

PETNET Solutions

September 30, 2009

Kevin G. Null
Materials Licensing Branch
U.S. NRC Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4352

Re: New Nuclear Regulatory Commission (NRC) Radioactive Material (RAM) License Application for our existing PETNET facility in St. Louis, MO

Dear Mr. Null,

The purpose of this letter is to submit a new NRC Radioactive Material (RAM) License Application for our existing facility PETNET Solutions, Inc. in St. Louis MO.

In our facility we have a cyclotron for the production of radiochemicals, and an area for the manufacturing and packaging of PET radiochemicals and radiopharmaceuticals for distribution to authorized licensees. PETNET Solutions, Inc. requests a new NRC RAM license for the manufacturing activities, transfer and/or distribution of PET radiochemicals and radiopharmaceuticals to authorized recipients. A separate RAM license application was submitted for the production, and possession of radioactive materials. This facility is located at:

3635 Vista Ave., First Floor
St. Louis, MO 63110

Enclosed with this letter are two copies of the completed RAM License Application for the manufacturing and distribution of radioactive materials, and a check for \$7,400 for the license fee. Attachment I has two copies of the RAM License Application, and Attachment II has the check for the license fee.

We believe that we have provided all the information that the Agency needs to grant this request. If you have any questions, please contact me at the number below, or contact Delis Maldonado at (865) 218-3239.

RECEIVED OCT 0 1 2009

Sincerely,



David J. Krueger, CHP
Corporate Radiation Safety Officer
PETNET Solutions, Inc.
Voice: 818-620-6569
Fax: 865-218-3018
david.j.krueger@siemens.com

att: License Application
Check for \$7400

cc: Rita Gentilcore, M.S., R.Ph., Facility RSO
Delis Maldonado, Regional Health Physicist

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NRC FORM 313
(4-2008)
10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 10/31/2008

Estimated burden per response to comply with this mandatory collection request: 4.4 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 and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-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, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

APPLICATION FOR MATERIALS LICENSE

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:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, 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 BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
612 E. LAMAR BOULEVARD, SUITE 400
ARLINGTON, TX 76011-4125

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 _____
- C. RENEWAL OF LICENSE NUMBER _____

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

PETNET Solutions, Inc.
810 Innovation Drive
Knoxville TN 37932

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

3635 Vista Ave.
First Floor
St. Louis, MO 63110

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

David J. Krueger, CHP

TELEPHONE NUMBER

(818) 620-6569

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. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY **3C.** AMOUNT ENCLOSED **\$ 7,400.00**

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

David J. Krueger, CRSO

SIGNATURE



DATE

9/25/09

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

ITEM 5: Radioactive Material

(8) Element and Mass Number	(9) Chemical or Physical Form	(10) Maximum Activity Requested	Proposed Use *
a. Fluorine-18	a. Any	a. 10 Ci	a. Production and possession for transfer or distribution
b. Carbon-11	b. Any	b. 2 Ci	b. Production and possession for transfer or distribution
c. Nitrogen-13	c. Any	c. 2 Ci	c. Production and possession for transfer or distribution
d. Oxygen-15	d. Any	d. 3 Ci	d. Production and possession for transfer or distribution
e. H-3 (tritium)	e. Liquid	e. 5 mCi	e. Incidental to production. It is produced in the bombardment of O-18 target material (water)
f. Cobalt-57	f. Sealed Sources **	f. 6 mCi	f. Check of instruments and calibration
g. Cesium-137	g. Sealed Sources **	g. 300 µCi	g. Check of instruments and calibration
h. Sodium-22	h. Sealed Sources **	h. 300 µCi	h. Check of instruments and calibration

* Details are included in ITEM 6 of this RAM license application.

** We would prefer to have the authorization in 10 CFR 35.65 rather than a line item for each sealed source.

Financial and Recordkeeping for Decommissioning

Aside from the sealed sources and tritium, the radioactive materials requested in this license application do not have half-lives greater than 120 days. The requested possession limit for tritium in this application does not exceed the threshold requiring decommissioning funding specified in 10 CFR 30.35 (b) & (d).

A Decommissioning Funding Plan (DFP) is included as part of our NRC Production RAM license application.

ITEM 6: Purpose for Licensed Material

PETNET Solutions, Inc. (PETNET), requests approval for a new Nuclear Regulatory Commission (NRC) Radioactive Material (RAM) license for the manufacturing, preparation, possession, receipt, transfer and/or distribution of PET radiochemicals and radiopharmaceuticals to authorized licensees.

Unsealed Sources (ITEM 5, Column (8) lines a-d)

PETNET's St. Louis facility will produce PET radiochemicals (F-18, N-13, C-11, O-15) using an on-site cyclotron or we will receive PET radiochemicals from other properly authorized and licensed PET facilities (in case the cyclotron is not operational). We will operate a nuclear pharmacy for the manufacture, preparation, quality control, quality assurance testing, compounding, dispensing, and distribution of PET radiopharmaceuticals, such as F-18 FDG, F-18 FLT, N-13 Ammonia, NaF-18, C-11 Methionine and O-15 water and gas to authorized recipients. PETNET will also transfer and/or distribute PET radiochemicals (e.g. F-18 Fluoride ion) to other authorized PET pharmacies, as needed, for them to perform the chemical synthesis (i.e. compounding) to produce radiopharmaceuticals for their customers or to authorized recipients for research activities. In the future, other PET radiopharmaceuticals may be produced, using our licensed radionuclides, and distributed from this facility. Below is a description of some of the PET radiopharmaceuticals that may be produced at this facility.

FDG is an abbreviated name for the radiopharmaceutical Fluorodeoxyglucose (2-deoxy-2-[F-18] Fluoro-D-glucose), a sugar compound that is labeled with F-18. FDG is used in the molecular imaging modality called Positron Emission Tomography (PET). FDG is administered intravenously and is used to determine how certain organs and tissues in the body are functioning at the cellular level by measuring glucose metabolism. It is widely used for functional studies in neurology, cardiology, and oncology. Since diseases are manifestations of biological processes, functional imaging through PET has shown to be a significant diagnostic approach in medicine.

Nitrogen-13 [N-13] Ammonia, Carbon-11 [C-11] Acetate and Methionine, and Oxygen-15 [O-15] water and gas may also be produced and distributed. N-13 Ammonia is used for cardiac liability testing. Also, N-13 is a byproduct of F-18 production. C-11 Acetate is mainly used for cardiac imaging, and C-11 Methionine is used for brain tumor imaging. O-15 water and gas is used to evaluate the benefit of bypass surgery in patients identified as having symptomatic occlusion of one carotid artery.

PET radiochemicals and radiopharmaceuticals are time-sensitive products, due to their short half-lives. The amount of radioisotope initially received must be large enough to accommodate decay during the time required for chemical synthesis, quality control, quality assurance testing, transportation packing, and transportation time. The amount of PET radiochemicals and radiopharmaceuticals produced also must be based upon demand in addition to the decay time.

This nuclear pharmacy is licensed by the State's Board of Pharmacy and is therefore subject to the laws and regulations set forth by the Board of Pharmacy. Attachment A contains a copy of our pharmacy license from the Missouri Board of Pharmacy. In addition, the nuclear pharmacy will comply with the applicable provisions of the Federal Food, Drug, and Cosmetic Act and The Food and Drug Administration Modernization Act of 1997.

Requests for PET radiopharmaceuticals from physicians (M.D. or D.O.) will be handled and treated as a prescription. Distribution to authorized licensees will be assured by maintaining a current copy of the recipient's radioactive material license or state registration on file at the facility.

Prior to distribution to authorized facilities by the nuclear pharmacy, written protocols for synthesis, compounding, and quality control for all radiopharmaceuticals produced at this facility will be available and maintained on file for inspection by the State's Board of Pharmacy or the Food and Drug Administration.

Radiopharmaceuticals distributed for human use by PETNET will be:

1. Manufactured or compounded in accordance with the regulations of the Missouri Board of Pharmacy and the Food and Drug Administration (FDA).
2. Compounded or manufactured and tested using written procedures.
3. Dispensed upon receipt of a physician's prescription using written procedures.

PET compounds that are under IND status will be dispensed:

1. In accordance with directions provided by the sponsors of the IND, and
2. Only the physicians who have been accepted by the sponsors of the IND to participate to clinical evaluations of the drug, and
3. With the understanding that the physician is responsible to the sponsors of the IND for use of the drug in accordance with protocols and information obtained through the use of the drug.

Tritium (ITEM 5, Column (8) line e)

PETNET uses Oxygen-18 enriched water as the target material for the production of Fluorine-18 and due to the high cost of O-18 water on a per gram basis we try to utilize as much of the water as possible through recycling of the water. Siemens Molecular Imaging recycles our O-18 water.

Our information about tritium in O-18 water comes from an analysis performed by an independent laboratory on the O-18 water that is received from the PETNET sites for recycling. Samples were collected from various stages of the recycling process. The analysis found that the concentration in all stages of the process was 3.4 $\mu\text{Ci/g}$ of H-3 in the O-18 water. Our facility will generally store 400-500 grams (1.4 mCi to 1.7 mCi of H-3) per month of O-18 water before we ship the O-18 water to Siemens for recycling.

Sealed Sources (ITEM 5, Column (8) lines f-h)

Sealed sources (e.g. Cs-137) will be used to perform calibrations and constancy checks on dose calibrators, stack monitors, and radiation survey and analysis instruments.

ITEM 7: Individuals Responsible for Radiation Safety Program and Their Training Experience

Corporate Radiation Safety Officer (CRSO): David J. Krueger, CHP
Email Address: david.j.krueger@siemens.com
Office Telephone Number: (818) 620-6569
Facility Radiation Safety Officer (RSO): Rita Gentilcore, M.S., R.Ph.
Email Address: rita.gentilcore@petnetsolutions.com
Office Telephone Number: (314) 577-8800

Mr. David J. Krueger, CHP is currently the Corporate RSO for PETNET Solutions, Inc. A copy of his resume is found in Attachment B. Ms. Rita Gentilcore is currently the Facility RSO under Missouri Radioactive Material Registration #6145. Ms. Gentilcore is an Authorized Nuclear Pharmacist and has the training and experience to be the RSO for this facility. Ms. Gentilcore has over 30 years of experience as a Nuclear Pharmacist. Approximately 18 years of her experience is in PET radiopharmacy, handling the types and quantities of the radioactive materials listed in ITEM 5. In addition, she has been an RSO for this PETNET facility for approximately 8 years. Attachment B has copies of Ms. Gentilcore's Curriculum Vitae, training and Pharmacist license. A copy of our facility's Registration of Radioactive Material #6145 is included in Attachment C listing Ms. Gentilcore as the facility RSO.

A. CRSO Responsibilities

1. The PETNET CRSO's primary responsibilities are to provide leadership and direction in developing, implementing, and maintaining the corporate Radiation Protection Program and Compliance Program, and to assure continuous improvements in the program.
2. The CRSO administers the Corporate Radiation Protection Program (RPP) in accordance with the applicable regulations, company policies and procedures, and the provisions and conditions of the PETNET RAM licenses and cyclotron registrations.
3. The CRSO is provided with sufficient authority and organizational freedom to identify RPP issues and initiate, recommend, or provide solutions, and verify implementation of corrective actions.
4. The CRSO, with the assistance of the regional health physicists, performs his/her role and responsibilities, which include the following:

- a. Establish the corporate radiological compliance related policies and procedures;
- b. Ensure consistent and uniform implementation of the regulatory requirements as well as the company policies and procedures by all PETNET facilities;
- c. Perform periodic regulatory compliance audits and ensure accurate and timely corrective actions for the deficiencies;
- d. Provide standardized system and procedures for all aspects of the corporate radiological compliance program for radiation monitoring and surveys, training, incident investigations, problem identification and corrective actions program, radiological emergency procedures, notification and reporting systems, DOT related activities, design of new facilities, licensing, and other programs as needed;
- e. Provide liaison between PETNET corporate office and PETNET facilities and various regulatory agencies (Agreement States, Non-Agreement States, NRC, DOT, etc.);
- f. Provide assistance to the PETNET facility RSOs and the employees to ensure radiological safety for workers, the general public, and the environment, and to ensure timely and accurate license applications and amendments, as needed;
- g. Provide leadership and resources (technical, regulatory, program management) to the PETNET corporate management, the PETNET Facility Managers and RSOs, and the Regional Directors to assure a superior corporate regulatory compliance program;
- h. Coordinate and implement the corporate Radiation Safety Committee (RSC) activities and decisions, and present appropriate reports at the RSC meetings;
- i. Provide input to the PETNET senior management to incorporate radiological program issues into the corporate strategic decisions;
- j. Provide guidance, assistance, and review for RPP related investigation reports (exposures, contamination, releases, and other events);
- k. Review and approve corporate wide and/or site-specific corrective actions for RPP and regulatory compliance deficiencies;
- l. Initiate corporate projects for continuous improvements in the radiological compliance program;
- m. Facilitate trending and tracking program related to radiation activities and ensure appropriate implementation;
- n. Communicate lessons learned from internal (PETNET operations) and external (other nuclear pharmacies and material licenses) activities to PETNET sites for timely implementation and mitigation of consequences; and
- o. Conduct a formal review of the RPP's content and implementation, at least annually.

