Triad Isotopes®
patient focused. community driven.

31 August 2011

J-6

United States Nuclear Regulatory Commission
Division of Nuclear Materials Safety
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Triad Isotopes, Inc.-Milford RAM License #09-31406-01MD
180 Pepes Farm Road
Milford, CT 06460

03038249

Dear License Reviewer:

Per our phone conversation, the following supplemental information is attached to support the amendment request dated 8/18/11:

1. Additional training and experience materials for Nicholas Plumeri and Christopher Stanton, who are listed as approved nuclear pharmacists in New York . See Hicksville, NY RAM License in Appendix A, including License Condition 10A that indicates that pharmacists certified by New York Board of Pharmacy are authorized. See Appendix B for the training and experience used to add Mr. Plumeri and Stanton to the Certified Nuclear Pharmacists list that was previously provided.

2. Please, update the Orlando corporate office address to Triad Isotopes, Inc., 4205 Vineland Road, Suite L-1, Orlando, FL 32811.

Please, let me know if you need additional information. We appreciate an expedited review of this request. Please contact Brigette Nelson, Senior Director, Quality and Safety, if you have any questions at 904-220-7210. A completed copy of the amendment request can be sent to the Triad Corporate offices at 4205 Vineland Rd., Ste. L1, Orlando, FL 32811 and/or to the Milford pharmacy address to the RSO's attention.

Thanks,

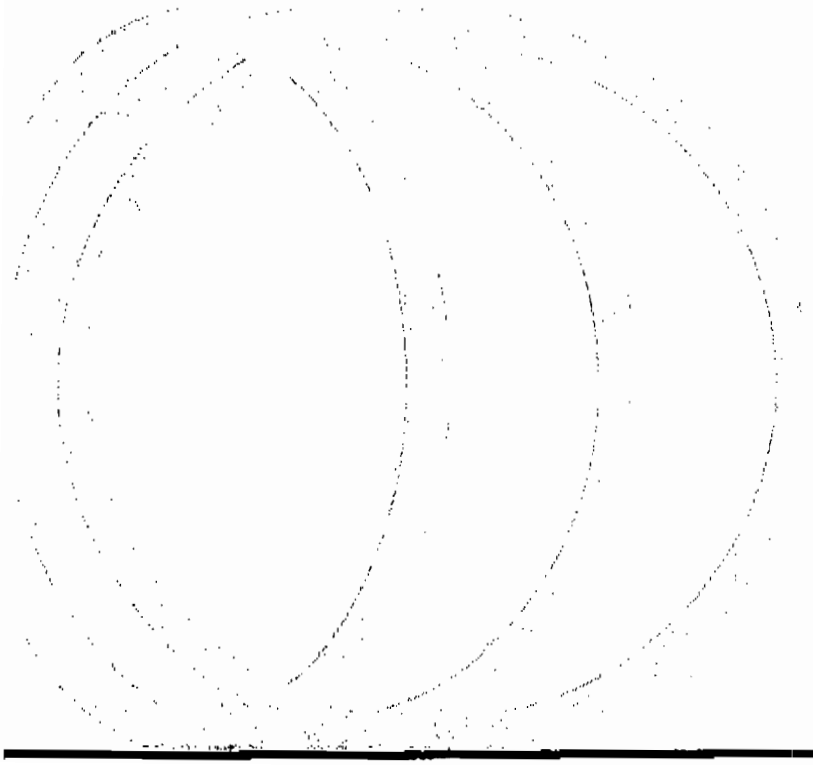
Brigette Nelson, MS, PharmD, BCNP
Sr. Director, Quality & Safety
1554 Nottingham Knoll Drive
Jacksonville, FL 32225
(904)-220-7210 (office)
(904)-220-6980 (fax)
[redacted]cell)
bnelson@triadisotopes.com

cc: Shannon Julian, file, Nell Stubbs

575823
NMSS/RGN1 MATERIALS-002

Triad Isotopes®
patient focused. community driven.

Attachment A
Hicksville, NY RAM license



4205 Vineland • Suite L1 • Orlando, FL 32811
www.triadisotopes.com

STATE OF NEW YORK
DEPARTMENT OF HEALTH
Flanigan Square 547 River Street Troy, New York 12180-2216

Richard F. Daines, M.D.
Commissioner

James W. Clyne, Jr.
Executive Deputy Commissioner

Triad Isotopes, Inc.
108 Charlotte Avenue
Hicksville, New York 11801-2620

OCT 28 2010

Attention: Nicholas Plumeri
Radiation Safety Officer

RE: NYS Dept. of Health Radioactive Materials License No. C5413
DH Nos. 10-21, 10-416 & 10-474

Dear Licensee:

Enclosed is New York State Department of Health Radioactive Materials License No. C5413, which authorizes the use of the materials listed in the license subject to the conditions therein and to the applicable regulations of Part 16 of the New York State Sanitary Code and Industrial Code Rule 38. You should become familiar with the conditions of your license and the provisions of Part 16 and Industrial Code Rule 38 as they relate to your facility.

Please note that in your license application you agreed to adhere to certain criteria and procedures established in Radiation Guide 1.8. Therefore, you should make copies of those procedures for reference and keep them on file with the license, as they are part of the licensing document. You are also bound by statements and representations in documents listed in Condition No. 11 of the license. These are also a part of the licensing document and must be maintained with it. If you have employed the services of a consultant for assistance in the preparation of any portion of the application or subsequent supporting information, ensure that you have a copy of all correspondence and submissions.

One of our Radiological Health Specialists will periodically inspect your installation and respond to any radiation incidents. Any questions concerning the license or your radiation program should be directed to this office at 518/402-7590 or:

New York State Department of Health
Bureau of Environmental Radiation Protection
Radioactive Materials Section
547 River Street, Flanigan Square - Room 530
Troy, New York 12180-2216

Sincerely,

Charles J. Burns, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

CJB/WTV:ks

Enclosures: RML No. C5413
Notice to Employees
Security Awareness Notice

NEW YORK STATE DEPARTMENT OF HEALTH

RADIOACTIVE MATERIALS LICENSE

Pursuant to the Public Health Law, Part 16 of the New York State Sanitary Code, Industrial Code Rule 38, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing radioactive material(s) for the purpose(s), and at the place(s) designated below. The license is subject to all applicable rules, regulations, and orders now or hereafter in effect of all appropriate regulatory agencies and to any conditions specified below.

