50 | 50 |
| TOTALS | 80 | 30 | 30 | 20 | 40 | 250 |

Course dates: January 12 - March 23, 2004

Nicki Hilliard

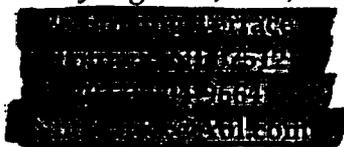
Nicki L. Hilliard, Pharm.D., BCNP
Associate Professor of Nuclear Pharmacy

Jeffery Norenberg, Pharm. D., M.S., BCNP
Assistant Professor of Nuclear Pharmacy

Mar 31 04 02:07P

(FRI) APR 16 2004 11:41/ST. 11:40/NO. 6308608100 P. 6

Michael J. Agnello, RPh, BCNP



QUALIFICATIONS

- * Board Certified Nuclear Pharmacist.
- * Appointed as Clinical Instructor for University of New Mexico College of Pharmacy
- * Licensed New Jersey pharmacist for twenty-two years with experience as retail pharmacist-in-charge and certified consultant pharmacist
- * Excellent communication and interpersonal skills having dealt with physicians, nurses, suppliers, and customers

EXPERIENCE

Eastern Isotopes, Little Ferry, NJ *March 2001-present*
Mallinckrodt Medical, Pine Brook, NJ *October 1999-March 2001*
Synchor International, Kenilworth, NJ *February 1996-October 1999*

- * Compound and dispense time-critical radiopharmaceuticals for diagnostic and therapeutic use including I-131 and FDG.
- * Supervise and train pharmacy staff in all aspects of radiation safety and radiopharmacy procedures.
- * Work closely with sales force and nuclear medicine technologists providing clinical information and support.
- * Skilled in batch preparation of custom compounded radiopharmaceuticals including sterility, pyrogen, and filter integrity testing.
- * Preceptor for new pharmacist training through NUCLEAR EDUCATION ONLINE program of University Of New Mexico College of Pharmacy

ACCOMPLISHMENTS

- * Received "Top Gun" Award after completing Synchor authorized user training program.
- * Developed and implemented Phase I and II of Customer Service training program as team project manager. Worked closely with human resources department in 'train the trainer' program.
- * Elected to Open Book Management Implementation Team as team leader. Successful in achieving goals including cost reductions in labor, delivery, and inventory that led to cash rewards.
- * Earned title of Board Certified Nuclear Pharmacist after passing Board of Pharmaceutical Specialties exam in October 1998.
- * Initiated custom compounding program of I123-MIBG radiopharmaceutical as lead pharmacist. Implemented compounding protocols, training, record keeping and radiation safety.

EDUCATION

- * Rutgers University College of Pharmacy
Bachelor of Science degree in Pharmacy, May 1980
- * Synchor International Authorized User Training Course
Authorized Nuclear Pharmacist, May 1996

ORGANIZATIONS

- * Active member of American Pharmaceutical Association since 1980
- * APPM Section on Nuclear Pharmacy Practice-Education Committee

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bps Board of Pharmaceutical Specialties

December 16, 1998

Michael J. Agnello

~~25 Sterling Dr
Towson, MD 21286-2485~~

Dear Mr. Agnello:

The Board of Pharmaceutical Specialties (BPS) is pleased to notify you that you achieved a passing score on the specialty certification examination and have been granted certification. You may now use the title Board Certified Nuclear Pharmacist and the initials BCNP. For your information, 76% of this year's candidates achieved a passing score.

Your confidential score report from Professional Examination Service (PES), the BPS testing consultant, is enclosed. You should receive your inscribed certificate within about 90 days.

You have earned a valuable credential and the Board wishes to officially share the news of your accomplishment with your supervisor(s). BPS will send a letter to whomever you name, detailing the requirements you fulfilled in earning board certification and credit your supervisor(s) for having a pharmacist of your caliber on staff. You will receive a copy of the letter, as well. If you would like this letter to be sent to your supervisor(s), please complete the enclosed form and return it to BPS.