B. Facility RSO Responsibilities

The facility RSO must be a qualified individual who meets the NRC's requirements. Each facility RSO shall be approved by the NRC and be listed on the site-specific RAM license.

Each facility Radiation Safety Officer (RSO) is responsible for ensuring radiological safety and compliance with the NRC and U.S. DOT regulations, compliance with the license application and license conditions, and compliance with company policies and procedures.

Typically, the site-specific duties and responsibilities include the following:

- a. Provide general surveillance over the Radiation Protection Program (RPP);
- b. Ensure license conditions are being followed and the terms and conditions are understood by the relevant facility employees;
- c. Ensure that the license changes and amendments and rules and regulations are executed in a timely manner;
- d. Ensure personnel radiation monitoring is performed;
- e. Ensure timely and accurate radiation surveys, monitoring, and associated measurements are performed;
- f. Ensure the proper storage and disposal of radioactive materials;
- g. Perform incident investigation, as necessary;
- h. Ensure that a system for incident response and termination of activities is implemented, as necessary;
- i. Ensure occupational and public doses are maintained as low as reasonably achievable (ALARA) and appropriate investigations are performed, as needed;
- j. Ensure all relevant and appropriate RPP records are maintained;
- k. Ensure all RPP records are reviewed in a timely manner and appropriate actions taken;
- l. Notify the CRSO of non-routine activities (incidents, unusual exposures, regulatory inspections, and registration changes);
- m. Emphasize the ALARA philosophy to all personnel working with radioactive material, and instruct workers to review current procedures and propose changes to the procedures to reduce exposure levels, as necessary;
- n. Exhibit good role model characteristics through good radiation protection practices;
- o. Perform audits, as needed;

- p. Furnishing consultation services on all aspects of radiation safety to personnel at all levels of authority;
- q. Distributing and processing personnel monitoring equipment, keeping personnel exposure records, and notifying individuals and their supervisors of exposures approaching maximum permissible amounts and recommending appropriate remedial action; and,
- r. Ensuring personnel receive training in the proper procedures for the safe handling of licensed material prior to use; at periodic intervals thereafter (refresher training); and as required by changes in procedures, equipment, and regulations; and,
- s. Immediately terminate a project that is found to be a threat to health or property of the employees or the general public.

Training for RSO

As stated in NUREG 1556, Vol. 13, revision 1 (2007), "Any individual who has sufficient training and experience to be named an ANP is also considered qualified to serve as the facility RSO."

Ms. Gentilcore is an ANP. A copy of NRC License 17-32715-01MD, naming her as an ANP is located in Attachment B. Copies of her initial PETNET radiation safety and DOT training are located in Attachment B; annual retraining documentation is maintained at the site. Her Missouri Board of Pharmacy Pharmacist License is located in Attachment B.

C. Authorized Users

We request two types of Authorized Users: Authorized Nuclear Pharmacists and non-pharmacist Authorized Users.

Authorized Nuclear Pharmacists (ANPs) will use and/or supervise the use of licensed radioactive materials for the purposes of manufacturing, compounding and distributing of radiochemicals/radiopharmaceuticals.

The following individuals are Authorized Nuclear Pharmacists who currently use or directly supervise the use of radioactive materials. Individuals #1-3 listed meet the grandfathering requirements listed in 10 CFR 35.57 (a) (3) and 10 CFR 32.72 (b) (4).

1. Rita Gentilcore, M.S., R.Ph. (Authorized Nuclear Pharmacist)
2. John Beyer, R.Ph. (Authorized Nuclear Pharmacist)
3. Alan Bilbrey, R.Ph. (Authorized Nuclear Pharmacist)

Ms. Rita Gentilcore is currently listed as an ANP in NRC RAM License 17-32715-01MD found in Attachment B, along with her Pharmacist license and training documents. Attachment D has the state BOP licenses and initial training certificates for Mr. John Beyer and Mr. Alan Bilbrey. Mr. Alan Bilbrey is currently listed in an Agreement State RAM License found in Attachment D.

Non-pharmacist Authorized Users (AUs) will use, and/or supervise the use of licensed radioactive materials, for purposes of manufacturing radiochemicals/radiopharmaceuticals, maintenance of the cyclotron and other equipment related to the facility's operation, such as, chemistry synthesis units.

By adding non-pharmacist AUs we can allow individuals who meet the requirements of the FDA to operate the manufacturing area, use or supervise the use of licensed material, produce radiochemicals/radiopharmaceuticals, and handle radioactive materials such as activated and/or contaminated components (e.g., preventative maintenance and repair of the cyclotron or other equipment) without the physical presence of an Authorized Nuclear Pharmacist. Such individuals include Production Specialists, Field Service Engineers, Cyclotron Engineers and other qualified individuals.

The following individual is a non-pharmacist AU who will use, and/or supervise the use of licensed radioactive materials for non-medical use:

4. Ranajit Bera, Ph.D. (Chemist)

Dr. Ranajit Bera has the education, training and experience to be an Authorized User in this license. Dr. Ranajit Bera has approximately 18 years of experience working at this PET production/radiochemistry facility and handling the types and quantities of the radioactive materials listed in ITEM 5. Training documentation for Dr. Bera is in Attachment D.

Training requirements for PETNET employees are provided in the next ITEM.

ITEM 8: Training for Individuals Working in or Frequenting Restricted Areas

This section includes the training required for Authorized Nuclear Pharmacists and Authorized Users that PETNET is requesting for this RAM License. In addition, the training required for all PETNET Employees, and Ancillary Staff is defined.

Authorized Users Duties and Training

Duties	Training
<ul style="list-style-type: none"> Individuals who will handle and supervise the handling of licensed material in the course of operation and maintenance of the production equipment. They will dispense radio-chemicals and radio-pharmaceuticals, and oversee the preparation of packages for off-site shipment. These are Authorized Nuclear Pharmacists 	<ul style="list-style-type: none"> ANPs, other than those grandfathered under the provisions of 10 CFR 35.57 (a) (3), will have completed at least 200 hours of didactic training in the following areas: radiation physics and instrumentation, radiation protection, math pertaining to radioactivity, radiation biology, and radiopharmaceutical chemistry. These ANPs have also received at least 500 hours of supervised nuclear pharmacist experience from other authorized nuclear pharmacists. Authorized Nuclear Pharmacists, are required to receive PETNET's formal Radiation Protection training, and DOT/Hazardous Material , with annual retraining.
<ul style="list-style-type: none"> Individuals who will handle and supervise the handling of licensed material in the course of operation and maintenance of the production equipment. They will oversee the preparation of packages for off-site shipment. These are non-pharmacist Authorized Users. 	<ul style="list-style-type: none"> Non-pharmacist Authorized Users are required to receive PETNET's formal Radiation Protection and DOT/Hazardous Materials training, with annual retraining. Those that operate the cyclotron and the automated chemistry units will receive additional training

Radiation Protection Training for all of PETNET's Employees that are radiation workers who will routinely frequent the restricted area:

PETNET radiation protection training is provided to all PETNET employees who will be handling, using, working with, and supervising the use of radioactive materials and/or cyclotron operations. The radiation protection training is a three day course (approximately 24 hours).

- Training will be provided:
 1. Orientation training will be provided before they are allowed to work at the facility.
 2. Formal training before assuming duties involving the handling of radioactive materials.
 3. Annual refresher training (Radiation Safety and DOT).
 4. Whenever there is a significant change in duties, regulations, the terms of the license, or PETNET policies and procedures.

- Training will be of sufficient scope so that workers are:
 1. Informed of the storage, transfer, or use of radiation and/or radioactive material;
 2. Informed of issues associated with exposure to radiation and/or radioactive material, precautions and procedures to minimize exposure and contamination, and in the purposed functions of protective devices employed and safe use and handling of radioactive materials;
 3. Instructed in the policies, procedures, radioactive materials licenses, and license conditions related to the scope of radiological operations at this facility;
 4. Instructed with respect to their responsibility to report promptly to the RSO any condition which may lead to or cause a violation of the NRC's regulations and licenses or unnecessary exposure to radiation and/or radioactive material;
 5. Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material;
 6. Advised as to the radiation exposure reports which workers may request; and
 7. Informed about radiation hazards and appropriate precautions for those individuals whose duties may require work in the immediate vicinity of radioactive material.

- Records of initial and refresher training include:
 1. Name of the individual who provided the instruction;

2. Names of the individuals who received the instruction;
 3. Date(s) of instruction;
 4. List of the topics covered during training; and
 5. Tests and grades, as applicable.
- The contents of the PETNET radiation protection and DOT training program include:
 1. Applicable regulations;
 2. Terms and conditions of the license, including pertinent parts of the application submitted to receive the license;
 3. Areas where radioactive material and cyclotron components are used and/or stored;
 4. Potential hazards associated with radioactive materials;
 5. Precaution for exposure controls (time, distance, shielding);
 6. Precautions for contamination controls (PPE, engineering controls, enclosures);
 7. Biological effects of radiation exposure;
 8. Proper use of survey and analytical instruments;
 9. Appropriate response to radiological spills, emergencies, or other unsafe conditions;
 10. Obligation to report unsafe conditions to the facility RSO;
 11. Rights of the employees to be informed about their radiation exposure and to receive annual reports;
 12. PETNET RPP procedures, as applicable, to the employee's job functions;
 13. Location where the facility RSO has made available information included in the "Notice to Employees" and other information such as, license(s), pertinent regulations, procedures, and any other relevant information; and
 14. U.S. DOT regulations and training requirements (general awareness, function specific, safety related, and security awareness), as required by 49 CFR Subpart H.
 - A. General Awareness/Familiarization with DOT Requirements
 1. Applicable Regulations
 2. Hazardous Materials Classification
 3. Packaging Configurations
 4. Package Markings
 5. Package Labeling
 - B. Function Specific Training
 1. Types and Handling of Radioactive Material
 2. Radiation and Contamination Surveys
 3. Packaging Performance/Tests
 4. Shipping Papers- Ground/Air

- C. Safety Training
 - 1. Radiation Protection Features
 - 2. Emergency Response/Contacts
 - 3. Vehicle Loading/Unloading
- D. Security Training
 - 1. Awareness of security risks
 - 2. Methods to enhance transportation security
 - 3. Recognition of possible security threats
 - 4. Responding to possible security threats
 - 5. PETNET's Security Plan and procedures

A written test is required to assess comprehension of training materials provided at the course. Evidence that the individual's knowledge has been examined will be maintained on file at the site. The test will be graded and the passing grade is a minimum of 70% for the new employee training.

PETNET's annual retraining for Radiation Protection and DOT is provided using a web-based training (WBT) tool. WBT uses an abbreviated presentation of the formal training. It notifies individuals at least 30 days in prior to training due date. Individuals are required to take a web-based test that they must pass with 80% correct score to pass. When the individual passes a training certificate is generated and can be printed to keep on file.

Radiation Protection Training for Ancillary Personnel:

The ancillary personnel that are not directly handling radioactive materials, but who may require access to the restricted area, will be provided instructions in:

- 1. Location and access requirements of the restricted areas;
- 2. Identification of radiation sources and radiation areas;
- 3. Radiation monitoring and surveys, as required; and
- 4. Reporting of non-routine and unusual radiological situations to the RSO.

Cleaning staff, etc., who may have to enter the restricted but will not work directly with radioactive materials, will receive the training outlined above. As these are simple instructions, there is no annual retraining requirement. However, if any of the instructions change, then these personnel will be given new instructions and it will be documented.

ITEM 9: Facilities and Equipment

PETNET's facility is located inside St. Louis University Hospital, 3635 Vista Avenue, First Floor Firmin Desloge Tower East Expansion, St. Louis MO 63110. This facility serves as a production, manufacturing and distribution center to provide radiochemicals and radiopharmaceuticals to authorized licensees in Missouri and surrounding states. This facility is located on the first floor of St. Louis University Hospital. The PETNET facility is below ground and the area above the cyclotron room is a garden with public access restricted. Attachment I has a satellite view of the building and surrounding area.

The facility is divided into two areas: a restricted area and an unrestricted area. Doors equipped with locks control access to the restricted areas. Attachment E contains a drawing of the current layout of the facility. PETNET's restricted and unrestricted areas of the facility are indicated on the drawing. In addition, a drawing showing the delivery lines' conduit from the cyclotron to the manufacturing equipment is included.

The unrestricted area includes an entry alcove and office area. PETNET's restricted area consists of the following: a cyclotron room, a manufacturing area with mini-cells for chemical synthesis, a quality control area for testing of PET radiopharmaceuticals, a pharmacy area with a hot cell for dispensing and dose measurement and a shipment preparation area. Access to the restricted area is by authorized personnel and escorted guests only.

Cyclotron

The cyclotron is a Siemens RDS-112 self-shielded cyclotron placed inside a shielded room. Details on the safety precautions for the cyclotron are included in our NRC Production RAM license application.