1. NAME OF LICENSEE	3. LICENSE NUMBER
FEIN 43-1479062 Triad Isotopes, Inc. Phone (516) 933-7888	C5413 4. EXPIRATION DATE June 30, 2013
2. ADDRESS OF LICENSEE	5a. REFERENCE / b. AMENDMENT NO.
108 Charlotte Avenue Hicksville, New York 11801-2620	DH 10-21 DH 10-416 DH 10-474 --

6. Radioactive Materials (elements in mass number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
A. Any radiopharmaceutical, except alpha emitters or as otherwise specified below	A. Any	A. 5 curies
B. Molybdenum 99	B. Generators	B. 100 curies
C. Technetium 99m	C. Any	C. 100 curies
D. Iodine 123	D. Any	D. 10 curies
E. Iodine 131	E. Any	E. 2.5 curies
F. Xenon 133	F. Gas in unit dose containers	F. 1.5 curies

NEW YORK STATE DEPARTMENT OF HEALTH

RADIOACTIVE MATERIALS LICENSE

3. License Number C5413 **5a. Reference DH's 10-21, 10-416 & 10-474**

6 Radioactive Materials (elements in mass number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
G. Palladium 103	G. Sealed sources	G. 500 millicuries
H. Any radionuclide	H. Calibration and reference standards	H. 40 millicuries
I. Depleted Uranium	I. Metal	I. 400 kilograms
J. Carbon 14	J. Prepackaged Kits	J. 10 millicuries

9. Authorized use for materials listed in Condition Nos. 6, 7 and 8:

A. through F. Preparation and distribution of radioactive drugs, including compounding of radioiodine and redistribution of unused molybdenum 99/technetium 99m generators to authorized recipients in accordance with 12 NYCRR 38.35 (j). If any beta-emitting radionuclide dosages (where beta radiation is the radiation of interest) are to be prepared, a dose calibrator appropriate to measuring such dosages shall be used, along with calibration procedures that ensure traceability of all dosages to an accepted standard for each nuclide.

G. Redistribution of brachytherapy sources initially distributed by a manufacturer licensed by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The licensee is authorized to distribute sealed sources to persons possessing a License issued pursuant to 10 CFR 35.400 or equivalent regulations of an Agreement State; except that non-byproduct materials may be distributed to persons possessing a License issued pursuant to equivalent regulations of a Non-Agreement State.

H. Receive, use or distribute calibration and reference standards authorized for initial distribution in a license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to persons authorized pursuant to 10 NYCRR 16.123 (e) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement State, or as otherwise authorized in a license issued by the U.S. Nuclear Regulatory Commission or an Agreement State; except that non-byproduct materials may be distributed to persons possessing a License issued pursuant to equivalent regulations of a Non-Agreement State.

NEW YORK STATE DEPARTMENT OF HEALTH

RADIOACTIVE MATERIALS LICENSE

3. License Number C5413 **5a. Reference DH's 10-21, 10-416 & 10-474**

9. (Continued)

I. As shielding for Mo-99/Tc-99m generators used or distributed under this license.

J. Transfer individually prepackaged kits for in vitro clinical or laboratory testing to persons specifically licensed pursuant to 10 NYCRR 16.123 (d), or the equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. All kits intended for distribution shall be authorized in a license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State for such distribution.

10. A. Licensed materials shall be used by, or under the supervision of, persons certified as Nuclear Pharmacists by the New York State Board of Pharmacy.

B. All Pharmacy activities using radioactive materials authorized under the License shall be conducted in accordance with the policies and regulations of the New York State Board of Pharmacy.

C. The activities of Pharmacy Technicians performed under the license shall be restricted to those outlined in Appendix IV.

D. The licensee shall use differing activity concentrations in preparing different radiopharmaceuticals, and shall ensure that any discrepancy between the calculated volume of a dosage and the volume found to be required to achieve the prescribed activity is resolved before the dosage is dispensed. Records of actions taken to resolve any such discrepancy must be made and maintained for three years.

E. The Radiation Safety Officer for this license is Nicholas Plumeri.

F. The RSO will be provided with regular on-site health physics support by Edward J. O'Connell. This person will be physically available and able to respond to accidents and incidents in a timely manner, and shall visit this facility for at least one working day per month to provide the routine support described in Appendix A of Radiation Guide 1.8 (Rev. 4/95). This person will also conduct or participate in the required annual audits of the licensee's radiation protection program and the performance of the RSO.

11. Except as specifically provided otherwise in the License, the licensee shall conduct its program in accordance with the statements, representations and procedures contained in the documents, including any enclosures, listed below. The Department's Regulations and the conditions of this license shall govern, unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the Regulations and license conditions.

NEW YORK STATE DEPARTMENT OF HEALTH

RADIOACTIVE MATERIALS LICENSE

3. License Number C5413 **5a. Reference DH's 10-21, 10-416 & 10-474**

11. A. Renewal Application dated February 9, 1996, signed by Les Sabo and Joseph Fery.

B. Letter dated February 12, 1996, signed by Les Sabo.

C. Letters dated February 14, 1996, August 29, 1996, and September 13, 1996, signed by Joseph Fery.

D. Letter dated February 24, 1997, signed by Joseph Fery.

E. Letter dated December 21, 1999, signed by Vito Deliso, R.Ph.

F. Letter dated August 1, 2003, signed by Franklyn J. Robinson, R.Ph.

G. Letter dated September 11, 2003, signed by Dale J. Simpson, with attachments.

H. Letter dated December 4, 2003, signed by Vito Deliso, R.Ph., with attachments.

I. Letter dated October 15, 2004, signed by Nicholas Plumeri, R.Ph., with attachments.

J. Letter dated March 10, 2005, signed by Kay Yoder, with attachments.

K. Letter dated March 21, 2005, signed by Nicholas Plumeri, R.Ph.

L. Letter dated October 4, 2007, signed by Vito Deliso, R.Ph., with attachments.

M. Letter dated January 7, 2010, signed by Patricia H. Duft and William P. McCormick, with attachments.

N. Letter dated April 23, 2010, signed by Kay Yoder, with attachments.

O. Letter dated May 12, 2009, signed by Kay M. Yoder, with attachments.

12. Licensed material shall only be used or distributed at the location specified in Condition 2 of this License.

13. Unit dose containers and sealed sources containing licensed material shall not be opened by the licensee.

NEW YORK STATE DEPARTMENT OF HEALTH

RADIOACTIVE MATERIALS LICENSE

3. License Number C5413 **5a. Reference DH's 10-21, 10-416 & 10-474**

14. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources used under the License. The records of the inventories shall be maintained for three (3) years from the date of the inventory for inspection by the Department, and shall include the quantities and kinds of licensed material, manufacturer's name and model Number, location of sealed sources, the date of the inventory, and the identity of the person performing the inventory.

15. The licensee shall elute generators and process radioactive materials with reagent kits in accordance with the manufacturer's instructions for radiation safety.