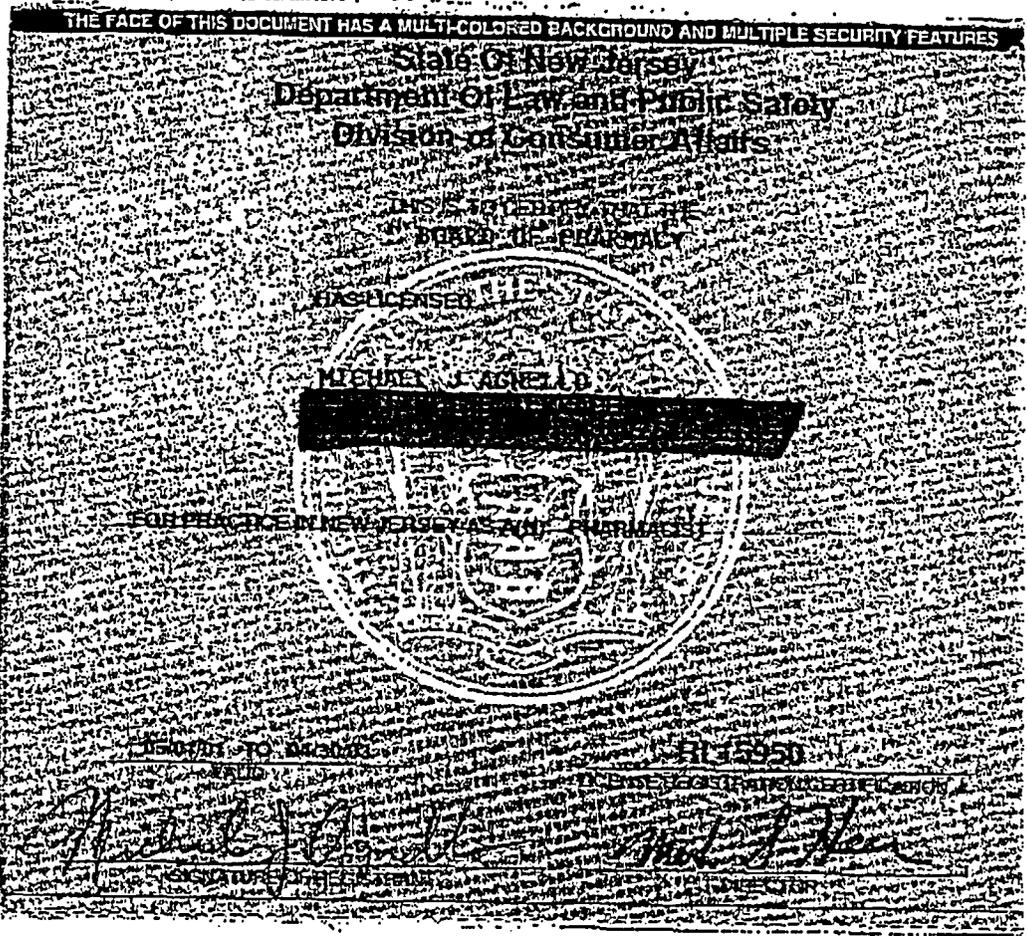
~~On behalf of the Board of Pharmaceutical Specialties, I wish you ongoing success in your professional endeavors.~~

Sincerely,



Richard J Bertin, PhD, RPh
Executive Director

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**PERSONAL INFORMATION WAS REMOVED
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Butler University

College of Pharmacy and Health Sciences



Michael Agnello

*has successfully completed the
Nuclear Pharmacy Authorized Users Program*

July 25, 1996

Wayne Bist
Program Director

Robert D. Schuman
Dean

State of New Jersey

Department of Environmental Protection
 Bureau of Environmental Radiation
 Radioactive Materials Section
 PO Box 415, Trenton, NJ 08625-0415
 Phone (609) 984-5462