The operation of the cyclotron is performed remotely by computers located in the restricted area. The targets are remotely loaded and unloaded via computer control. Once the target material is irradiated, the PET radiochemicals (e.g. F-18, C-11) are delivered via an attached delivery line that runs through a shielded conduit. There is section of the conduit in the cyclotron room that is shielded with 2 inches of lead, but is not buried 18 inches below the floor. This section of the conduit is inside a trench in the cyclotron room; personnel do not occupy this area during delivery. The rest of the conduit is located within the concrete floor (at least 18 inches below the surface) to its destination (mini cell or hot cell).

Processing and Dispensing of RAM and Radiopharmaceuticals

After the PET radiochemicals are assayed they are transferred to an automated chemistry module located in a mini-cell via shielded delivery lines where chemical synthesis is performed. After the completion of the chemical synthesis, the radiopharmaceutical is transferred via shielded delivery lines to the hot-cell. The hotcell with remote manipulators is used to dispense drugs for human use. A shielded dose calibrator is mounted below the surface of the hot cell. Individual dosage forms (syringes, vials) are measured and placed into shipping pigs.

Quality control samples are taken from either the mini cell or hot cell. Quality control is performed behind a PET L-block surrounded by a lead brick shield. An area radiation monitor with an alarm will be located in the manufacturing area of the facility.

Once the radiopharmaceutical doses are dispensed they are placed in syringe shields, removed from the hot cell and packaged into the proper shipping containers. Packages are checked for exposure rates and contamination. Once the packages meet DOT requirements and paperwork is completed, they are transferred to the couriers for delivery to customers.

Effluent Control & Monitoring

Airflow in the facility is a decreasing pressure gradient with the lowest air pressure in the cyclotron room. The exhaust from the cyclotron, hot cell and mini-cells are separate from the facility HVAC equipment. The exhaust from the mini-cells and hotcells is filtered and then combined with the exhaust from the cyclotron. The exhaust is monitored for radioactivity, and then released through a stack.

Exhaust from the mini-cells, and hotcells is filtered using a KEP3S zero-bypass filter system then combined with the exhaust from the cyclotron. The combined exhaust is then monitored for radioactivity using a Laboratory Impex (LI) Stack Monitor before release through a stack. The KEP3S filter unit consists of one pre-filter, one HEPA filter, and two carbon Filters. This system will minimize the release of effluents by trapping F-18. A drawing of the KEP3S filter housing and information on the carbon filters is provided in Attachment F. The KEP3S is shielded with 1 inch of lead and it is located inside the cyclotron room (see location on floor plan in Attachment E). This filtration system has been installed at many other PETNET sites and rated to effectively remove 99% of the exhausted volatile F-18. The system is rated for 500 CFM while allowing the appropriate residence time in the carbon banks. Attachment G contains a schematic of the radioactive exhaust system.

The combined exhaust will be monitored for radioactivity and then released through a stack.

The type of stack monitor that PETNET will use at this facility is a Laboratory Impex Systems. Details on that system are provided in Attachment F. The LIS stack monitor extracts a small sample stream from the duct and counts the radioactive gases in a remote, plastic scintillator. The system is capable of detecting at least 1×10^{-8} $\mu\text{Ci/ml}$.

The Lab Impex system also monitors flow rates. The combined effluent from the cyclotron, mini-cells, and hot cells will be sampled for radioactivity and flow rate after filtration and prior to release. The system displays concentrations and running totals on the display.

LIS has developed a method to perform a calibration check using a sealed source. The calibration procedure is found in Attachment F. The calculated calibration factor determined by the procedure has to be within $\pm 10\%$ of the existing calibration factor; otherwise, recalibration or repair will be required.

The system has an alarm set point of 50 mCi per day – the value used at most PETNET sites – which has been demonstrated to insure compliance with the 10 mrem constraint rule at most PETNET facilities. Annually, we will assess public doses from effluent releases via the COMPLY program.

Ventilation system maintenance will be performed every six months. Ventilation system maintenance includes replacing drive belts, lubricating the blower as recommended by the manufacture. The exhaust system checks shall be performed weekly and includes using a velometer to check room entrances, fume hoods, mini-cells, and hot cells for proper air flow. Exhaust system prefilters on the new system should be replaced monthly, and HEPA shall be replaced when the pressure drop exceeds twice the new filter value. The charcoal filters will be replaced when the measured releases increase over 50% of routine values, over a four-week period, and the increase is not explainable by increases in production or failures in chemistry. In any case carbon filters shall be replaced at least every two years.

ITEM 10: Radiation Safety Program

PETNET Solutions, Inc. will continue to operate under the existing PETNET Solutions' Radiation Protection Program (RPP) in all of its elements such as standard operating procedures (SOPs), ALARA reviews, annual program reviews and oversight by PETNET's Radiation Protection/EHS Department.

The Radiation Protection Program (RPP) contains the following functional elements in compliance with the NRC regulations (complete copies of PETNET's RPP and implementing procedures are available at the site with procedures maintained in an electronic document management system):

1. Audit Program

PETNET's Corporate Radiation Protection/EHS (RP/EHS) Department will perform an annual audit to ensure the following:

- Compliance with NRC and DOT regulations (as applicable), and the terms and conditions of the license;
- Occupational doses and doses to members of the public are ALARA;
- Compliance with the PETNET RPP policies and procedures; and
- Records of audits and other reviews of program content are maintained for 3 years.

The audits will be conducted by the RP/EHS staff or Authorized Users from other PETNET facilities who do not routinely work at the facility. A non-health physicist auditor will have had a minimum of 3 years experience working in an active PETNET site, have been through the PETNET RSO Training Course, had enough training and experience to be named on an Agreement State or NRC RAM license as an ANP or AU, and have conducted at least two audits under the supervision of a health physicist. All audit reports are reviewed by the CRSO or designee prior to finalizing the audit report. Once the audit is completed by the RHP, the audit findings and potential corrective actions will be discussed with the RSO, and a timeline will be established for addressing any unresolved issues. The CRSO will submit a final audit report to the RSO and to PETNET Management. The RSO will provide a written response to the RHP, if necessary for any corrective action.

RPP Annual Review

An annual review of the Radiation Protection Program's (RPP) content and implementation will be performed. This review will evaluate the following:

- The adequacy of the RPP elements and resources;

- The radiological safety features and the ALARA program; and
- The overall compliance with the regulatory and licensing requirements

This review shall be performed by the CRSO and the facility RSO, and the results will be presented to the RSC and the executive management by the CRSO.

2. Radiation Monitoring Instruments

Radiation monitoring instruments will be used to evaluate possible radiation hazards that may be present. Instruments used for quantitative radiation measurements will be calibrated annually for the radiation measured.

Appropriate calibrated radiation detection/measurement instruments will be used to perform, as necessary, the following:

- Package surveys;
- Personnel and facility contamination measurements;
- Sealed source leak tests;
- Air effluent measurements; and
- Dose rate surveys

For the purposes of this document, radiation-monitoring instruments are defined as any device used to measure the radiological conditions at the PETNET facility.

Calibration of hand and foot monitors, portable survey meters, and area monitors, will be performed by persons or companies specifically authorized by NRC, or an Agreement State to perform that function.

A list with the radiation detection instruments that is to be used in this facility is provided. The number indicated will be the minimum required. Some items may be sent out for calibration, but another instrument will serve as a back up during off-site calibration.

Radiation Detection Instruments

<u>Type</u>	<u>Manufacturer Make/Model¹</u>	<u>Number</u>	<u>Sensitivity Range</u>	<u>Units</u>	<u>Type of Use</u>
Energy compensated Side wall Beta/Gamma Exposure Rate Meter	Ludlum Model 14 C Meter High Range Internal Detector & 44-38 Side Window Probe	2	0-2000	mR/hr	Beta/Gamma Exposure Rate Surveys
Beta/Gamma Contamination Survey Meter	Ludlum Model 3 Meter coupled with 44 - 9 Pancake Probe detector	1	0-500,000	cpm	Beta/Gamma Contamination Surveys
Beta/Gamma Alarmed Ratemeter coupled with hand/body and Foot Detectors	Ludlum Model 177 Meter with 44-9 Pancake Detector & 44-26 Foot Monitor	1	0-500,000	cpm	Beta/Gamma Personnel Contamination Monitoring/Exit Monitor
Gamma Counter (NaI)	Ludlum Model 2200 With Ludlum Model 203 shielded well counter utilizing a NaI(Tl)	1	1-500,000	cpm	Stationary Single Channel Analyzer (SCA) used to count wipe tests

¹ Or equivalent to manufacturer make and model

<u>Type</u>	<u>Manufacturer Make/Model²</u>	<u>Number</u>	<u>Sensitivity Range</u>	<u>Units</u>	<u>Type of Use</u>
Alarming Area Monitor with external high volume audible alarm.	Ludlum Model 375/2	2	0.1 - 1000	mR/hr	Exposure Rate Area Monitoring
Remote Display for Alarming Area Monitor	Ludlum Model 272	1	0.1 - 1000	mR/hr	Exposure Rate Area Monitoring Remote Display
Electronic Personal Dosimeter (Alarming)	SAIC Model PD10i or 3i or Thermo EPD	3	0-999,000 0-500,000	mR mR/hr	Personnel and Visitor Exposure Monitoring
Stack Monitor	Eberline Model FHT-3511 Stack Monitor	1	5E-8 -1.3E-2	uCi/cc	Measurements of air effluents
Radiopharmaceutical Dose Calibrator	Capintec CRC-15 Dual PET	1	0-20,000	mCi	Radiochemical and radiopharmaceutical product assays
Radiopharmaceutical Dose Calibrator	Capintec CRC-127 RH	1	0-8000	mCi	Radiochemical and radiopharmaceutical product assays

² Or equivalent to manufacturer make and model

Calibration of Instruments

PETNET will use equipment that meets the radiation monitoring instrument specifications published in Appendix J to NUREG - 1556, Vol. 13, revision 1, Consolidated Guidance About Materials Licenses Program – Specific Guidance About Commercial Radiopharmacy Licenses published November 2007.

Instruments and equipment used for quantitative radiation measurements (other than dose calibrators) will be calibrated:

1. by a person licensed or registered by the Department, another agreement state, a licensing state, or the NRC;
2. at intervals not to exceed 12 months;
3. after each instrument or equipment repair;
4. for the types of radiation used and at energies appropriate for use;
5. at two points on each scale used for radiation protection purposes (at least up to 1 R/hr); and
6. at an accuracy within 10% of the true radiation level.

Records of each survey instrument calibration will be retained for at least 3 years after calibration. Records will include:

1. the original calibration certificate from the instrument vendor;
2. the date of the calibration;
3. a description of the source used and the certified exposure rates from the source;
4. the rates indicated by the instrument being calibrated;
5. the correction factors deduced from the calibration data; and
6. the identity of the individual who performed the calibration.

Survey instruments will be calibrated by a vendor licensed to perform calibrations.

3. Material Receipt and Accountability

PETNET will ensure the security and accountability of all licensed material. We have developed and will maintain written procedures that track all the licensed material from receipt or production through to final disposal in order to ensure that material will not be lost, stolen, or misplaced, and ensure that license possession limits are not exceeded.

PETNET has developed and will implement and maintain written procedures for safely opening packages that meet the requirements of 10 CFR 20.1906.

PETNET will conduct physical inventories of sealed sources at intervals not to exceed six months.

PETNET 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 removal;
- licensed material not in storage is maintained under constant surveillance or locked control; and
- records of receipt, production, transfer and disposal of licensed material is maintained.

No shipments of radioactive material will be received after operation hours and no routine radioactive material packages are expected to be received. However, occasionally, PETNET may receive radioactive material packages. Our procedures for ordering, and receiving materials during working hours are outlined below:

Ordering Radioactive Materials

The RSO must verify that the material to be ordered is within the possession limits listed in the Radioactive Material License.

Receiving Radioactive Materials

- Packages containing radioactive material will be monitored within 3 hours of receipt during normal business hours, or within 3 hours from the beginning of the next working day if packages are received after working hours.
- Check package labeling and shipping documents to insure that the material received is the material that was ordered.
- Put on gloves to prevent possible hand contamination
- Visually inspect the package for any sign of damage. If damage is noted, stop the procedure and notify the RSO.
- Measure the exposure rate of the package at one meter and on all surfaces. Compare these values to the allowable D.O.T. limits (e.g. White I, Yellow II). If these values exceed the listed maximum exposure rates, stop the procedure and immediately notify the RSO.
- Verify that the wipe test counter has passed its daily constancy.
- Wipe test the surface of the package. Wipe, using a dry wipe with moderate pressure, over at least 100 cm² of the surface of each package face.

- Place the wipe sample in the counter and count for a time sufficient to detect 2200 dpm.
- Calculate the dpm/100 cm² and record all data on the package receipt log. If the wipe test measurement is greater than 2200 dpm and the exposure rate reading is greater than 200 mR/hr then notify the RSO and CRSO immediately.