16. A. PERSONNEL TRAINING PROGRAM

1. Authorized Nuclear Pharmacists

a. All persons who will perform the duties of Nuclear Pharmacists at this facility will be certified as such by the New York State Board of Pharmacy, and will act in accordance with all Board requirements, rules and regulations.

b. Nuclear Pharmacists will also be trained in the policies, procedures and license requirements of this facility, and the provisions of Code Rule 38, before assuming duties under this license.

c. Nuclear Pharmacists will also receive annual refresher training appropriate to their duties. This will include any changes/improvements in dosage preparation, and any other changes in facility policies and procedures or in the license, which have occurred during the year.

2. Other Professional Personnel

a. All professional personnel other than Nuclear Pharmacists (such as nuclear medicine technologists or health physics staff) will have received formal training in nuclear medicine technology and/or health physics, and be experienced in the use and handling of the types and quantities of radioactive materials to be used under the license. The duties of all professional personnel are specified in job descriptions.

b. Such staff will also be trained in the policies, procedures and license requirements of this facility, and the provisions of Code Rule 38, before assuming duties under the license.

NEW YORK STATE DEPARTMENT OF HEALTH

RADIOACTIVE MATERIALS LICENSE

3. License Number C5413 **5a. Reference DH's 10-21, 10-416 & 10-474**

16. c. Such staff will also receive annual refresher training appropriate to their duties. This will include any changes in facility policies and procedures, or in the license, which have occurred during this year.

3. Other Personnel Performing Work Under the License

a. Minimum hiring qualifications and job descriptions specifying tasks to be performed shall be developed for all other personnel who will perform work under the license, along with a detailed training program for each job description and the tests to be given as a part of the program. This training shall be given in a classroom setting in the presence of a qualified instructor, to all personnel who will handle radioactive materials or perform tasks essential to compliance with regulations, and will include at least forty hours of classroom instruction. The training will be given before personnel assume duties under the license, and after successful completion of a test or tests demonstrating understanding of the instruction given.

b. All ancillary staff shall also be trained in the policies, procedures and license requirements of this facility, and the provisions of Code Rule 38, before beginning work under the license.

c. All such staff shall also receive annual refresher training appropriate to their duties.

A. 4. All Personnel

a. All personnel who handle radioactive materials shall participate in annual retraining in emergency procedures, which will include "dry runs."

b. All personnel who are involved in incidents or accidents (such as dosage errors, personal contamination, delivery or pickup errors, exposures exceeding ALARA levels, etc.) shall receive individual retraining designed to prevent a recurrence.

c. Records of all training, identifying the individuals who conducted the training, the personnel trained, dates of training, and the content covered, will be maintained.

NEW YORK STATE DEPARTMENT OF HEALTH

RADIOACTIVE MATERIALS LICENSE

3. License Number C5413 **5a. Reference DH's 10-21, 10-416 & 10-474**

16. B. INSTRUCTIONS TO VISITORS, AND SUPERVISION

Anyone other than licensee personnel who will be permitted to enter posted areas, or work on potentially contaminated items or equipment, shall first receive appropriate instruction, and shall be supervised during their presence in posted areas.

Potentially contaminated equipment and objects shall be surveyed for fixed and removable contamination, and decontaminated if necessary, before anyone is allowed to repair or otherwise work on or handle such equipment or objects.

17. The licensee shall notify the Department immediately of any revocation, modification or suspension of the Registration issued by the New York State Board of Pharmacy.

18. A. An alarming intrusion and fire detection security system shall be installed, and shall be maintained in good operating condition at all times by the licensee.

B. The licensee shall submit to the Department a detailed description of any proposed changes to the facilities and equipment described in the license application and supporting documents, before making any such changes. This shall include, but not be limited to, changes in floor plans, ventilation system and usage areas contiguous to areas where radioactive materials are used and stored.

19. A. The licensee shall submit complete decontamination procedures to the Department for approval ninety (90) days prior to the termination of operations involving radioactive materials and/or vacating Installation pursuant to 12 NYCRR 38, Section 38.23.

B. A site will not be considered acceptable for unrestricted use unless the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, and the residual radioactivity has been reduced to levels that are ALARA.

20. The licensee shall submit full information on any proposed changes of ownership or control of licensed premises, at least 90 days prior to the proposed action.

21. A. Individuals who elute, prepare, assay or dispense millicurie quantities of radioactive material shall wear whole body badges, which are exchanged monthly, and at least one extremity monitor, which is exchanged weekly.

B. Persons whose work requires entry to restricted areas shall be issued whole body badges.

NEW YORK STATE DEPARTMENT OF HEALTH

RADIOACTIVE MATERIALS LICENSE

3. License Number C5413 **5a. Reference DH's 10-21, 10-416 & 10-474**

21. C. A bioassay program will be conducted for any staff who handle millicurie quantities of iodine 131. Thyroid uptakes will be measured on a weekly basis, or 24 to 48 hours after handling occurs if it is infrequent, using an uptake system that provides a reproducible geometry and an adequate lower limit of detection.

D. Any weekly extremity dose exceeding 500 millirem will be investigated by the RSO, and his/her assessment of whether actions are warranted to reduce doses will be documented.

E. Any weekly extremity dose exceeding 750 millirem will be investigated immediately by the RSO, and action will be taken to reduce doses and will be documented.

22. A. The licensee shall maintain records of information important to safe and effective decommissioning at the location specified in Condition 2 and at other locations as the licensee chooses. The records shall be maintained until this license is terminated by the Department and shall include:

i. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site;

ii. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination, such as buried pipes which may be subject to contamination.

iii. Records of the cost estimate performed for the decommissioning funding plan or the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

B. Upon transfer of this license, all such records shall be transferred to the new licensee.

23. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 days for decay-in-storage before disposal in ordinary trash, provided that:

A. Affected radioactive waste is held for decay a minimum of ten (10) half-lives.

B. Prior to disposal as normal waste, radioactive waste is surveyed with an appropriate instrument to determine that its radioactivity cannot be distinguished from background. All radiation labels will be removed or obliterated, and a record shall be made of each disposal and survey.

NEW YORK STATE DEPARTMENT OF HEALTH

RADIOACTIVE MATERIALS LICENSE

3. License Number C5413 **5a. Reference DH's 10-21, 10-416 & 10-474**

23. C. Generator columns are segregated so that they may be monitored separately to ensure decay to background levels prior to disposal, and procedures for storage and breakdown of generators are in accordance with Appendix I of this license.

24. The licensee shall provide a calibrated (annually) microrem meter or equivalent, and ensure its use for surveys of non-radioactive waste before disposal, and for surveys of the hands and clothing of workers after leaving a restricted area.