New Jersey Radioactive Materials License

Pursuant to the New Jersey Radiation Code, and to reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive or use the naturally occurring and/or accelerator produced material(s) (NARM) designated below; and to such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the State Department of Environmental Protection, now or hereafter in effect, and to any conditions specified below.

| | |
|---|--|
| 1. License No. NJSL-20779/01/005 | 2. Expiration Date 10/31/2008 |
| 3. Licensee: PHARMALOGIC P.T. SERVICES OF NEW JERSEY, LLC | 4. Address: 608 Commerce Way Totowa NJ 07512 |
| Radiation Safety Officer: Gregory Hlaci | County: Passaic |
| Administrator: Gerard Strupala | Telephone: (518) 464-0871 |
| 5. Reference No.: 3000 | |

RADIOACTIVE MATERIALS DATA (A)

| 6. Material | 7. Limit (mCi) | 8. Form |
|---|----------------|-----------------------------------|
| A. Any radioactive material with atomic number 3-83 | 3500.0000 | Activation Products |
| B. CO-57 | 15.0000 | Sealed Source |
| C. F-18 | 10,000.0000 | FDG |
| D. F-18 | 10,000.0000 | Liquid |
| E. Ga-67 | 350.0000 | Citrate |
| F. In-111 | 200.0000 | Any |
| G. Rb-82 | 1000.0000 | Liquid Sodium Chloride Suspension |
| H. Sr-82 | 1000.0000 | Solid |
| I. Sr-85 | 5000.0000 | Solid |
| J. Tl-201 | 1000.0000 | Chloride |

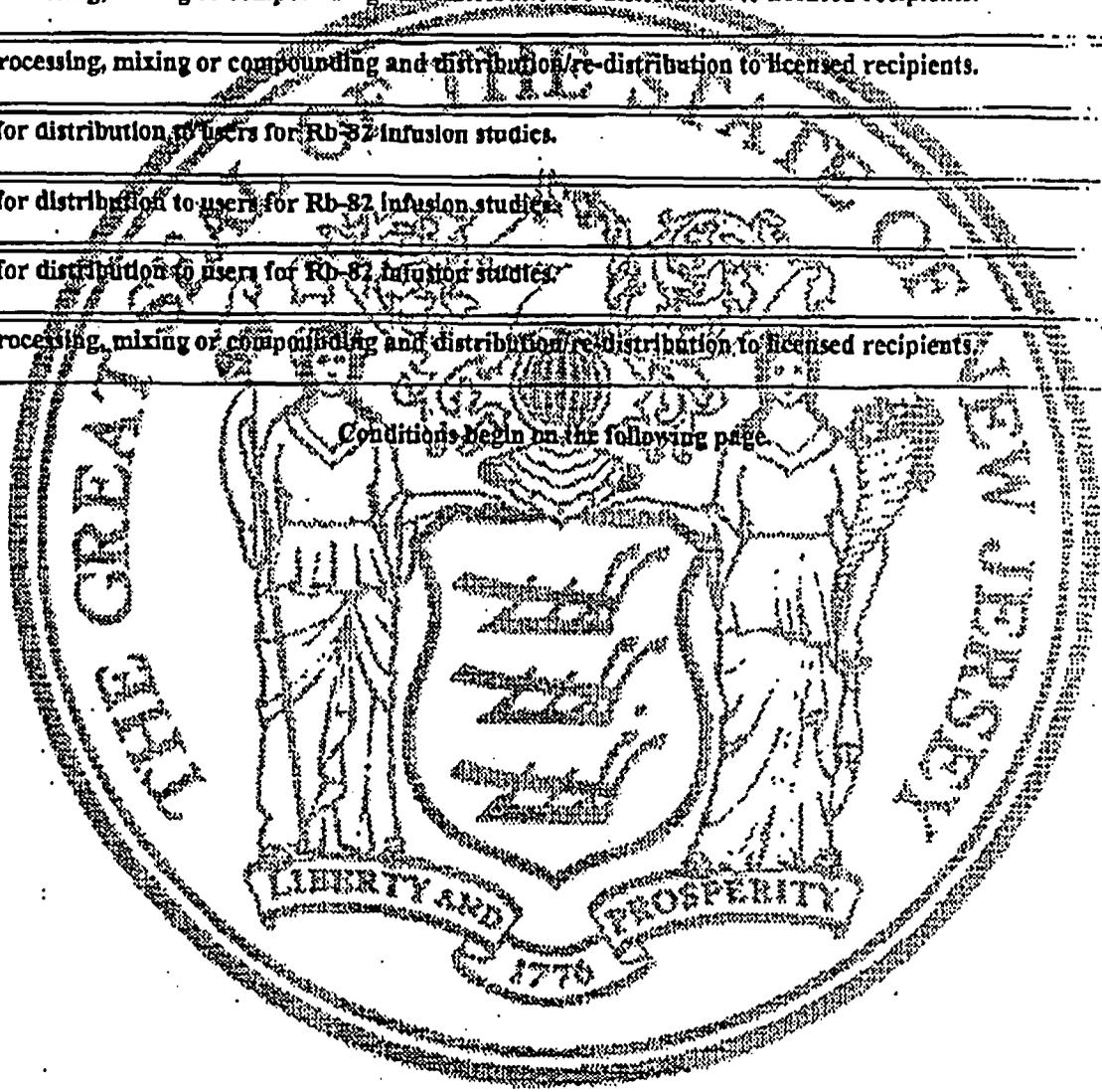
RADIOACTIVE MATERIALS DATA (B)