4. Occupational Dose

ALARA Program

The primary concept of the ALARA philosophy is that unnecessary exposure to radiation should be avoided. The objective is to reduce occupational exposures (both individual and collective), effluents released to the environment, and public exposures as far below regulatory limits as is reasonably achievable by means of good radiation protection planning and practice, as well as by a management commitment to policies that deter departures from good practices.

The three primary methods of minimizing exposure to radiation are: time, distance and shielding. When working with sources of radiation, workers should always minimize the time, maximize the distance, and make use of available shielding to keep exposures ALARA.

The management of PETNET Solutions, Inc. is committed to the program described herein for keeping individual and collective doses, occupational as well as public, as low as is reasonably achievable (ALARA). In accordance with this commitment, we hereby describe an administrative organization for the radiation protection program (RPP) and the development of the necessary written policies, procedures, and instructions to foster the ALARA concept within our company.

It will be a management priority that all personnel working with radioactive material and radiation producing machines be made aware of our commitment to the ALARA philosophy and that they be instructed in the procedures to be used to keep their exposures as low as possible.

Management has delegated the authority to the PETNET CRSO to ensure adherence to ALARA principles. Management will support the CRSO in instances where this authority must be asserted.

The CRSO will make all reasonable modifications to procedures, equipment and facilities to reduce exposures, unless the cost is considered to be unjustified.

Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in the judgment of the CRSO or the RSC, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, PETNET will document the reasons for not implementing them.

In addition to maintaining doses to individuals ALARA, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. All reasonable efforts will be made to decrease individual as well as collective dose.

PETNET's ALARA policy is based on the following two-tier approach. First, quarterly and annually Corporate Action Levels and "Restriction Levels" shall provide a framework for "upper boundary limits" for corporate actions. The corporate quarterly and annual ALARA "Action levels" and "Restriction" Levels are:

Type	Action Level		Restriction Level	
	Quarterly (mrem)	Annual (mrem)	Quarterly (mrem)	Annually (mrem)
Whole Body	750	N/A	1,000	4,000
Extremity	7,500	N/A	10,000	40,000

Second, quarterly site-specific ALARA levels I and II, based on dose history and facility throughput, shall provide the action levels for the facility RSO for ALARA investigations.

The site-specific ALARA Level I and the corporate Action Level are used to help prevent the individual from exceeding the site-specific ALARA Level II and corporate Restriction Level, respectively. If the site-specific ALARA Level II is exceeded an investigation is performed by the RSO. This investigation will include the root cause for exceeding ALARA Level II and the corrective actions that will be performed to prevent reaching Level II in the future. Once the RSO has completed his/her investigation a report is submitted to the CRSO for review and possibly further action. If the corporate quarterly restriction level is exceeded, the worker will be restricted from handling radioactive materials for the balance of the quarter, or the balance of the year, if the annual corporate restriction is exceeded. The site-specific and corporate levels are reviewed annually by the CRSO, and the Corporate Radiation Safety Committee (RSC) approves recommended changes.

Personnel Monitoring Program

- PETNET will evaluate the potential occupational exposures of all workers and monitor occupational exposure to radiation whenever exposure is likely to exceed 10% of the limits in 10 CFR 20.1201, 1202, 1203, 1204 and 1208. PETNET policy states that all employees whose work involves handling radioactive material will be monitored for external exposure.
- Employees that are required to be monitored will wear whole body dosimeters and extremity dosimeters.
- PETNET will eliminate the potential for airborne activity by the use of engineering controls such as an exhaust system, which is separate from the facility's HVAC equipment.

Personnel Monitoring Devices

PETNET will use appropriate dosimeters (OSL, film, TLD) that are supplied by a NVLAP-approved processor (e.g., Landauer, Inc.) to monitor for external exposure to personnel. The whole body dosimeters will normally be exchanged monthly. The extremity dosimeters will be exchanged on a weekly or monthly basis depending on the job duties.

The whole body dosimeter will monitor beta and gamma exposures to all personnel.

PETNET's workers will also be using electronic dosimeters. The exposure range for these dosimeters is from 0.0 mR to 999,000 mR. The electronic dosimeters are worn by PETNET employees as supplementary dosimeters to track real-time exposures. Electronic dosimeters are used to provide information for ALARA investigations, by tracking exposures from various tasks or identifying sources of elevated exposure. Electronic dosimeter readings will be compared to whole body dosimeter exposure reports. Therefore, electronic dosimeters will be worn in close proximity to the whole body dosimeters for accurate comparisons. Electronic dosimeters will be calibrated annually. All visitors who enter the restricted area will be required to wear a pocket dosimeter, although a single electronic dosimeter may be used to monitor a group of visitors.

Fetal Protection Program

PETNET will assure compliance with the pregnancy declaration process, mutually agreed upon work restrictions, and maintain dose to the embryo/fetus of a declared pregnant worker within the regulatory limits and with appropriate ALARA considerations. PETNET's procedure outline for declared pregnant workers is as follows:

- The employee must provide the voluntary declaration of pregnancy, in writing, to the Facility Radiation Safety Officer (RSO).
- The declaration must include an estimated date of conception for the determination of the accumulated dose the embryo/fetus may have received prior to pregnancy.
- The declaration will remain in effect until the declared pregnant worker withdraws the declaration, in writing, or is no longer pregnant.
- A second personal monitoring device (fetal badge) will be issued and worn on the abdomen in order to separately monitor the dose to the embryo/fetus during the gestation period.
- The fetal badge will be exchanged weekly.
- The fetal badge dose Action Level is 10 mrem/week.
- If the fetal badge dose exceeds the Action Level, then the RSO and CRSO must review the declared pregnant worker's work practices.

Monitoring for Internal Exposure:

All potentially volatile radionuclides are handled within ventilated enclosures that will prevent the possibility of inhalation intakes to personnel. Due to these engineering controls, prior experience, and the very high ALIs for PET nuclides, we have determined that monitoring for internal exposures is not required.

As described in Facilities and Equipment, volatile radioactive materials are only handled inside of ventilated enclosures (transfer lines, mini-cells and hot cells). These enclosures are maintained at negative pressure relative to where employees work and the enclosures remain closed during processing. An audible alarm alerts employees if the ventilation system is not functioning. Weekly tests of the ventilation system are recorded and graphed to reveal trends. Since these systems have been deployed at over 40 PETNET sites, no evidence of intakes has ever been shown from airborne radioactivity.

All systems are maintained at negative pressure. As described in emergency procedures, we have a ventilation failure alarm system and we require evacuation of an area if there is a failure. Any time there is an event in which volatile material escapes, or if there is a contamination event outside the shielded enclosures, all the instruments in the area (area monitors, Geiger counters) will reveal the presence of increased radiation levels. Everyone immediately knows of such an event and PETNET procedures require evacuation and evaluation prior to the continuation of operations

Manual intervention in the automated chemistry procedure is highly unlikely to cause an airborne release. Such interventions are typically to resolve blocked and disconnected lines. The main volatile components are N-13 gases, which are vented upon delivery from the cyclotron to the collection vial in the negative pressure cells; and, F-18 in the heating phase of the automated chemistry, where no intervention is possible. At this time C-11 is not being produced at this facility. We have never experienced releases into the room air from opening the mini-cell during chemistry unit operations.

In the unlikely event that volatile radioactivity escapes the enclosure and produces airborne activity, two methods can be employed to assess employee doses. First, the DAC for F-18 and C-11 (and other PET nuclides) is based on submersion. Therefore, whole-body dosimeters will monitor exposure. If there were intakes, urine samples would be the only method of determining uptake. Many years ago, a ventilation failure event at another PETNET site (prior to ventilation alarms) occurred and urine samples were taken; no activity was detected.

Ingestion or absorption through the skin is prevented by not handling loose, uncontained radioactive materials. PETNET has a procedure for assessing skin contamination. PETNET commits to collecting urine samples if there is ever any significant airborne release, skin contamination or evidence of nasal or mouth contamination. The very short half lives and large ALIs of the PET nuclides would require urine samples be collected and counted (via the SCA) within a few hours.

The NRC Regulatory Guide 8.32 "Criteria for Establishing a Tritium Bioassay Program" sets a standard for handling or working with HTO and other tritiated compounds that would require a bioassay program at 100 mCi (0.1 Ci) handled in a month. Since we will be storing no more than 5 mCi in a month this would not require us to have a bioassay program. Furthermore, since the Annual Limit on Intake (ALI) is 80 mCi and the regulations require individual monitoring if it is likely that an individual receives doses of 10% of the limit or more, we would not have to perform bioassays because we would possess less than 8 mCi of Tritium.

PETNET has written procedures for monitoring occupational doses that meet the requirements in 10 CFR 20 as applicable.

5. Public Dose

PETNET will demonstrate compliance with public dose limits by performing surveys and measurements in order to:

- Ensure that licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 100 mrem (TEDE) in one year from licensed activities (appropriate occupancy factors taken into account);
- Ensure that radioactive material released in gaseous effluents are constrained to less than 10 mrem per year by calculation of the annual dose to the maximally exposed member of the public (using a tool such as the US EPA COMPLY code);
- Ensure that the dose in any unrestricted area will not exceed 2 mrem in any one hour, from licensed operations; and
- Prevent unauthorized access, removal, or use of licensed material.

6. Safe Use of Radionuclides and Emergency Procedures

PETNET has developed and will maintain written procedures for the safe use of radioactive material. We employ the following rules for the safe use and storage of radioactive materials:

- Whole body dosimeters, ring dosimeters, and electronic dosimeters must be worn as required.
- Lab coats must be worn upon entrance to a radiological restricted area.
- Gloves must be worn at all times while handling radioactive materials or any potentially contaminated object.
- Procedures should be well planned with RAM area segregated to maintain occupational dose ALARA and prevent contamination and potential spills.
- Monitor hands and clothing periodically, and monitor hands, feet, and clothing upon exiting the restricted areas.
- Do not eat, drink, smoke, or apply cosmetics within the restricted areas.
- Do not transfer food through a restricted area into an unrestricted area.
- Dispose and store radioactive waste only in designated, labeled, and properly shielded containers.
- Survey your work areas frequently with appropriate survey meters to identify contamination or elevated exposure levels.
- Cover work areas with absorbent paper and change the paper frequently.
- Cover all RAM containers (vials, bottles, etc.) with lids.
- Confine RAM sources in properly shielded containers/areas, which are appropriately marked with a radiation sign/symbol.
- Store and transport RAM or activated parts in shielded containers.
- Use remote handling devices (tongs) when handling doses and activated cyclotron parts whenever possible.
- Items taken out of the restricted area must be surveyed to prevent inadvertent transfer of contamination/exposure to an unrestricted area.

Safe handling for Tritium

Due to the high cost of O-18 water, the staff at this facility are very careful in handling the O-18 water in order to ensure as little material as possible is lost. This in turn provides assurances that potential for contamination with H-3 is minimized.

Exposure Control

PETNET will provide the appropriate radiation exposure controls and implement them through the following:

- Radionuclides shall be handled in such a manner as to keep exposure and contamination ALARA;
- External radiation exposure shall be controlled and minimized through the effective use of time, distance, and shielding concepts;
- The chemistry synthesis units shall be placed within properly shielded mini-cells or other enclosures to ensure that dose to the workers is maintained ALARA;
- The routine dispensing of the radiopharmaceuticals shall be performed inside properly shielded enclosures, using remote manipulation tools. In case of temporary malfunctioning of the manipulation tools or any aspects of the shielded enclosures, the facility RSO should resolve the alternate dispensing method(s) with the CRSO;
- The Quality Control (QC) activities shall be performed behind properly designed shielding configurations;
- The DOT certified shielded packaging configurations shall be used to transfer the final products to the customers;
- Activity to be transferred within a facility shall be placed in a shielded safe, and transferred on a cart, in an effort to minimize worker exposure and potential for spills;
- Whenever practical, local shielding shall be utilized to minimize personnel exposure;
- Direct contact with an unshielded source shall be avoided;
- Remote handling devices (tongs) shall be used to transfer syringe shields, or other RAM sources; and
- Prolonged contact with RAM sources shall be avoided.

Emergency Procedures

PETNET has developed and will maintain written procedures for emergency procedures. The following procedural outline will be used to respond to a radiological spill depending upon the magnitude of the spill.

Minor Spills: (< 500 mR/hr at 1 foot)

- Notify persons in the area that a spill has occurred. Prevent the spread of contamination by covering the spill with absorbent paper, (if possible and safe) and prevent access to the area by unauthorized personnel.
- Wearing personal protective equipment (gloves, lab coat) and a dosimeter, clean up the spill using absorbent paper handled with remote handling tongs. Place the materials used in the cleanup in a plastic bag for transfer to a radioactive waste container.
- Survey the area with a low-level survey meter. If no significant level is detected, perform wipe testing of the affected and surrounding areas (including equipment, etc.) to ensure no removable contamination is detected.
- Perform personnel contamination survey on hands, shoes, clothing, and any exposed body parts to ensure no contamination is detected.
- Report the incident to the RSO.
- The RSO will follow-up on the cleanup of the spill and will complete a radioactive spill contamination survey and report.