25. A. Emergency response procedures will be carried in vehicles, and otherwise provided to responders to on-site emergencies, and will include the information in Appendix II of this license.

B. The emergency procedures for radioactive spills and contamination, which are contained in Appendix III of this license, shall be posted in accordance with 12 NYCRR 38.27(b), and shall be included in the instruction given to personnel pursuant to Condition 15 of this license.

26. A nuclear pharmacy that dispenses both radioactive and non-radioactive drugs shall maintain separate areas for the storage and dispensing of each type of drug. The area for storage and dispensing of radioactive drugs shall be a controlled area, and access to the area shall be limited to authorized personnel.

27. Each person handling radioactive material under this license shall meet education and training requirements approved by the Department as appropriate to the specific duties assigned.

28. The licensee shall report to the Department, immediately by telephone, upon learning of any error in its preparation or distribution of radiopharmaceuticals.

29. The licensee is authorized to receive back radioactive materials, which were distributed under this license, and any associated containers.

30. Any proposed changes in packaging or shielding of radioactive materials distributed or received back under this license must be submitted to the Department for approval prior to implementation.

31. A. The licensee shall perform a test to detect and quantify the activity of Molybdenum-99 contamination in each elution of Technetium-99m from a Molybdenum-99/Technetium-99m generator.

NEW YORK STATE DEPARTMENT OF HEALTH

RADIOACTIVE MATERIALS LICENSE

3. License Number C5413 **5a. Reference DH's 10-21, 10-416 & 10-474**

31. B. The licensee shall not distribute Technetium-99m for human use if it contains more than one hundred fifty (150) nanocuries of Molybdenum-99 per one (1) millicurie of Technetium-99m. The expiration date and time shown on package labels shall be such that these limits will not be exceeded for any dosage.

C. The licensee shall establish written procedures for personnel performing tests to detect and quantify Molybdenum-99 contamination. These procedures shall include all necessary calculations, and the steps to be taken if activities of Molybdenum-99 in excess of the limits specified in Paragraph B. above are detected.

D. Personnel performing tests to detect and quantify Molybdenum-99 contamination shall be given specific training in performing these tests prior to conducting such tests.

E. 1. The licensee shall maintain for inspection by the Department records of the results of each test performed to detect and quantify Molybdenum-99 contamination and records of training given to personnel performing these tests.

2. Records described in Paragraph E.1. above shall be maintained for three (3) years following the performance of the tests and the training of personnel.

FOR THE NEW YORK STATE DEPARTMENT OF HEALTH

Date: OCT 28 2010

By _____

Charles J. Burns, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

CJB/WTV:ks

APPENDIX I

GENERATOR BREAKDOWN PROCEDURES

A. All generators will be stored for at least sixty (60) days from their expiration dates before dismantling.

B. A nuclear pharmacist or the licensee's Health Physics consultant will select the generators to be broken down after this minimum decay period, and will personally perform the disassembly and surveys. Only generators that exhibit survey readings indistinguishable from background (measured in a low background area) shall be disassembled.

C. The nuclear pharmacist or the licensee's Health Physics consultant will wear gloves, lab coat and personnel monitoring badges while handling the generators.

D. Generator components will be surveyed with a microrem meter or a sodium iodide probe, and shall not be disposed of as normal trash if any readings above background are detected. Generator columns that exhibit readings above background shall be stored for the additional time necessary to decay to background levels, or shall be disposed of as radioactive waste.

E. Lead shielding and other generator components shall be determined to be free of radioactive contamination and disposed of promptly after obliteration or removal of all radiation labels.

APPENDIX II

GENERAL EMERGENCY RESPONSE PROCEDURES

FIRE

- The presence of radioactive material will not change the effectiveness of normal fire control techniques.
- Move containers from fire area if you can do it without risk.
- Do not move damaged packages; move undamaged packages out of fire zone.

Small Fires

- Use dry chemical, CO_2, water spray or regular foam.

Large Fires

- Use water spray, fog (flooding amounts).
- Dike fire-control water for later disposal.

SPILL OR LEAK

- Do not touch damaged packages or spilled material.

Liquid Spills

- Cover with sand, earth or other noncombustible absorbent material.
- Dike to collect large spills.
- Cover a powder spill with a plastic sheet or tarp to minimize spreading.

FIRST AID

- Medical problems take priority over radiological concerns.
- Use first aid treatment according to the nature of the injury.
- Do not delay the care and transport of a seriously injured person.
- Apply artificial respiration if a victim is not breathing.
- Administer oxygen if breathing is difficult.
- In case of contact with substance, wipe from skin immediately; flush skin or eyes with running water for at least 20 minutes.
- Injured persons who contacted released material may be a minor contamination problem to contacted persons, equipment and facilities.
- Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

TO OBTAIN HELP, CALL:

- _____
- _____

APPENDIX III

EMERGENCY PROCEDURES FOR RADIOACTIVE SPILLS AND CONTAMINATION

Accidental spillage of radioactive material may occur in various areas of nuclear pharmacies, and if they are undetected, contamination may be spread to workers, objects, and into public areas. To prevent this, employees must follow proper procedures for surveys and for responding to spills when they are detected.

The following is a general outline of the procedure to be followed in the event of a spill or the detection of contamination:

1. Confine a spill immediately, by dropping paper towels or other absorbent material onto it.
2. Put on impermeable gloves if you are not wearing them already.
3. Check shoes for visible signs of contamination. If it appears possible that they are contaminated, remove shoes when leaving the contaminated area.
4. Mark off or isolate in some way the entire suspect area and guard it to be sure that no one walks through it, and evacuate everyone from the area.
5. Detain all evacuees from the area in a place where they can be surveyed by the Radiation Safety Officer (RSO).
6. CALL THE RADIATION SAFETY OFFICER (RSO) or the Nuclear Pharmacist on duty, and report the spill or contamination. If you are contaminated, send someone else to get the RSO or Nuclear Pharmacist.
7. Cleaning up a spill or removing contamination must be done under the direct supervision of the RSO or Nuclear Pharmacist, and you must follow their instructions. Do not attempt to clean it up by yourself.
8. If any of the spilled material has splashed onto a person or clothing, immediate steps should be taken to remove it. Laboratory coats or outer garments should be removed and left in the contaminated area. Hands or other skin areas should be washed thoroughly with soap and water in the nearest wash basin. Care should be taken not to abrade or inflame the skin surfaces. If it is uncertain as to whether or not shoes are contaminated, the walkway to a washing facility shall be treated as a contaminated area until the RSO has certified that it is uncontaminated.
9. The RSO or Nuclear Pharmacist will bring decontamination materials and an appropriate survey meter* and the cleanup operation will proceed.
10. Careful monitoring of both the contaminated area and personnel must be performed by the RSO or Nuclear Pharmacist during this procedure.
11. The RSO or Nuclear Pharmacist must record final surveys of the contaminated area and personnel after decontamination is complete, and record the results.
12. For surfaces, reduction of the count rate to 2-3X background is usually satisfactory. Areas that show higher radiation levels even after vigorous attempts to decontaminate may be covered with plastic-backed absorbent paper, taped in place and shielded if necessary until sufficient decay occurs. If this is done, the area must be clearly posted with radiation warning labels. For personnel, surveys of the skin should be at or close to background before a person is allowed to leave.
13. When the operation is finished, gloves and other protective garments should be checked carefully for residual contamination. If any are found, the garments should be left with the other contaminated material in plastic bags for ultimate disposal by the RSO.
14. Life saving efforts and vital first aid have priority over contamination concerns.