9. Authorized Use

- A. Contamination, induced activity, or activation products resulting from Cyclotron Operations.
- B. For in-house calibration.

New Jersey Radioactive Materials License

- C. For processing, mixing or compounding and distribution/re-distribution to licensed recipients.
- D. For in-house calibration.
- E. For processing, mixing or compounding and distribution/re-distribution to licensed recipients.
- F. For processing, mixing or compounding and distribution/re-distribution to licensed recipients.
- G. Cart for distribution to users for Rb-82 infusion studies.
- H. Cart for distribution to users for Rb-82 infusion studies.
- I. Cart for distribution to users for Rb-82 infusion studies.
- J. For processing, mixing or compounding and distribution/re-distribution to licensed recipients.



New Jersey Radioactive Materials License

10. A. Radioactive material shall be used at 60H Commerce Way, Totowa, New Jersey.
- B. Radioactive material listed in Conditions 6G-I may be used at client facilities possessing a valid New Jersey Radioactive Materials License for those specific radioactive materials.
11. A. Radioactive material listed in Conditions 6, 7 and 8 shall be used by or under the supervision of the following:
- Gerard Strugala, R.Ph., BCNP
Thomas Boland, R.Ph.
Ernesto Sampel, R.Ph.
Mark Agnello, R.Ph.
Vincent DeFedele, R.Ph.
- B. Radioactive material listed in conditions 6, 7 and 8 may be used by Richard LaPierre and Andy Rodriguez for Non-Human Use only.
12. A. Compliance with other U.S. Agencies having jurisdiction and regulations for radioactive materials must be maintained.
- B. Compliance with U.S. DOT regulations in the transportation of radioactive materials must be maintained.
13. In addition to the reporting requirements stated elsewhere in NJAC 7:28, the licensee shall notify the Department as follows:
- A. The licensee shall notify the Department of any identified defects in any product containing naturally occurring and accelerator produced radioactive materials which present a substantial safety hazard. Notification of the Department shall include an initial notification by telephone within 2 days following receipt of the information of the product defect and a written notification within 30 days following receipt of the information of the product defect. The written report is to include the following:
- Name and address of individual informing the Department,
 - Identification of the product experiencing defect,
 - Name of company which supplied the defective product,
 - Nature of the defect or failure,
 - Date on which licensee was informed of the defective product,
 - Number and location of all such products distributed,
 - Corrective actions which have been or will be taken, and
 - Any advice related to the defect that has been, is being, or will be given to purchasers of the product.
- B. The licensee shall notify the Department in writing within 30 days of any confirmed problems, defects or customer complaints involving final products authorized under this license, distributed to customers that have resulted in a reportable event to the FDA.
14. The licensee shall not open sealed sources containing radioactive materials.
15. Strontium 82 and Strontium 85 will not be used clinically. Breakthrough testing will be performed according to the manufacturer's instructions for the presence of both contaminants. If the limit of 0.02 uCi/mCi of Sr-82 or 0.2 uCi/mCi of Sr-85 is exceeded in the Rb-82 eluate, all clinical procedures will be rescheduled until further testing is performed and results fall below the measured guidelines. The Department shall be notified within 24 hours. A report shall be filed with the Department in writing within 30 days describing the circumstances and the corrective action taken.