Major Spills: (\geq 500 mR/hr at 1 foot)

- Clear the area. Notify all persons not involved in the spill to vacate the room.
- Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. Perform personnel contamination surveys and, to prevent the spread of contamination, limit the movement of personnel who may be contaminated.
- Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
- Secure the area to prevent entry.
- Notify the RSO and RP/EHS representative immediately.
- Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water washing with mild soap.
- If contamination remains, induce perspiration by covering the area with plastic or gloves. Then wash the affected area again to remove any contamination that was released by the perspiration.
- Injured persons should be decontaminated and first aid performed, as necessary. If life-threatening injuries are present, the individual should be given immediate life-saving first aid and transported to a hospital for further medical treatment regardless of any contamination present. The hospital should be given prior notification that the patient is contaminated so the appropriate controls can be implemented.

- The RSO or his designee will supervise the cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey.

Although spills are rare at PETNET due to the engineering and administrative controls in place, we have experienced spills. We have had the 500 mR/hr action level in place for many years. PETNET does not have many nuclides; therefore, we are not defining spills by activity. All the unsealed PET radionuclides have similar radiological hazards. The main hazard is from the 511 keV photons, unless there is skin contamination. A typical batch can be up to 8 Ci. When a spill occurs, it is impossible to determine what activity is involved and a radiation level action point is much more practical. One also has to consider that the maximum half life of our materials is 110 minutes (all the other nuclides have $t_{1/2}$ of 20 minutes or less).

NUREG-1556, Volume 13, Rev 1, suggests a definition of a Major Spill as 250 mCi of F-18. That activity spread over a circular area with 30 cm (1 foot) diameter results in an exposure rate of 1000 mR/hr at 30 cm (1 foot) from the center. Our action level is less than that. See Attachment J for calculation.

As to the radiation level being in excess of the definition of a high radiation area, that may be true. Our procedures require positive control of the area to prevent access [10 CFR 20.1601(b)]. An F-18 spill reading 500 mR/hr would be below 100 mR/hr in a little over 4 hours and about 10 mR/hr in 10 hours. It is our assessment that if our procedures are followed that no one would be likely to have an intake of an ALI, let alone 5 ALI, nor would any worker receive any dose triggering notification (10 CFR 20.2202). The F-18 ALI is 70 mCi or about 1% of all the potential material in a worse case. We also believe that closing down an area due to a spill does not reach the threshold for a report under 10 CFR 30.50(b)(i-iii), because it would be over in less than 24 hours.

7. Surveys

Area Survey Procedures

PETNET will make surveys (radiation and contamination) of potential radiological hazards in the workplace and records of survey results will be maintained.

Radiation surveys are used to detect and evaluate contamination of:

- Facilities (restricted and unrestricted areas);

- Equipment;
- Incoming and outgoing radioactive packages; and
- Personnel (during use, transfer, or disposal of licensed material)

Surveys are also used to plan work in areas where licensed material or radiation exists and to evaluate doses to workers and individual members of the public. Surveys will be performed daily in areas where radioactive materials (RAM) are used. Weekly surveys will be performed in the unrestricted areas and areas within the restricted area where RAM has not been used.

Exposure Rate Surveys

An outline of PETNET's survey procedures is:

- a. Gamma radiation surveys will be performed:
 - i. For routine area surveys.
 - ii. Prior to performing maintenance inside the shields.
 - iii. Prior to allowing employees to enter cyclotron restricted area following a target emergency.
 - iv. Prior to cleanup of spills to determine necessary exposure controls for personnel involved in clean-up.
 - v. After decontamination of spills to determine if residual activity remains and to determine any additional temporary exposure controls.
- b. Exposure rate surveys will be performed of all areas where radioactive materials are handled and/or stored.
- c. Exposure rate surveys will be conducted so as to be able to detect dose rates as low as 0.1 mR per hour.
- d. Exposure rate surveys indicating radiation dose rates greater than or equal to established action levels for restricted areas (10 mR/hr) and unrestricted areas (2 mR/hr) require the individual performing the survey to promptly notify the facility RSO.
- e. Corrective actions taken by the facility RSO when these exposure rate levels are exceeded must be documented and maintained on file.
- f. The exposure rate survey records will include:
 - The date of the survey;
 - The facility plan indicating the areas surveyed;
 - The exposure rate action level established for the surveys;
 - The exposure rate at several points in each area surveyed;
 - The exposure rate in each area expressed in mR/hr;
 - The instrument used to make the survey; and
 - The initials of the individual who performed the survey.
- g. Survey records will be maintained at the facility for inspection.

Contamination Surveys

- a. Wipe surveys will be performed at appropriate times during the course of a shift. Typically, contamination surveys are conducted in the restricted area at the conclusion of each day's operations; however, spills, contamination detected upon exit of the restricted area, etc. would prompt additional surveys. Wipes in the unrestricted area are conducted at least once per week.
- b. Wipe surveys will be conducted and analyzed for detection of contamination of 2200 disintegrations per minute (dpm) per 100 cm² wipe for restricted areas, and 220 dpm per 100 cm² for unrestricted areas. PETNET has used the 2200 dpm/wipe action level for years. With the 110 minute half life of F-18, 2200 dpm becomes 2000 dpm in 15 minutes. We see no difference between the two and want to preserve our national, unified program. Given that DOT packages can have up to 2200 dpm/100 cm², it seems odd that there is an issue about this.
- c. Filter paper and/or cotton swabs will be used to perform contamination surveys and the samples will be collected in plastic and/or glass tubes.
- d. A single channel analyzer with a Sodium Iodide (NaI) detector will be used to analyze the samples.
- e. Corrective actions taken by the Facility RSO when these contamination action levels are exceeded must be documented and sent to the Corporate RSO.

Record Keeping

- a. The date of the survey;
- b. The facility plan indicating the areas surveyed;
- c. The contamination and dose rate action level established for the surveys;
- d. The detected dose rate at several points in each area surveyed in units of millirem (or microsievert) per hour or the removable contamination in each area expressed in units of dpm/100 cm²;
- e. The instrument used to make the survey or count the samples; and
- f. The initials of the individual who performed the survey.

Records of the surveys and wipe tests results will be maintained for inspection for a period of 3 years.

8. Dosage Measurement Systems

Dose calibrator(s) will be used to measure the radioactivity in radiopharmaceutical doses for human medical use. Radioactive drugs will be measured prior to distribution. PETNET confirms that it has developed and will implement and maintain written procedures that comply with 10 CFR 32.72(c).

Check and Tests of Dose Calibrators Used to Measure the Activity of Each Dosage of Photon-emitting Radionuclides Prior to Medical Use:

1. The dose calibrator will be checked for constancy on a daily basis, using a relatively long-lived source, such as Cs-137 or Na-22. Variations greater than $\pm 10\%$ from the calculated source activity indicate need for adjustment and/or repair.
2. The dose calibrator will be tested for accuracy on an annual basis, after installation, and after repair by using a NIST traceable source (e.g. Cs-137). A single energy point is appropriate for this facility because all PET isotopes listed for possession (See ITEM 5. above) emit only 511 keV photons. The average measured activity must agree with the calculated activity to within less than $\pm 10\%$. If the dose calibrator fails the accuracy test, the instrument must be repaired or replaced.
3. The dose calibrator will be tested for linearity on a quarterly basis, after installation, and after repair. The linearity test will be performed with an F-18 source, based on a decay method. The measured activity at each time during the 8-hour test must be within less than $\pm 10\%$ of the calculated activity.
4. The dose calibrator will be tested for geometry upon initial installation, repair, or relocation, using an F-18 source, and the final product vial, and syringes of various sizes used for dose distribution. The tests for geometry of the final product vial will be completed before acceptance of a new supplier for the final product vial. If the variation is greater than $\pm 10\%$, a correction factor will be utilized.
5. Records will be maintained for all the above dose calibrator checks.

The following procedures will be performed for the applicable dose calibrator tests:

Geometric Independence

Test will be performed upon initial installation, repair, and relocation of the dose calibrator.

A. Vial Geometry Testing

1. Verify the display is zero. If not adjust to zero.
2. Place empty vial in the dose calibrator and press the button of the PET isotope that will be used.
3. Inject 1 mL of PET isotope into the empty vial.
4. Assay the vial and subtract the background reading.
5. Inject 1 mL of saline or water and subtract the background reading. Continue to add saline or water to achieve applicable volumes.
6. Perform the calculations using the following:
 - a. Correct the measured activity for decay and record the corrected activity.
 - b. Divide the measured activity by the corrected reference activity to obtain the correction factor.
 - c. Record the correction factor.

Repeat steps A.1 – A.6 above for all other applicable vial sizes.

B. Syringe Geometry Testing

Repeat vial geometry steps A.1. through A.6 but, use an empty syringe instead of a vial.

Note: If any of the correction factors (vial or syringe) exceed $\pm 10\%$, they must be used when assaying radioactive materials.

Linearity Test

Test will be performed after installation, repair, and at least quarterly.

Adjust the background of the calibrator to zero.

Produce activity of PET Isotope that is greater than highest dose shipped and place into calibrator.

Measure the activity at several intervals during working hours and over the following day until the assayed activity is ≤ 1 mCi.

Calculate the activity remaining, at each assay time point.

Calculate the linearity

Note: The measured activity at each time during the test must be within $\pm 10\%$ of the calculated activity.

Accuracy Test

Test will be performed after initial installation, after repair and annually.

1. Using a NIST traceable sources ≥ 50 uCi. (e.g. Cs-137), calculate the current activity of the source at the time of measurement.
2. Adjust the background of the calibrator to zero.
3. Measure and record the activity of the source using appropriate range and isotope settings.
4. Perform the process at least three times.
5. Calculate the net activity
6. Calculate the Percent Deviation

Note: The measured activities must agree with the calculated activities to within $\pm 10\%$.

Dose Calibrator Constancy Test

Test will be performed every production day.

1. Using a NIST traceable source ≥ 50 uCi. (e.g. Cs-137)
2. Adjust the background of the calibrator to zero.
3. Select the proper range and appropriate setting for the PET Isotope on the dose calibrator.
4. Compare the values to the calculated decay-corrected activity for the source.

Note: Variations greater than $\pm 10\%$ from the calculated source activity indicate need for adjustment and/or repair.

Records for the calibration tests and checks specified above will be maintained for inspection for 3 years after each test or check.

9. Transportation

PETNET will implement and maintain safety programs for the transport of radioactive materials to ensure compliance with U.S. Department of Transportation (DOT) regulations. PETNET will provide its employees with initial DOT training and annual as described in ITEM 8.

The following is an outline of PETNET's Procedure for Packaging and Shipping Radioactive Materials

Packaging

1. Attach the recipient's address label to the shipping container.
2. Place syringe shield and the prescription for the dose in the shipping container.

3. Close the container and attach a security seal to the container that will show the integrity of the package has not been breached.
4. Perform a wipe test on the outside of the shipping container and measure the wipe test to see if it is below DOT required limits (e.g. 2200 dpm/100cm²). If wipe is greater than limit decontaminate the package and do a new wipe test.
5. Record the wipe results on the Bill of Lading.
6. Survey the shipping container on all surfaces with the appropriate meter and record the highest reading on the Bill of Lading.
7. Survey the shipping container at a distance of one meter from the side with the highest surface reading and record this reading on the Bill of Lading as the Transport Index (TI).
8. Determine the appropriate DOT label based on the package surface and the TI survey DOT limits and record the label type on the Bill of Lading.
9. Complete two DOT Radioactive labels and record the contents (e.g. F-18), the activity in becquerels, and the TI (If Yellow II or Yellow III label).
10. Place the two radioactive labels on opposite sides of the container.
11. Complete the Bill of Lading, which include the shipper's certification.

Examples of the prescription labels and shipping papers to be used for shipments to customers are found in Attachment H.

Shipment

1. Ensure that a current copy of the customers RAM license is on file and that the customer is approved to receive the radionuclide and activity contained in the package.
2. All shipments must include a copy of the Bill of Lading for all couriers that will handle the package and a copy for the customer.
3. Periodically check all couriers to ensure they comply with all DOT regulations for the transport of Radioactive Materials (e.g. blocking and bracing, emergency spill kit, necessary training, proper display of shipping papers, etc.).

PETNET and contracted couriers will perform the transportation of radioactive materials to customers outside of the facility. Packages of radioactive materials shall be secured in the trunk or the cargo area of the vehicle. The packages will be properly blocked and braced in the rear of the vehicle. The vehicle will be locked at all times when radioactive material packages are in the vehicle and the driver is not in or near the vehicle. The bill of lading will be kept within arms reach of the driver when the vehicle is in transit and left on the driver's seat when the driver is not in the vehicle as required per 49CFR.

PETNET and the couriers will comply with all applicable rules and regulations regarding transportation of hazardous materials. The facility RSO will be immediately notified in the event of an incident during transportation of radioactive materials and all regulatory notifications will be made as per 49 CFR.