* Condition 24 of this license specifies the type of survey meter to be used for surveying the skin and clothing of personnel.

APPENDIX IV

ACTIVITIES THAT APPROPRIATELY TRAINED PHARMACY TECHNICIANS MAY PERFORM IN A NYS DOH LICENSED NUCLEAR PHARMACY

1. Receiving orders[1]

   - Receive written prescription orders.
   - Receive electronically transmitted orders subject to review and initialing by the pharmacist or pharmacy intern in accordance with 8 NYCRR 29.7(a)(21)(i)(a).
   - Receive orders for non-prescription items (e.g., supplies, equipment, sealed sources, etc...).

2. Documentation

   - Generate a computer record of a prescription, subject to 8 NYCRR 29.7(a)(21)(i)(c).
   - Prepare a manual record of dispensing for the signature or initials of the pharmacist.
   - Prepare prescription labels.

3. Physical Inventory[1]

   - Perform physical inventory.
   - Establish reorder level for inventory.
   - Determine what inventory should be reordered.
   - Select manufacture and quantity of reorder.
   - Place order with manufacturer.

4. Receiving shipments[1]

   - Check in shipments.
   - Complete documentation of receipt.
   - Select appropriate storage conditions for items received.
   - Store inventory according to established procedures.

5. Quality control testing of compounded products

   - Perform quality control tests according to established procedures, subject to the pharmacist's decision whether to accept or reject.
   - Document results of quality control tests and enter results into computer file.

6. Unit Dose preparation of compounded and non-compounded (bulk) radiopharmaceuticals (batch preparation)[2,4]

   - Obtain compounded or bulk (e.g., Thallium, Gallium) radiopharmaceutical from storage.
   - Select unit dose container according to established procedures.
   - Prepare label and attach to unit dose container.
   - Draw pre-calculated unit dose radiopharmaceutical into syringe and assay.
   - Check the finished prescription for subsequent approval by the pharmacist.
   - Prepare batch record in accordance with 8 NYCRR 29.7(a)(15).

(APPENDIX IV, continued)

7. Repacking of radiopharmaceuticals into bulk vials according to customer's orders[3]

- Obtain compounded or bulk (e.g., Thallium, Gallium) radiopharmaceutical from storage.
- Select container according to established procedures.
- Prepare label and attach to container.
- Draw radiopharmaceutical into bulk vial and assay.
- Prepare batch record in accordance with 8 NYCRR 29.7(a)(15).

8. Monitoring/maintenance of equipment and environment/environmental controls[1]

- Clean laminar hoods.
- Document storage conditions (e.g., refrigerator temperature).
- Conduct decontamination of contaminated areas.
- Maintain and monitor fume hoods and glove boxes.
- Perform and document equipment tests (e.g., constancy, linearity, survey meters).
- Conduct leak testing of sealed sources.
- Conduct air monitoring for the release of radioactivity.
- Perform radioactive waste processing.
- Perform area surveys and wipe testing.

9. Preparation of radiopharmaceuticals and other radioactive material for shipment[1]

- Wipe test shielded containers and ancillary shielding for contamination.
- Package in shipping container.
- Survey shipping container.
- Wipe test shipping container.
- Prepare shipping labels and documentation.

10. Preparation of non-radioactive materials (e.g., non-radioactive non-drug ancillary supplies, cold kits, non-radioactive drugs) for shipment[1]

- Package materials in shipping container.
- Prepare shipping labels and documentation.

11. Preparation of white blood cell procedure[5]

- Set up and ship blood collection kits to hospitals.
- Disinfect biological hoods.
- Set up and label materials to be utilized by the pharmacist during the blood labeling procedure.

This activity is exempt from the pharmacist-to-unlicensed personnel ratio set forth in 8 NYCRR 29. (a)(21)(ii)(a).

1. The term "compounded radiopharmaceutical" includes radiopharmaceuticals that have been prepared (compounded) from various components (including a kit) by a pharmacist and are available in final formulation to be placed in containers for patient administration, either in unit dose syringes or in bulk vials from which patient doses may be drawn. The activities in item 6 must be performed under the immediate and personal supervision of a pharmacist.
2. The activities in Item 7 must be performed under the immediate and personal supervision of a pharmacist.
3. Pharmacy Technicians shall not elute generators or prepare kits.
4. Pharmacy Technicians shall not perform white blood cell labeling.

Triad Isotopes®
patient focused. community driven.

Attachment B
ANP Training and Experience for Plumeri and Stanton
New York Board of Pharmacy Certified Nuclear Pharmacists

PURDUE UNIVERSITY

WEST LAFAYETTE, INDIANA

SCHOOL OF PHARMACY AND PHARMACAL SCIENCES
Department of Medicinal Chemistry and Molecular Pharmacology
Division of Nuclear Pharmacy

This certificate is awarded to

Nicholas J. Plumeri

as evidence of completion of the

NUCLEAR PHARMACY CERTIFICATE PROGRAM

November 1998

Charles O. Rutledge
Dean, School of Pharmacy and Pharmacal Sciences

C. Anne Smith
Nuclear Pharmacy Program Director

DOCUMENTING EXPERIENCE HANDLING RADIOISOTOPES

(Actual use of radioisotopes under the supervision of an Authorized User)

NAME Nicholas Plumeri, R.Ph.