New Jersey Radioactive Materials License

16. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months.
- A. The test shall be capable of detecting the presence of 0.005 microcuries of removable radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surface of the device in which the sealed source is permanently mounted or stored.
 - B. If the test reveals the presence of 0.005 microcuries of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with the Department regulations. Within five days after obtaining results of the test, a report shall be filed with the Department describing the circumstances, the test results and the corrective action taken.
 - C. The sealed sources shall be tested for leakage and/or contamination by appropriately trained personnel.
17. Repair, initial leak tests and disposal of sealed sources containing radioactive material shall be performed only by the manufacturer or by other persons specifically licensed by New Jersey or the Federal Government to perform this service.
18. Radioactive material with a physical half life of less than 300 days may be disposed of as non-radioactive waste provided that (a) the radioactive waste is stored behind adequate shielding to meet the requirements of New Jersey Radiation Code 28-6; (b) the radioactive waste is held for ten half-lives of the longest lived radionuclide to be disposed of, (c) the radioactive waste is monitored with a GM meter prior to disposal to insure background levels, (d) all radiation labels are removed and obliterated and (e) a log shall be maintained to include the results of the radiation survey and date of disposal.
19. The licensee shall make the following items available to their staff:
- A. Copy of the New Jersey Radiation Protection Code.
 - B. Copy of the New Jersey State Radioactive Material License.
20. The licensee shall post the following items in an area frequented by employees engaged in the use of licensed materials:
- A. Notice to Employees - RPP-14
 - B. Emergency procedures involving major, minor spills including the names and phone numbers of people to contact.
 - C. Appropriate signs and labels in areas and/or containers and equipment in which radiation and/or radioactive material are contained. These postings are to conform to Subchapter 10 of the Code.
21. The following records shall be maintained:
- A. Radioactive materials received including but not necessarily limited to: date of receipt, radionuclide, activity, mass or volume of material, results of package survey, instrument used for surveys and surveyor's initials.
 - B. Survey instrument calibration performed annually and after instrument repair.
 - C. Sealed source leak tests at intervals not to exceed six months. Results are to be reported in microcuries.
 - D. Personnel dosimetry records including but not necessarily limited to name, social security number, and prior employment exposure history.
 - E. Daily personnel monitoring results including but not necessarily limited to instrument used, date performed and initials.

New Jersey Radioactive Materials License

- F. Copies of records and reports required by the US Food and Drug Administration (FDA) as per 21 CFR 211.198 and 310.305 regarding products containing naturally occurring and accelerator produced radioactive materials.
- G. Survey and wipe test of the client's facility prior to relocation to another client location to ensure there is no residual contamination.
- H. A log shall be maintained documenting the Rb-82 generator delivery to the client's facility. The log shall indicate the date and time of arrival and location of the facility.