PETNET does not intend to receive returned contaminated materials from its customers. We do have a written procedure for returned waste, but we do not request authorization to receive such items under this license. PETNET rarely receives radioactive packages at all – mainly check and calibration sources for internal use. In the rare case where our production accelerator is down, we might receive radiochemicals from another cyclotron facility.

10. Minimization of Contamination

PETNET will provide the appropriate radioactive contamination controls and implement them through the following:

- o PETNET hot cells, mini cells, and the restricted area shall be maintained under negative air pressure in order to minimize contamination of workers or the facility, due to a potential release of airborne radiation materials;
- o The Personal Protective Equipment (PPE- gloves and lab coats) shall be utilized to minimize worker contamination;
- o Other protective clothing such as gowns, shoe covers, or caps may be necessary during emergency situations; and
- o Care should be exercised when removing PPE to prevent potential spread of contamination.

The unsealed radionuclides with half-lives less than 120 days do not pose a source of long-term contamination; however, contamination at this facility will be minimized to the extent practicable.

11. Radioactive Drug Labeling for Distribution

Distribution

For each product that will be distributed provide the radionuclide and the maximum activity for each type of container, e.g., vial , syringe, etc., and indicate the maximum radiation level to be expected at the surface of each "transport radiation shield" when the radioactive drug container is filled with the maximum activity.

Labels affixed to radioactive drugs for distribution will have the required color, symbol, and wording. See samples labels in Attachment H.

PETNET will label each "transport radiation shield" to show the radiation symbol. The label will also include the words "CAUTION, RADIOACTIVE MATERIAL", the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. The "transport radiation shield" will be constructed of material appropriate for the isotope to be transferred for commercial distribution. The "transport radiation shield" does not refer to the outer suitcase, packaging, or other carrying device, even though that barrier may provide some radiation shielding.

Distribution Operations

The distribution of radiochemicals and radiopharmaceuticals will be done under our Nuclear Pharmacy RAM license.

PETNET Solutions, Inc.'s nuclear pharmacy is licensed by the State's Board of Pharmacy and is therefore subject to the laws and regulations set forth by the Missouri State Board of Pharmacy.

PETNET Solutions, Inc.'s nuclear pharmacy will continue to serve as a production and distribution center to provide radiopharmaceuticals and radiochemicals to authorized licensees in Missouri and surrounding states.

PETNET's nuclear pharmacy will be limited to the preparation of radioactive drugs by an authorized nuclear pharmacist or an individual under the supervision of the authorized nuclear pharmacist.

12. Radioactive Drug Shielding for Distribution

Shielding provided for each radioactive drug to be distributed will be adequate to meet DOT requirements in addition to safe handling and storage by PETNET's customers to maintain occupational exposures ALARA.

Radioactive Materials Shipping Containers

All packages offered for transport will meet the requirements of 49 CFR for transport by road or air.

Generally, the packaged radiopharmaceuticals will be labeled as a Yellow II in a Type A package. For Yellow II packages, surface dose rates may range from 0.5 mrem per hour to less than or equal to 50 mrem per hour at the

highest point. Dose rates at a one meter distance may be greater than background but will be less than or equal to 1 mrem per hour at the highest point.

Some shipments may require labeling as a Yellow III if they exceed a surface dose rate of 50 mrem per hour or a one meter dose rate of 1 mrem per hour at the highest location. Yellow III packages will not exceed the limits of 200 mrem per hour surface dose rate or 10 mrem per hour at one meter for transport under non-exclusive use conditions.

PETNET's packages were designed, as a unit, to meet the range of surface and one meter dose rate limits for a Yellow II or Yellow III label for normal activity at time of shipment. All Package designs are tested to meet or exceed U.S. DOT requirements in 49 CFR 178 Subpart M. Below is a description of the main types of packages we use at this facility. DOT certificates for any type of package in use will be maintained at the facility.

Unit Dose Syringe Shipment

Lead Shield Container (case) – CQR1
4" wide X 11 3/8" tall
0.75 " wall thickness
Quick Release Syringe Shield (fits inside shield above)
Lead, 0.425" shielding with 0.20" steel, O-ring Top

Lead Shield Container (case) – CQR2
4" wide X 11 1/2" tall
0.75 " wall thickness with 1/4" overlap in the middle
Quick Release Syringe Shield (fits inside shield above)
Lead, 0.425" shielding with 0.20" steel, O-ring Top

Lead Shield Container (case) – CQR3
4" wide X 9 5/16" tall
0.75 " wall thickness with 3/8" overlap in the middle
Quick Release Syringe Shield (fits inside shield above)
Lead, 0.425" shielding with 0.20" steel, O-ring Top

Lead Shield Container (case) – CQR4
4" wide X 9 5/16" tall
0.75 " wall thickness with 1/2" overlap in the middle
Quick Release Syringe Shield (fits inside shield above)
Lead, 0.425" shielding with 0.20" steel, O-ring Top

A-Tech QR Single:

Lead Shield Container (case) – P110 – PHL51
4.60" diameter X 10.83" tall
0.32" to 1.22" lead wall thickness

Quick Release Syringe Shield (fits inside shield above)- P110-PLS50
1.97" diameter X 9.21" tall
0.32" to 0.63" lead wall thickness

A-Tech QR Double:

Lead Shield Container (case) – P2110 – PHL51
4.72" ~ 6.85" diameter X 10.83" tall
0.32" to 1.30" lead wall thickness
Quick Release Syringe Shield (fits inside shield above)- P110-PLS50
1.97" diameter X 9.21" tall
0.32" to 0.63" lead wall thickness

A-Tech Tungsten Single:

Lead Shield Container (case) – P110 – PHL45
4.49" diameter X 10.60" tall
0.32" to 1.30" lead wall thickness
Tungsten Syringe Shield (fits inside shield above)-P110- PT44
1.73" diameter X 8.86" tall
0.14" to 0.47" tungsten wall thickness

Biodex Double:

Lead Shield Container (case) – 001-783-A005
11.75" L X 11.75" W X 12.5" H
Contour lead shield with top and bottom and more lead in the vertical center
Lead Syringe Shield (fits inside shield above) – 001-785

Unit Dose Vial Shipment

For 10 ml & 30 ml vials
Outer Lead: 4.55" Dia x 6.625" Dia with 1/2" wall thickness
Inner Vial shield: 3.75" Dia x 5.55" Dia with 1" wall thickness

Bulk Shipment

Outer Lead: 5 1/12" x 7" with 2" wall thickness
Inner Lead: 1 3/8" x 2 1/2" with 1/2" thickness
Extra trap and release shield: 1 3/8" thick

PETNET reserves the right to use other Type A packages with similar designs in the future.

Table of Activity and Surface Radiation Levels from Syringe and Vial Shields³

Configuration	Yellow II package		Yellow III package	
	Max Activity (mCi)	Exposure Rates (mR/hr)	Max Activity (mCi)	Exposure Rates (mR/hr)
DW-CQR-1				
Case	226	50	904	200
Syringe Shield		3865		15458
DW-CQR-2				
Case	510	50	2041	200
Syringe Shield		8725		34901
DW-CQR-3				
Case	778	50	3113	200
Syringe Shield		13308		53232
DW-CQR-4				
Case	1943	50	7773	200
Syringe Shield		33230		132918
A-Tech QR Single				
Case	2725	50	10900	200
Syringe Shield		35855		143421
A-Tech QR Double				
Case	3143	50	12570	200
Syringe Shield		20674		82697
A-Tech Tungsten Single				
Case	1075	50	4300	200
Syringe Shield		11715		46860
Biodex				
Double	259	50	1035	200

³ Exposure rates are at time of shipment, not necessarily at time of use. Syringe configurations are designed to hold individual syringes in individual transport radiation shields. Customers are expected to maintain doses in the package with integral shielding until just prior to injection. Typical PET doses are 10-30 mCi at time of injection.

13. Leak Tests

Leak tests performed at the frequency no greater than every 6 months to identify defective sources. Leak Tests of Sealed Sources are conducted according to the following requirements by trained personnel

- The sealed source is tested for leakage before its first use unless we have a certificate from the supplier indicating that the sealed source was tested semiannually before transfer to PETNET;
- The sealed source is tested for leakage at least semiannually or at intervals approved by the license and NRC;
- The leak tests must be capable of detecting 0.005 microcuries of radioactive material on the test sample; and
- Test samples are taken from the sealed source on which radioactive contamination might be expected to accumulate.

Process for Performing Leak Testing and Analysis

- For each source to be tested, identifying information such as sealed source serial number, radionuclide, and activity are documented.
- A separate wipe sample (e.g., cotton swab or filter paper) is used for each source.
- Each wipe is numbered to correlate with identifying information for each source.
- The most accessible areas of a sealed source where contamination could accumulate are wiped tested for leakage. Proper instrumentation is used that is sensitive enough to detect 0.005 microcuries of the radionuclide.
- Using the selected instrument, the leak test sample count and background count rate is measured, and recorded.
- The instrument's counting efficiency is checked using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics.
- The leak test data and calculations will be signed and dated by the individual performing the test and reviewed by the facility RSO. Records are retained for 3 years. If the wipe test activity is 0.005 microcuries or greater, the source will be withdrawn from use and evaluated for future action.

It should be noted that PETNET will not provide leak testing services or perform analysis of leak test samples for sources owned or possessed by other licensees.

ITEM 11: Waste Management

- A. PETNET Solutions, Inc. facility will maintain written procedures for waste management that meet the requirements of the NRC Regulations. Radioactive waste will be disposed of in accordance with regulatory requirements and license conditions. Appropriate records of waste disposal will be maintained.

The table below includes the types and retention times for the records that PETNET will maintain

Receipt	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer
Disposal	Until NRC terminates the license
Important to decommissioning	Until the site is released for unrestricted use

- B. No radioactive material is released into the sanitary sewers.
- C. Waste will not be disposed through on-site incineration.
- D. Disposal By Decay-in-Storage (DIS)
- i. Radioactive waste materials with half-lives of less than or equal to 120 days will be disposed by DIS. Adequate space and facilities are available for the storage of such waste. Procedures for management of waste by DIS include methods of segregation, surveys prior to disposal, and maintenance of records of disposal for radionuclides with half-lives greater than two hours.
 - ii. Waste for DIS is stored in properly shielded storage to decay until indistinguishable from background. After the decay period, surveys will be performed on the waste. If the surveys indicate waste is indistinguishable from background the waste will be disposed in normal trash. If surveys indicate activity above background, the waste will be held longer to decay until surveys indicate no activity above background. All radioactive signs and labels on the outside of the container will be removed or defaced prior to disposal of the waste.
- E. Long-lived Waste

- i. Long-lived radioactive waste with half-lives greater than 120 days are stored for future off-site disposal.
- ii. Long-lived radioactive waste will be disposed in accordance with NRC Regulations.

ITEM 12: License Fees

This is a new license application. From a review of 10 CFR 170.31 the fee to be submitted should be \$7,400. The fee category is 3C: Licenses issued under 10 CFR 32.72 and/or 10 CFR 32.74 that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material.”

A check for the amount of \$7,400 is included with this initial application.

ITEM 13: Certification

PETNET's Corporate Radiation Safety Officer, David J. Krueger, CHP, has been delegated the authority by PETNET's management to manage the corporate radiation protection program, which includes leading all areas of radiological compliance and safety within the company. In addition Mr. Krueger and his staff have been given authority to sign and commit the corporation on correspondences to agencies on radioactive materials license amendments and applications. Enclosed under this item is a copy of the delegation of authority and signature authority letters. In addition, an organizational chart shows the structure to explain the reporting and lines of authority.

PETNET Solutions

To: All PETNET Solutions Employees

Re: Delegation of Authority: Radiological Compliance Program

Date: July 13, 2009

David Krueger has been appointed Corporate Radiation Safety Officer (CRSO) for PETNET Solutions (PETNET), effective July 13, 2009. In this capacity, David has the responsibilities for the safe use of radioactive materials and radiation producing machines, and transportation of radioactive materials. The CRSO is responsible for managing the corporate radiation protection program, identifying radiation protection related issues, initiating, recommending, or providing corrective actions, verifying implementation of corrective actions, and ensuring compliance with regulations. The CRSO is hereby delegated the authority, organizational freedom, and management prerogative to:

1. Provide leadership in all areas of radiological compliance and safety;
2. Establish and facilitate implementation of the radiological compliance related programs and policies, and procedures;
3. Foster the corporate ALARA program and radiological safety culture;
4. Have unhampered access to all activities at PETNET facilities involving radioactive materials and radiation producing machines, and any other relevant organizational units to identify radiation protection related issues;
5. Immediately stop, without coordination with management, any activity involving the use of licensed materials by any user that might result in an unsafe situation or a violation of NRC/Agreement State/DOT requirements;
6. Initiate, recommend, or implement appropriate corrective actions;
7. Verify the implementation of actions taken to correct radiation protection related issues and promote a continuous improvement program; and
8. Coordinate the Corporate Radiation Safety Committee (RSC) activities.

All employees of PETNET Solutions have a critical responsibility in ensuring the safe use of radioactive materials. "The health and safety of our employees, customers, and community will never be compromised."