ISOTOPE	MAXIMUM AMOUNT USED AT ONE TIME	LOCATION WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE (Actual clock hours)	TYPE OF USE (see key below)
Mo-99	6000mCi	Mallinckrodt Medical Inc. Hicksville, New York	500 hours	1 - 6
Tc-99m	9000mCi			1 - 6
Ga-67	20mCi			1 - 5
I-123	200uCi			1 - 5
I-131	200mCi			1 - 5
Cr-57	250uCi			1 - 5
Co-57	1uCi			1 - 5
Xe-133	20mCi			1 - 5
In-111	1mCi			1 - 5
Sr-89	5mCi			1 - 5

Key for Type use

The number or numbers entered under "Type of Use" correspond to experience in following activities:

1. Ordering, receiving, and unpacking radioactive materials safely, including performing related radiation survey.
2. Calibrating dose calibrators, scintillation detectors, and survey meters.
3. Calculating, preparing, and calibrating patient doses, including properly using radiation shields.
4. Following appropriate internal control procedures to prevent mislabeling errors.
5. Learning emergency procedures to handle and contain spilled materials safely, including related procedures for decontamination, surveys and wipe tests.
6. Eluting technetium-99m generator systems, assaying the eluate for Tc-99m and for Mo-99, and processing the eluate with reagent kits to prepare Tc-99m labeled radiopharmaceuticals.

Nick Plumeri

Nick Plumeri

MALLINCKRODT

Mallinckrodt Inc.
108 Charlotte Avenue
Hicksville, NY 11801

Telephone (516) 933-7888
Facsimile (516) 933-1015

Lawrence Mokhibar, Executive Secretary
NYS Board of Pharmacy
Cultural Education Center
Albany, New York 12230

December 1, 1998

RE: Nicholas Plumeri, RPh.

Dear Mr. Mokhibar:

Please accept this letter as a documentation of Mr. Plumeri's experience practicing as a Nuclear Pharmacist. He has performed all the skills of a Nuclear Pharmacist in a commercial nuclear pharmacy setting successfully for more than 500 hours under my supervision at the Mallinckrodt facility in Hicksville, NY.

Sincerely,

Vito M. Deliso, RPh. RSO.

PURDUE UNIVERSITY

SCHOOL OF PHARMACY AND
PHARMACAL SCIENCES

TO: Nicholas J. Plumeri

FROM: Anne Smith, Nuclear Pharmacy Program Director

DATE: November 6, 1998

SUBJECT: Nuclear Pharmacy Certificate Program Completion

Enclosed you will find the following:

- Your Certificate for completing the Nuclear Pharmacy Certificate Program, signed by Dean Rutledge and me, suitable for framing;
- TWO originals of the completion letter signed by Dr. Stanley M. Shaw stating that you have completed the course successfully; and
- The Nuclear Pharmacy Certificate Program Outline with the hourly breakdown of your training in the categories specified by the U.S. Nuclear Regulatory Commission.

Please make a copy of the certificate to send with the license amendment application, as you will want to keep the original. Recently we have learned that having more than one original completion letter could be an advantage, so we now enclose two. If you need a third letter for some reason, please be sure to make a copy. The NRC or state agency will want an original of the letter of completion; a copy of the certificate is usually an optional enclosure. They will not return what you submit, so do not submit the original of the certificate.

I would like to take this opportunity to congratulate you on completing the course. I encourage you to continue your education in nuclear medicine and nuclear pharmacy by routinely reading the Journal of Nuclear Medicine and the Journal of Nuclear Medicine Technology and by participating in your local nuclear medicine organization. Purdue's Certificate Program has given you a foundation that you can build on, and our faculty remains available to you if you have questions at a later date. I join with Dr. Shaw in hoping that you will find nuclear pharmacy as satisfying a profession as we have. I hope to see you at some future date at one of the regional or national meetings.

Enclosures

DIVISION OF NUCLEAR PHARMACY • DEPARTMENT OF MEDICINAL CHEMISTRY AND MOLECULAR PHARMACOLOGY
1333 HEINE PHARMACY BUILDING • WEST LAFAYETTE, IN 47907-1333
(765) 494-1441 • FAX: (765) 494-1414

PURDUE UNIVERSITY

SCHOOL OF PHARMACY AND
PHARMACAL SCIENCES

November 6, 1998

Nicholas J. Plumeri
Mallinckrodt Medical Inc.
108 Charlotte Ave.
Hicksville, NY 11801

Dear Nicholas:

We are pleased to provide the enclosed certificate to recognize formally your completion of the Nuclear Pharmacy Certificate Program. We enjoyed the brief opportunity to share our knowledge from the world of academia. We wish you the very best for a gratifying and successful professional career.

Sincerely,

Stanley M. Shaw

Stanley M. Shaw, Ph.D.
Head
Division of Nuclear Pharmacy

SMS/cas

DIVISION OF NUCLEAR PHARMACY • DEPARTMENT OF MEDICINAL CHEMISTRY AND MOLECULAR PHARMACOLOGY
1333 HEINE PHARMACY BUILDING • WEST LAFAYETTE, IN 47907-1333
(765) 494-1441 • FAX: (765) 494-1414

CERTIFICATE OF CONTINUING PHARMACEUTICAL EDUCATION PARTICIPATION

PROVIDER INFORMATION

PURDUE UNIVERSITY
SCHOOL OF PHARMACY AND PHARMACAL SCIENCES

PROGRAM INFORMATION

ACPE UNIVERSAL PROGRAM NUMBER	TITLE	DATE	CE CONTACT HOURS
018-000-98-002-H04	*Rad. Prot. & Instrum.*	10/30/98	26.0
018-000-98-003-H04	*Nuc. Phys. & Radiopharm. I*	10/30/98	48.0
018-000-98-004-H01	*Radiopharm. & Diagnostic*	10/30/98	46.0
018-000-98-005-H04	*Radiation Biology*	10/30/98	30.0
018-000-98-006-E04	*Basic Prin. of Nuc. Pharm.*	8/29/98	73.0

TOTAL CONTINUING EDUCATION CONTACT HOURS: 223.0

Robert W. Bennett
Authorized Signature

Date: November 1998

PARTICIPANT INFORMATION:

Name: Nicholas J. Plumeri

Address: 110 Suffolk Rd.

City, State, Zip: Massapequa NY 11758

NUCLEAR PHARMACY CERTIFICATE PROGRAM

Synopsis of Clock Hours of Training

School of Pharmacy and Pharmacal Sciences

Department of Medicinal Chemistry and Molecular Pharmacology

Division of Nuclear Pharmacy

Purdue University

West Lafayette, Indiana 47907

Nuclear Pharmacy Certificate Program Outline

Contents:

Abbreviations Used:

RPI:	Radiation Physics Instrumentation
RP:	Radiation Physics
MA:	Math
RB:	Radiation Biology
RC:	Radiochemistry

Nuclear Pharmacy Certificate Program Concept

The School of Pharmacy and Pharmacal Sciences at Purdue University offers a Certificate Program in Nuclear Pharmacy. The goal of the certificate program is to provide fundamental information to post-graduate pharmacists that will serve as a foundation for attaining competency as practitioners in nuclear pharmacy. The program follows the guidelines for nuclear pharmacy training prepared by nuclear pharmacists in the American Pharmaceutical Association, Section on Nuclear Pharmacy Practice.