22. The following tests shall be performed as a minimum:

A. Surveys of:

1. All radioactive materials received.
2. All radioactive waste decayed to background levels prior to release.
3. Controlled areas, where licensed materials are used on days they are used.
4. Personnel on days the material is used.

B. Wipe tests of:

1. Controlled areas, weekly, where unsealed sources of licensed materials are used during weeks the material is used.

23. While utilizing radioactive material, personnel shall use protective equipment and clothing including but not necessarily limited to: remote handling equipment, adequate shielding, laboratory coats and disposable gloves.

24. Eating, drinking, smoking and applying cosmetics shall not be permitted in controlled areas.

25. Except as specifically provided by this license, the licensee may possess and use radioactive material described in this license only in accordance with statements, representations and procedures contained in New Jersey Radioactive Materials License Application dated November 1, 2002 signed by Gerard Strugala, R.Ph. and letters dated January 21, 2003, February 21, 2003, March 26, 2003, May 28, 2003, June 11, 2003, April 14, 2004, fax dated June 13, 2003, September 20, 2004 and November 23, 2004.

New Jersey Department of Environmental Protection Signature

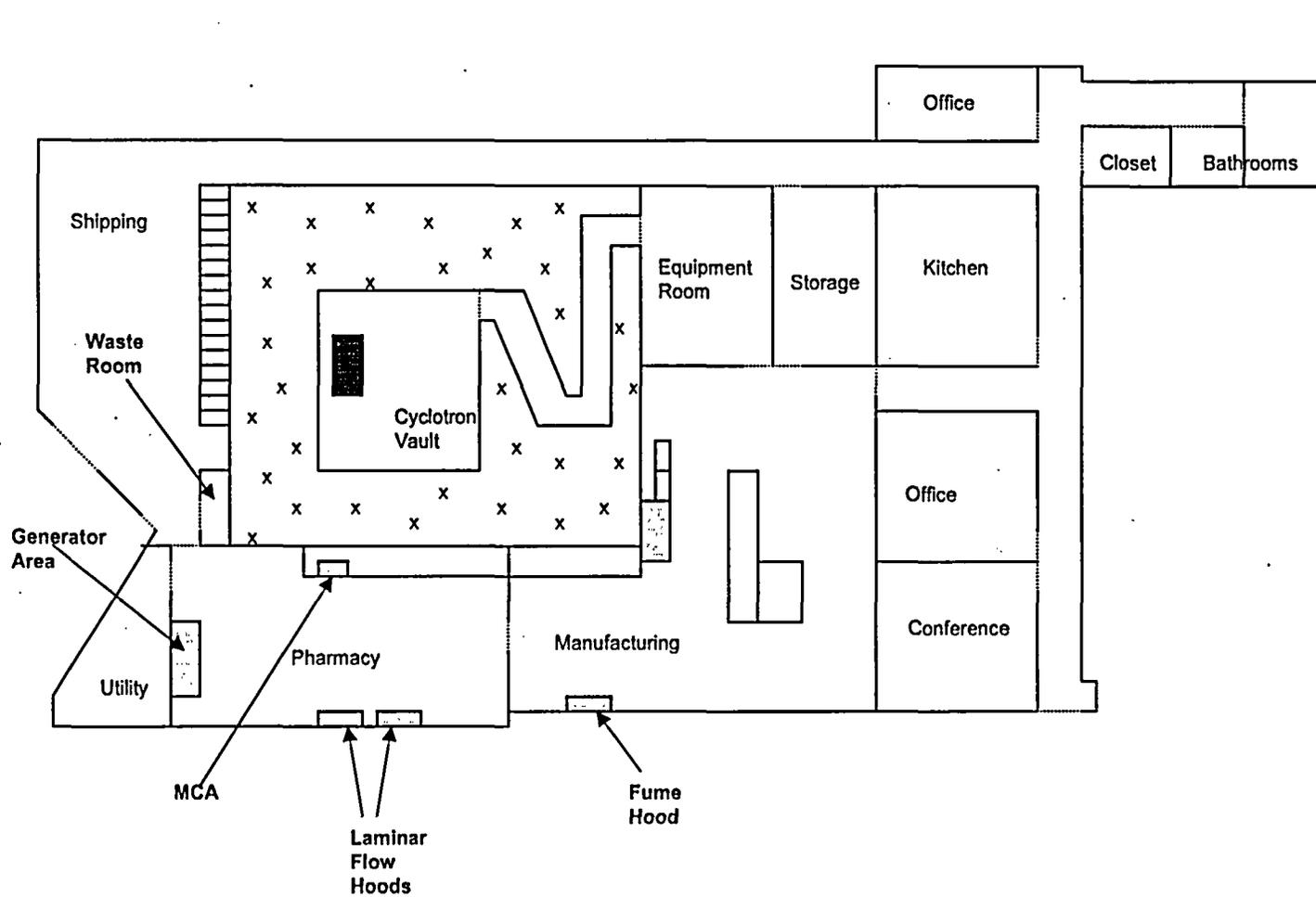
Date:

12/22/04

By:

William P. Casazza
For the NJ Department of Environmental Protection

Pharmalogic P.E.T. Services of New Jersey, LLC



60H Commerce Way, Totowa, NJ

Tc99m-GI BLEEDIND
1.00mCi06:00@01-10-05
Study #: 39694 - TEST SCRIPT



← on syringe

PHARMALOGIC/PET SERVICES 1-800-580-7129
25 WALKER WAY
ALBANY, NEW YORK 12206
HOSPITAL TEST SCRIPT

STUDY: 39694
DATE: 01-10-2005
DOCTOR:
PT: TEST SCRIPT

PROCEDURE: GI BLEEDIND
DRUG: Tc99m / In-house prep.
LOT NO: 5160/111111
EXP. TIME 06:00 CAL. TIME 01-10@06:00 DOSE REQUESTED 1.00mCi
EXP. DATE 03-26-2005 VOL. 0.20ml DISP. 1.00 mCi
SPECIAL Mo-99 content < 0.15 uCi/mCi at expira
INSTRUCTIONS NO PRODUCT CONTAINED
CAUTION: To be used as directed.
WARNING: This U.S. Nuclear Regulatory Commission has approved the radio-pharmaceutical for distribution pursuant to 10 CFR Part 35, or under equivalent licenses of Agreement States
BY JF



← on outside of lead shield (pig) "the insert"

Tc99m-GI BLEEDIND
1.00mCi06:00@01-10-05
Study #: 39694 - TEST SCRIPT



← on two sides of the shipping container "label"

NOTE: Pharmalogic Ships white-I + Yellow-II packages under this license

This is to acknowledge the receipt of your letter/application dated

1/6/2005, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 29-30786-d There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 136274.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (R1)
(6-98)

Sincerely,
Licensing Assistance Team Leader

BETWEEN: : (FOR LFMS USE)
 : INFORMATION FROM LTS
 : -----
 :
 License Fee Management Branch, ARM : Program Code: 03124
 and : Status Code: 0
 Regional Licensing Sections : Fee Category: 3P
 : Exp. Date: 20130131
 : Fee Comments: _____
 : Decom Fin Assur Reqd: N
 :

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
 Applicant/Licensee: PHARMALOGIC P.E.T. SVCS OF NJ, LLC
 Received Date: 20050112
 Docket No: 3036157
 Control No.: 136274
 License No.: 29-30786-01
 Action Type: Amendment

2. FEE ATTACHED
 Amount: _____
 Check No.: /

3. COMMENTS
 Signed W.A. Perkins
 Date 1/27/2005

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /_/_/)

1. Fee Category and Amount: _____
 2. Correct Fee Paid. Application may be processed for:
 Amendment _____
 Renewal _____
 License _____
 3. OTHER _____

Signed _____
 Date _____