Sincerely,



Thomas E. Welch
CEO, PETNET Solutions, Inc.

PETNET Solutions

Regulatory Signature Authority

I understand that all statements in the radioactive materials license applications or amendments, cyclotron registration/licenses and environmental permits to State and Federal Regulatory Agencies, including those previously made, as well as those made in the future, are considered legally binding.

I hereby delegate responsibility for future radioactive materials, cyclotron and environmental applications, licenses, permits, and registrations to be signed by the following individuals:

Name: David J. Krueger, CHP Title: Corporate Radiation Safety Officer

Phone Number: (818) 620-6569

Name: Christi Elam Title: Regional Health Physicist

Phone Number: (865) 218-2235

Name: Frank Plastini Title: Regional Health Physicist

Phone Number: (518) 357-8645

Name: Delia Maldonado-Ortiz Title: Regional Health Physicist

Phone Number: (865) 218-3239

Name: Kerry Barnett Title: Env. Health & Safety Specialist

Phone Number: (865) 218-2537

Signature and Title of Certifying Official:

 July 23, 2009
Signature

Thomas E. Welch
CEO, PETNET Solutions, Inc.

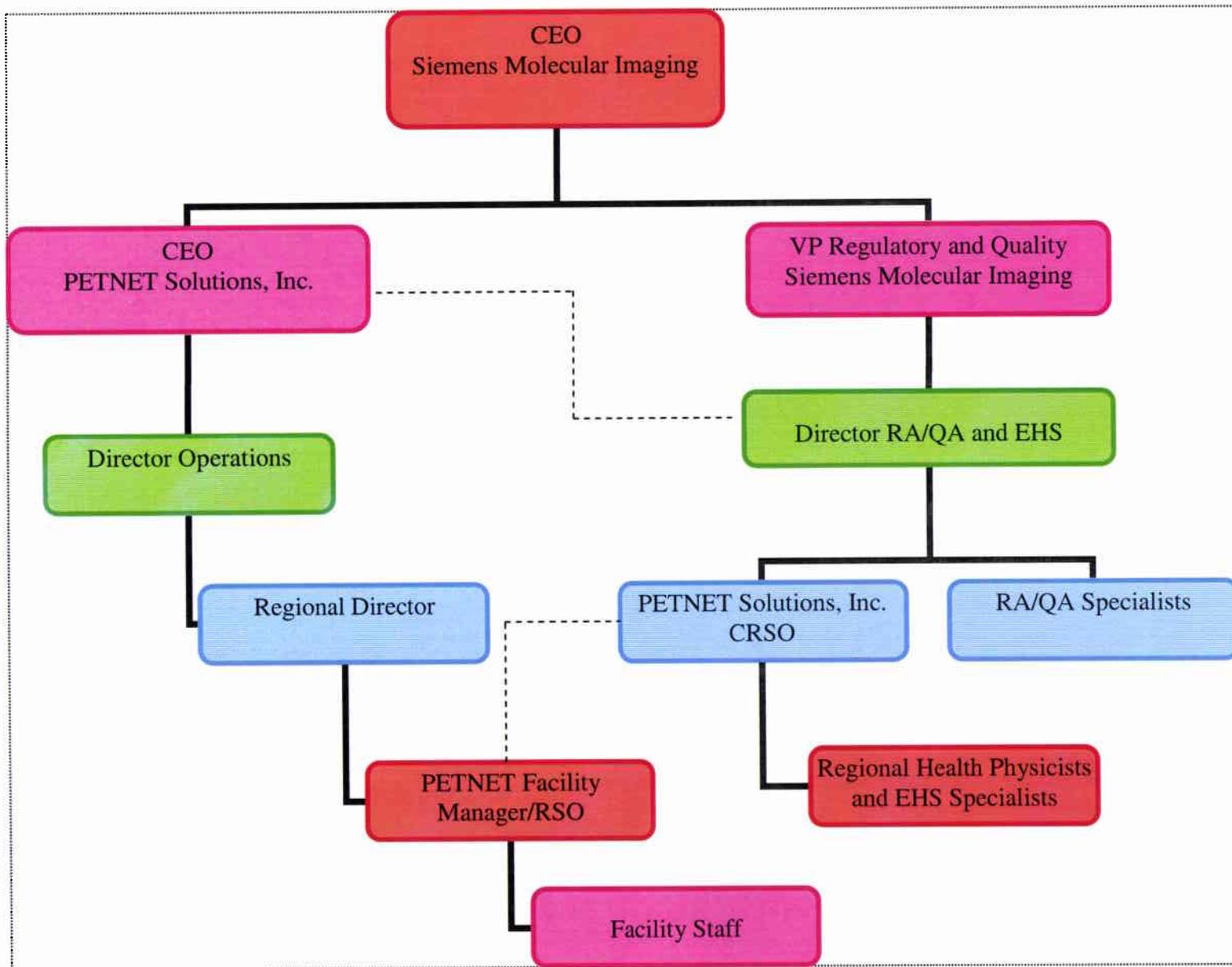
PETNET Solutions, Inc.
A Siemens Company

810 Innovation Drive
Knoxville, TN 37932

Tel: (800) 738-0488
Fax: (865) 218-3018

PETNET Solutions, Inc. Management Structure

This chart shows reporting paths and flow of authority between Executive Management and the Radiation Safety Officers. In addition, it shows reporting path for PETNET's Radiation Protection/EHS Department's Management.



ATTACHMENT A: PETNET Solutions, Inc. (St. Louis) Missouri Board of Pharmacy License

State of Missouri

Department of Insurance, Financial Institutions and Professional Registration
Division of Professional Registration
Missouri Board of Pharmacy
Pharmacy



VALID THROUGH OCTOBER 31, 2009
ORIGINAL CERTIFICATE LICENSE NO. 207744819
John J. Beyer - 045306

PETNET SOLUTIONS, INC.
PETNET SOLUTIONS, INC.
JOHN J. BEYER, PIC
3636 VISTA AVE, 1ST FLOOR
SAINT LOUIS MO 63118
USA

Selma C. Ringgenberg
EXECUTIVE DIRECTOR

David J. Broeker
DIVISION DIRECTOR

ATTACHMENT B: Training and Experience for the Facility RSO and CRSO

Facility RSO, Rita Gentilcore, MS, RPh

Rita Gentilcore

– Curriculum Vitae –

Curriculum Vitae

Rita Gentilcore

6033 Terri Lynn Drive
St. Louis, MO 63123
(314) 832-6263

EDUCATION: University of Southern California.
M.S. in Radiopharmacy, 1976

St. Louis College of Pharmacy, B.S. in Pharmacy, 1975. Minor: Chemistry

**HONORS
AND AWARDS:** Rho Chi Honor Society
Fellowship: Veterans Administration Traineeship Program in Radiopharmacy,
1975-6
Honored Member Strathmore's Who's Who 2001-2004 editions

**PROFESSIONAL
EXPERIENCE:**

Nuclear Pharmacist
PETNET Solutions, Inc.
July 2001-present

Adjunct Clinical Instructor
St. Louis University (formerly Veterans' Administration) Technologists' Training
Program, St. Louis, Missouri
September 1987-2001

Associate Professor In Pharmacy Practice
St. Louis College of Pharmacy, St. Louis, Missouri
September 1981-present

Nuclear Pharmacist
St. Louis University Hospital, St. Louis, Missouri
September 1976-July 2001

P.E.T. Pharmacist
St. Louis University Hospital, St. Louis, Missouri
July 1991-July 2001

Instructor in Radiopharmaceuticals
Veterans Administration Technologists' Training Program, St. Louis, Missouri
September 1976-September 1987

PUBLICATIONS: Journal articles (6), Book Chapter (1), Abstracts (23)

**ACTIVITIES/
PROFESSIONAL
SOCIETIES:**

Academy of Molecular Imaging
American Pharmaceutical Association
Greater St. Louis Society of Nuclear Medicine Technologists
Society of Nuclear Medicine
Missouri Valley Chapter of the Society of Nuclear Medicine
*Secretary/Treasurer
American Society of Hospital Pharmacists
Member, St. Louis University Radiation Safety Committee 1987-present
Member, PETNET Radiation Safety Committee, 2002-2006

PHARMACY LICENSURE:

Registered Pharmacist, Missouri, by examination

REFERENCES: Available Upon Request

Curriculum for Ms. Gentilcore's Master of Science in Radiopharmacy

AUG-06-2009 09:23

From: 3142697507

Page: 8/13

D. Curriculum for the M.S. in Radiopharmacy

The M.S. in Radiopharmacy requires the completion of 36 units as outlined below. This Program is scheduled to be completed in a 3 semester (one calendar year) sequence. The first semester consists of 16 units, Biomed. Chem. 615L-618L. The second semester also consists of 16 units, Biomed. Chem. 619L-621L and Biomed. Chem. 590 (Research and Seminar). The last semester (summer session) consists of Biomed. Chem. 619, which involves a 3 months residency in a center for nuclear medicine, and may be performed at any suitable location in the country that has been approved and so designated by the Radiopharmacy Committee.

A student may transfer up to eight units of course credit to the Program, provided that the Radiopharmacy Committee considers such courses taken at other universities to be academically equivalent.

E. Description of Course Offerings

BIOMEDICINAL CHEMISTRY 615L

Physical Foundations of Radionuclides (4)

Nuclear physics, production of radionuclides and nuclear chemistry; the interaction of nuclear radiation with matter; radiation detection and nuclear medical instrumentation.

BIOMEDICINAL CHEMISTRY 616L

Chemical and Biological Effects of Ionizing Radiation (4)

Radiochemistry; radiation chemistry; dosimetry; chemical dosimetry; radiolysis and auto-oxidation; properties of metastable species; free radicals; radiation biology; and radioprotective agents.

BIOMEDICINAL CHEMISTRY 617L

Synthesis and Purification of Labeled Compounds (4)

General principles, nomenclature, selection of radionuclides, synthetic and biosynthetic methods, purification of labeled compounds; preparations with short-lived radionuclides.

BIOMEDICINAL CHEMISTRY 618L

Metabolism of Labeled Compounds (4)

General principles; toxicity; modes of administration to biological species; radiochemical purity; specificity of the label, exchangeability; body pools, compartments, turnover; catabolism of labeled compounds.

BIOMEDICINAL CHEMISTRY 619L

Health Physics; Dosimetry (4)

Principles of health physics; radiation hazards; health physics instrumentation and records of exposure; local, state and national laws and regulations; shielding, decontamination and dosimetry.

BIOMEDICINAL CHEMISTRY 620L

Radiopharmaceutics (4)

Principles of Radiopharmaceutics, "official", new, and extemporaneous radiopharmaceuticals; dosage forms; quality control; records; radio-chemistry laboratory; design of new compounds; industrial production, use in manufacture, and research.

BIOMEDICINAL CHEMISTRY 621L

Elements of Nuclear Medicine (4)

Introduction; desiderata of tracers; scanning agents and metabolic function agents; diagnostic and therapeutic agents. Fundamentals and principles of nuclear medicine.

BIOMEDICINAL CHEMISTRY 590**Research and Seminar (4)**

Research in radiopharmacy, including seminars, review of the literature and conferences on special topics.

BIOMEDICINAL CHEMISTRY 629**Internship in Radiopharmaceuticals (4)**

Participation in supervising the preparation, purchasing, storage and dispensing of radiopharmaceuticals in a hospital or nuclear medical clinic; record maintenance; preparation of doses; assistance in research.

P. Internships

After consultation with the Radiopharmacy Staff, internships are arranged according to availability and desires of the student with regard to geographical, financial, and field of interest considerations.

A list of the internships served by the class of 1970 is included to offer some indication of the possibilities.

Morton Barak	Donner Laboratories University of California Berkeley, California
Clyde N. Cole	Letterman General Hospital Presidio, San Francisco, California
Nelson Der	Peter Bent Brigham Hospital Harvard Medical School Cambridge, Massachusetts
Ted Blankamp	LAC/USC Medical Center Los Angeles, California
Raymond Parks	National Institutes of Health Bethesda, Maryland
Allan Gobuty	William Beaumont Hospital Royal Oak, Michigan
Tomu Kawada	V. A. Center, Los Angeles; V. A. Center, Palo Alto, California
Richard Keenan	Upstate Medical Center Syracuse, New York
Joseph Litvack	V. A. Sepulveda, California
Cecilia Motra-Otero	Brookhaven National Laboratory Upton, L.I., New York; C.S.A., Seeluy, Paris, France
Kenneth Petrucci	Chicago Wesley Memorial Hospital Chicago, Illinois
Bennett M. Zwicker	V. A. Center, Los Angeles, California

G. Application Procedure

Inquiries and requests for application forms should be directed to Dr. Walter Wolf, Director, Radiopharmacy Program, University of Southern California, Los Angeles, California, 90007.

In order to process the completed application, it is necessary to complete the following steps:

1. Submission of the completed application form to the Office of Admissions, together with the application fee.
2. Submission of two transcripts from each college or University attended, to the Office of Admissions.