There are two distinct phases of the certificate program. The first part utilizes self-study concepts, including lectures on videotape and correlated reading assignments. The nuclear pharmacy manager, or other qualified nuclear pharmacist at the practice site, serves as the clinical instructor and mentor for the pharmacist in training. This portion is self-paced by the trainee with regular examinations returned to Purdue to assist in monitoring the learning process. Successful completion of the didactic phase qualifies the trainee to attend a two-week long training session at Purdue. While on campus, the trainee participates in laboratory exercises and has opportunities for personal interaction with the instructors during lectures presented. Certification is awarded to those trainees who have completed the program and are able to demonstrate their knowledge and competence by examination in each of the key areas addressed by the program.

Form Updated 01/98

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES*

Location of Training	Date(s) of Attendance	Nuclear Pharmacy Certificate Program	Total Clock Hours of Course	Breakdown of Course Content in Clock Hours								
				Radiation Physics & Instru-mentation		Radiation Protection		Math Pertaining to Radio-activity		Radiation Biology		Radio-pharma-ceutical Chemistry
				A	B	A	B	A	B	A	B	A
Purdue University		Video-Workbook	150	54		37		11		23		25
		On-Site	73	26		19		13		4		11
Column "A" refers to a Lecture/Laboratory Course			223	80		56		24		27		36
Column "B" refers to a Supervised Laboratory Experience			TOTAL HOURS	80		56		24		27		36

* This form is representative of that which is used to apply for an NRC license amendment for an authorized user.

Nuclear Pharmacy Certificate Program

Videocassette and Workbook (Self-Study Portion) Clock Hours

Instructor	Material	Clock Hours	
Dr. Stan Shaw	Physics and Overview	RPI	30
	Radiation Energy	RP	2
	Atomic Structure	MA	4
	Nuclides	RC	12
	Radioactive Decay and Half-Life		
	Ideal Radionuclide for Imaging		
	Modes of Radioactive Decay		
	Interaction of Ionizing Radiation with Matter		
	Radiation Detection Methods		
	Radiopharmaceuticals: Characteristics and Chemistry		
	Central Nervous System		
	Pulmonary System		
	Liver and Hepatobiliary System		
	Spleen		
	Cardiac Imaging		
	Skeletal System		
	Renal System		
	Endocrine System		
	Miscellaneous Procedures and Radiopharmaceuticals		
	In Vivo Radiopharmaceuticals Not Requiring Imaging		
	Radiopharmaceuticals Used in Therapy		

Dr. Robert Landolt	**Radiation Protection**	**RP**	**16**
	Terms and Units		
	Protection from External Exposure		
	Portable Survey Instruments		
	Personnel Monitoring		
	Internal Dose Calculations		
	Contamination Control		
	Waste Management		
	Packaging, Labels and Placards		
	10 CFR Standards for Protection Against Radiation		
	10 CFR Notices, Instructions, and Reports to Workers		
Mr. Jim Ponto	**Drugs & Radiopharmaceuticals**	**RPI**	**4**
	Drugs & Radiopharmaceuticals, Parts 1 and 2:	**RP**	**4**
	Interactions and their effect on diagnostic accuracy of	**MA**	**4**
	Nuclear Medicine Procedures	**RC**	**8**
	Drugs & Radiopharmaceuticals, Part 3:		
	Interventions used to improve differential diagnosis in		
	Nuclear Medicine Imaging		
	Criteria for Product Selection		
	Instrument Quality Assurance		
	Technetium Chemistry; Radiolytic Decomposition		
	Pediatric Dosage Calculations		
	Adverse Reactions to Radiopharmaceuticals		
	Record Keeping		
	Preparation and Dispensing of Radiopharmaceuticals		
	Formulation Problems		

Anne Smith	Radionuclide Generator: Mo-99/Tc-99m Generator	RPI	3
	Quality Control Testing of Radiopharmaceuticals	RP	2
		MA	1
Dr. Richard Kowalsky	Radiopharmaceuticals for Brain Imaging	RPI	5
	Radiopharmaceuticals for Heart Imaging Update	RP	5
	Radiopharmaceuticals for Kidney Imaging Update	RC	5
	Radiopharmaceuticals for Treatment of Bone Pain	RB	1
	Monoclonal Antibodies for Radioimmunodiagnosis		
	Somostatin Receptor Imaging		
Dr. Wayne Kessler	**Instrumentation**	RPI	8
	Spectrometry	MA	2
	Counting Efficiency		
	Coincidence Loss		
	Background		
	Liquid Scintillation Counting		
	Statistics of Radioactivity		
Dr. Paul Simms	Radionuclide Production, Part 1	RPI	4
	Radionuclide Production, Part 2		
Dr. Stan Shaw	**Radiation Biology and Protection**	RB	20
	Energy Transfer	RP	8
	Mechanisms of Change		
	Aqueous Radiation Chemistry		
	Target Theory and Dose-Response		
	Radiation Effects on Macromolecules		
	Radiation Effects on Cells		
	Acute Effects		
	Delayed Effects		
	Genetic Effects		
Dr. William Widmer	Late Effects of Ionizing Radiation	RB	2

Nuclear Pharmacy Certificate Program

On-Site Laboratory Schedule

Instructor	Laboratory	Clock Hours
Dr. Stan Shaw	Contamination and Decontamination	RP 3
	Basic Radiation Safety	RP 4
	G.M. Counting	RPI 3
Brigette McGhee	I-131 Handling Techniques	MA 2
		RB 2
Anne Smith	Gamma Ray Scintillation Spectrometry I	RPI 4
	Gamma Ray Scintillation Spectrometry II	RPI 3
	Multichannel Analyzer	RPI 3
	Dose Calibrator	RPI 3
	Shipping and Receiving	MA 1 RP 2
	Elution of the Tc-99m Generator and Quality Control of the Eluate	RPI 2 MA 2
	Radiochemical Purity Testing	RPI 2 RC 1
	Preparation and Dispensing of Selected Radiopharmaceuticals	RPI 2 MA 2
	Aseptic Technique and Sterility Testing	RC 3
	Gamma Camera Instrumentation	RPI 3
	Review of Math Used in Nuclear Pharmacy	MA 3
	Counting Statistics in Nuclear Pharmacy Practice	MA 3

Nuclear Pharmacy Certificate Program

On-Site Lecture Schedule

Instructor	Topic	Clock Hours	
Dr. Mark Green	Chemistry of Metal-Labeled Radiopharmaceuticals	RC	5
	PET Radiopharmaceutical Chemistry	RPI	1
	PET Imaging and Concept		
	Radionuclide Generator for PET		
Dr. Stan Shaw	Regulatory Agencies	RP	4
	10 CFR Parts 19 and 20		
Mack Richard	10 CFR Part 35 Medical Regulations	RP	2
	Performance Criteria for Radiobioassay	RB	2
Anne Smith	Formed Element Labeling and Aids Safety Procedures	RC	2
Dr. Gordon Born	DOT Hazardous Materials Handling	RP	2
Dr. Robert Landolt	Film Badge Dosimetry	RP	2

TATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK / ALBANY, NY 12230

h Stone Board of Pharmacy, 89 Washington Ave., 2nd Floor, Albany, NY 12234
ca R. Mobilia, Executive Secretary
8) 474-3817 ext 130 518-473-6995; Web www.op.nysed.gov; Email pharmbd@mail.nysed.gov

NUCLEAR PHARMACIST APPLICATION

NAME Christopher Warren Stanton DATE 4/13/10

ADDRESS 9134 251 ST Bellerose New York 11426

PHONE (718) 347 1819 LICENSE # 054336

REQUIREMENTS

Are you certified as a Nuclear Pharmacist by the Board of Pharmaceutical Specialties of the American Pharmaceutical Association?

Yes ____ Date & Certification Number ____ No

If yes: send copy of certification

or

Have you completed 200 contact hours of didactic instruction? (attach evidence)

✓ Yes ____ No

Have you completed a minimum of 500 hours of clinical nuclear pharmacy under the supervision of a Board Of Pharmaceutical Specialties Certified Nuclear pharmacist? (attach evidence)

✓ Yes ____ No

Present Employer: Name [redacted]

Address [redacted]

Phone (516) 933-7828

Signature [signature] Christopher Stanton

Date 4/14/2010 4/14/10

Reference: part 63 Pharmacy Law 63.6 (b) (6)

THE OHIO STATE UNIVERSITY

COLLEGE OF PHARMACY
UNIVERSITY MEDICAL CENTER

[redacted]

NUCLEAR PHARMACY CERTIFICATE PROGRAM

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Christopher Stanton

Location of Training	Dates of Attendance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radiopharmaceutical Chemistry
The Ohio State University, Columbus, OH	March 1, 2010 through March 26, 2010	Nuclear Pharmacy Certificate Program	214	88	45	20	22	39
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category) TOTAL HOURS			214	88	45	20	22	39

Authorized Nuclear Pharmacist/Authorized User: George H. Hinkle

George H. Hinkle, RPh,MS,BCNP,FASHP,FAPhA

DATE: March 26, 2010

THE OHIO STATE UNIVERSITY
COLLEGE OF PHARMACY
UNIVERSITY MEDICAL CENTER

NUCLEAR PHARMACY CERTIFICATE PROGRAM

RADIONUCLIDE HANDLING EXPERIENCE

Name: Christopher Stanton Date: March 26, 2010

Document the actual use/handling of radioactive material under the supervision of an Authorized Nuclear Pharmacist.

RADIONUCLIDE	RADIOACTIVITY	USE see below	EXPERIENCE Actual clock hours (Include date range of experience)	LOCATION
Mo-99	10 Curies	1,2,3,4,5,6,7	3/1/10 through 3/26/10	The Ohio State University Medical Center Columbus, OH
Tc-99m	8 Curies	1,2,3,4,5,6,7		
I-131	200 mCi	1,2,3,4,5,6		
I-123	1 mCi	1,2,3,4,5,6		
Ga-67	25 mCi	1,2,3,4,5		
Tl-201	50 mCi	1,2,3,4,5		
In-111	7.5 mCi	1,2,3,4		
Sr-89	5 mCi	1,2,3,4,5,6		
Sm-153	100 mCi	1,2,3,4,5,6		
F-18	200 mCi	1,2,3,4,5,6		
Cs-137	0.2 mCi	1,2,5	TOTAL HOURS: 40 hours	

Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each radionuclide.

1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys.
2. Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if applicable, instruments used to measure alpha- or beta-emitting radionuclides.
3. Calculating, assaying and safely preparing dosages for patients or human research subjects.
4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product material.
5. Using procedures to prevent or minimize contamination and using proper decontamination procedures.
6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys and wipe tests.
7. Eluting Tc99m from generator systems, assaying the eluate for Tc99m and for Mo99 and processing the eluate with reagent kits to prepare Tc99m labeled radioactive drugs.

Authorized Nuclear Pharmacist: George F. Hinkle, RPh, MS, BCNP Date: March 26, 2010

The Ohio State University
College of Pharmacy
and
University Medical Center
Department of Pharmacy

By this certificate warrants that

Christopher Warren Stanton

has satisfactorily fulfilled all requirements
and completed the prescribed course

Nuclear Pharmacy Certificate Program

March 26, 2010

George W. Hinkle
Director, Nuclear Pharmacy
Associate Professor of Pharmacy

Robert W. Brueggemeier
Dean, College of Pharmacy

Gerald L. Cable
Director, Outreach and Engagement
College of Pharmacy

Chair, Pharmacy Practice
and Administration

APPENDIX B

NRC FORM 313A (ANP) (10-2006) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.55]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2009

Name of Proposed Authorized Nuclear Pharmacist	State or Territory Where Licensed
Christopher Warren Stanton	NY

PART I – TRAINING AND EXPERIENCE
(Select one of the two methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the nuclear pharmacy uses.

☐ 1. Board Certification

a. Provide a copy of the board certification.

b. Skip to and complete Part II Preceptor Attestation.

☒ 2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	SEE ATTACHED		
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			
Total Hours of Training:		200	

APPENDIX B

NRC FORM 313A (ANP) (10-2006) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist (continued)

b. Supervised Practical Experience in a Nuclear Pharmacy.

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Shipping, receiving, and performing related radiation surveys	Mallinckrodt Inc. 108 Charlotte Ave. Hicksville NY 11801 021716	105	12/7/09 to 4/13/10
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides	Mallinckrodt Inc. 108 Charlotte Ave. Hicksville NY 11801 021716	180	12/7/09 to 4/13/10
Calculating, assaying, and safely preparing dosages for patients or human research subjects	Mallinckrodt Inc. 108 Charlotte Ave. Hicksville NY 11801 021716	250	12/7/09 to 4/13/10
Using administrative controls to avoid medical events in administration of byproduct material	Mallinckrodt Inc. 108 Charlotte Ave. Hicksville NY 11801 021716	30	12/7/09 to 4/13/10
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	Mallinckrodt Inc. 108 Charlotte Ave. Hicksville NY 11801 021716	53	12/7/09 to 4/13/10
	Total Hours of Experience:	618	

Supervising Individual [signature] d29469

c. Go to and complete Part II Preceptor Attestation.

PAGE 2