Ms. Gentilcore is listed as an ANP in NRC License No. 17-32715-01MD:

NRC FORM 374 U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 3 PAGES Amendment No. 01

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		In accordance with letter dated May 8, 2009.
1. Pioneer Pharmacy		3. License number 17-32715-01MD is amended in its entirety to read as follows:
2. 7525 Picardy Avenue Suite 120 Baton Rouge, LA 70808		4. Expiration date December 31, 2018
		5. Doctel No. 030-37831 Reference No.
6. Byproduct, source, and/or special nuclear material:	7. Chemical and/or physical form	8. Maximum amount the licensee may possess at any one time under this license
A. Molybdenum-99	A. Any	A. 60 curies
B. Technetium-99m	B. Any	B. 60 curies
C. Radium-201	C. Any	C. 500 millicuries
D. Any byproduct material authorized under 10 CFR 35.65	D. Sealed sources	D. 30 millicuries
E. Depleted Uranium	E. Metal	E. 600 kilograms

9. Authorized use:

A. through C. Preparation and distribution of radioactive drugs to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals to authorized recipients for nonmedical use.

D. Calibration and checking of the licensee's instruments.

E. Shielding for molybdenum-99/technetium-99m generators.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at Pioneer Pharmacy, 1968 Innerbelt Business Center, Overland, Missouri.

11. Licensed material shall be used by, or under the supervision of:

2002

Pioneer Pharmacy

1968 Innerbelt Business Center, Overland, Missouri

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
17-32715-01MD
Docket or Reference Number
030-37831
Amendment No. 01

- A. Monitors byproduct material at the surface before disposal and determines that its radioactivity can be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding;
- B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee;
- C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
- 19. The licensee is authorized to retrieve, receive, and dispose of radioactive waste from its customers limited to radiopharmacy-supplied syringes and vials and their contents.
- 20. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, Packaging and Transportation of Radioactive Material.
- 21. Except as specifically provided otherwise in this 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 U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated September 4, 2008;
 - B. Letter dated October 8, 2008, and
 - C. Facsimiles dated November 21, 2008 and July 24, 2009.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

AUG 04 2009

Date _____

By: *Toye L. Simmons*
Toye L. Simmons
Materials Licensing Branch
Region III

Training Certificate

This certificate is awarded to

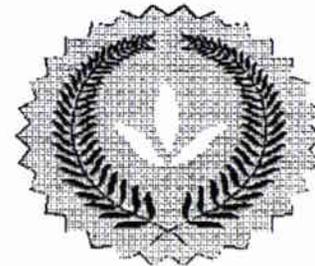
Rita Gentilcore

In recognition of successful completion of

Radiation Protection

Ashok Dhar & Roger Moroney
Instructor

11/07/2001;11/08/2001
Dates of Training



 **PETNet™** Pharmaceuticals, Inc.
Fueling the Power of PET

Training Certificate

This certificate is awarded to:

Rita Gentilcore

In recognition of successful completion of the Transportation of Radioactive Materials Class, on regulations of the United States Department of Transportation, concerning the legal transportation of materials designated as hazardous and for achieving a passing grade.

D.O.T./Hazardous Materials Training

November 15-17, 2002

This training is designed to satisfy the General Awareness, Function-Specific and Safety Training Requirement of 49 CFR 172.704(A). Training was conducted at PETNET Pharmaceuticals, Inc. in Overland Park, Kansas.

Ashok Dhar

Instructor Name

Ashok Dhar

Instructor Signature

February 21, 2003

Date Issued



Ms. Gentilcore's Pharmacist License

State of Missouri

*Division of Professional Registration
Pharmacist*

VALID THROUGH OCTOBER 31, 2018
ORIGINAL CERTIFICATE LICENSE NO. 029088
RITA C GENTILCORE
6033 TERRI LYNN DRIVE
SAINT LOUIS MO 63123
USA

RITA C GENTILCORE
6033 TERRI LYNN DRIVE
SAINT LOUIS MO 63123
USA



David J. Krueger, CHP

Professional Experience

2005-Present

Siemens
Molecular
Imaging,
Knoxville, TN

Corporate RSO, PETNET Solutions, Inc. and Siemens Biomarker Research,

- Responsible for managing radiological compliance at 50 manufacturing/pharmacy facilities involved in production of PET radiopharmaceuticals and two biomarker research facilities. Conduct compliance audits. Manage license amendments/renewals. Interface with industry groups (CORAR) on new regulatory initiatives. Responsible for stack monitoring and skin dose assessment. Review of new and remodeled facility plans for compliance purposes.

2002-2005

Syncor/
Cardinal Health
Woodland Hills, CA

Senior Manager Health Physics

- Responsible for managing a staff of seven in the support of 200 radioactive material licenses for a network of nuclear pharmacies and cyclotrons. Responsible for reporting health physics data to the Corporate Radiation Safety Committee. Performed research on hand exposure; met with NRC in the development of industry standards on the adequacy of finger dosimeters. Ran a multi-disciplinary committee to approve new products for use in the compounding and delivery of radiopharmaceuticals. Perform internal regulatory compliance audits. Taught ANP classes.

1999-2001

Reliable Ballast,
Inc, Stanton, CA

President

- Ran family-owned electronics business (electronic ballasts for HID and compact fluorescent lighting). Manufacturing in China and US/European distribution. Sold 2001

1995 – 1999

ICN
Pharmaceuticals
Costa Mesa, CA

Director Environment, Health & Safety

- Responsible for Corporate-wide EH&S compliance. Audited six North American facilities involved in manufacturing, distribution and research of pharmaceuticals, radioimmunoassay kits, radiochemicals, biochemicals and dosimetry service. Manage the radioactive materials licenses for four divisions as Corporate RSO. Manage radioactive, hazardous, and infectious waste programs. Developed Chemical Hygiene, Respiratory Protection, Bloodborne Pathogen, Illness & Injury Prevention Programs, including training of staff and researchers. Oversaw asbestos monitoring and abatement programs. Developed and administered licenses, permits and certificates for use, storage, release and disposal of hazardous materials. Report to Worldwide Vice President for Manufacturing. Supervised eight employees. Interface with Customer Service, Maintenance, Sales and Operations Departments to comply with the myriad of EPA, NRC, and OSHA regulations. Managed remediation projects (radioactive and chemical clean ups at legacy sites).

1987 – 1994

ICN
Biomedicals, Inc
Irvine, CA

Radiation Safety Officer/Health Physicist

- Day-to-day management of Radiochemical Division Safety Program. Designed and built a kilocurie tritium vacuum system. Responsible for surveys, inventory, waste, air and water monitoring. Responsible for employee/staff training in radiation and chemical safety. Developed license renewal package, including establishment of new regulatory limits (ALI & DAC) for C-14 bioassay and air sampling. Established a Hazard Communication/Chemical Hygiene Plan, Waste Water Management, computerized chemical inventory system. Chair of Facility Safety Committee.

1985 – 1987

University of
California

Health Physicist

- Responsible for the decommissioning of a 100 kW Research Reactor. Planned and implemented the dismantling and disposal of the reactor components. Radiation safety inspections at the Medical Center, Engineering and Biochemistry Departments. Established in

Los Angeles, CA

house instrument calibration program. Assisted in the development of the Radiation Safety Training Program for faculty and students. Assisted in the auditing of several cyclotron facilities
Designed x-ray shielding.

1983 - 1985

University of
Illinois
Urbana, IL

Health Physicist

- Responsible for all laboratory surveys. Rotated through as: Health Physicist at a 1.5 MW research reactor; Accelerator HP at a 67 MeV Linac; Veterinary Medicine School HP; Trainer for x-ray machine users and support staff (police, fire).

1983 – Present

Consulting
Various Locations

- Decommissioning Plans/Remediation: Ford Aerospace/Noral in Newport Beach, CA – 1994
Nuclear Engineering Corp. in West Mifflin, PA – 1997-9; ICN Radiochemicals in Irvine, CA, (in association with NES) – 2000.
- Exposure Investigations: Western Digital, Irvine, CA – 1990; ITT (x-rays) in Costa Mesa, CA 1991; Uranium contaminated home in Garden Grove, CA (*OC Register*) – 1990.
- Design of a Radiochemical Labeling Facility: Amgen, Thousand Oaks, CA – 2005-6.

Education

1983

University of Illinois

Urbana, Illinois

Bachelor Degree: Nuclear Engineering

- Focused on Bioengineering and Health Physics. Graduate-level work in Radiation Biology

Short Courses & Seminars

- Health Physics Society Professional Development Schools:
Accelerators 2008, Public Protection from Terrorism 2004, Internal Dosimetry 2003,
Non-ionizing Radiation 1997, Internal Dose Assessment 1994, Radiation Biology 1991,
- Multi-day Courses
Hazardous Waste in California, 2009, PETNET Radiation Safety Officer 2005, OSHA 16-
hour Small Qty Spill Response 1997, Hazardous Waste Management Annually 1994-1998,
Internal Dose Assessment 1989, Implementation of the New 10 CFR 20 1992, Incineration
of Radioactive Waste 1986, Hazardous Materials Transportation, 1984
- Single Day or Shorter
 - Medical Internal Dose Assessment 2006, Skin Dosimetry and Varskin 3 2006,
 - Neutrons – Sources, Detection and Safety 2006, EPCRA Compliance 1998,
 - OSHA Recordkeeping Compliance 1997, Asbestos Awareness/Worker Training 1996,
 - Workers Compensation Management 1996

**Accreditations &
Assignments**

Certification in Comprehensive Health Physics, American Board of Health
Physics. Diplomate, American Academy of Health Physics. 1990. Recertified through 2012.

Clinical Instructor, Univ. of Arkansas for Medical Sciences, School of Pharmacy,

2002-2005

**Professional
Memberships**

Health Physics Society: Plenary member since 1983. So. Cal. Chapter Secretary 1990-
1992, President 1992-94.

California Radioactive Materials Management Forum: Board Member 1995-1999, Chair
1998-99.

**Publications
& Papers**

"Assessment of Hand Exposures from Nuclear Pharmacy Operations Using a Multi-element Glove Dosimeter," D.J. Krueger, J.L. Coffey, W. Regits, C.T. Walters, J. Gray. Presented at the 50th Annual Meeting of the Health Physics Society, Spokane, WA. 2005

Radiation Safety: Handbook for Laboratory Workers in the USA, Eileen D. Hotte and David J. Krueger (HHSC Handbook No. 25, 2000), ISBN 0-948237-37-6. ©2000, Association of University Radiation Protection Officers, UK.

"Radiation Surveys of Decorative Uranium Glazed Tile Found in Los Angeles Area Residences", J.H. Kleck, S.H. Benedict and D.J. Krueger. Presented at the 34th Annual Meeting of the Health Physics Society, 1989 (poster)

"Residual Radioactivity in Ash from Incineration of Animal Carcasses Labeled with Radioactive Microspheres", D.J. Krueger and J.E. McLaughlin. Presented at the 1987 Conference on Incineration of Radioactive and Mixed Wastes, St. Charles, IL.

"Characterization of X-rays Produced at a Continuous Current Tokamak", D.J. Krueger and J.H. Kleck. Presented at the 20th Mid-year Symposium of the Health Physics Society, Reno, NV. Published in the Proceedings, 1987

"Health Physics Considerations at a Neutron Therapy Facility Cyclotron", J.H. Kleck, D.J. Krueger, J.E. McLaughlin and J.B. Smathers. Presented at the 20th Mid-year Symposium of the Health Physics Society, Reno, NV. Published in the Proceedings, 1987

ATTACHMENT C: Most Recent MO RAM Registration



Missouri Radiation Control Program

PENDING Re-Registration of Radioactive Materials



P.O. Box 570 1617 Southridge, Jefferson City MO 65102 Phone: 573-751-6083 Fax: 573-751-6158

DHSS Registration # **6145** Facility **PETNET SOLUTIONS, INC / St. Louis Univ Hospital, 1st Floor** PHONE: (314) 577-8800

FAX: **314-268-7507** Address **3635 VISTA AVENUE** ST. LOUIS MO 63110

County **ST LOUIS** Alternative Address:

Parent Facility: **SIEMENS MEDICAL SOLUTIONS USA, INC** Physician

Primary Facility Contact Person: **Roger Moroney, Corp RSO** Radi Safety Officer: **Rita Gentileone, R.Ph., Facility RSO**

Radioactive Materials Authorized Users

Current RAM Registration Date: **09/21/2005**

Approval is pending based on successful completion and submission of this form.

Registration Expires: **August 10, 2009**

Note: Please include all NRC regulated RAM on this form, although this will not be included in the final version sent back to you.

RAM comment:

Isotope Symbol/Name	Max Qty	Chemical/Physical Form	RAM Usage	Usual Dose
C 11 Carbon 11	2 Ci	Any	Radiopharmacy	unknown
Ce 56 Cobalt 56	200 mCi	Activated foils	Byproduct activation	unknown
Ce 57 Cobalt 57	100 mCi	Activated foils	Byproduct activation	unknown
Ce 67 Cobalt 67	12 mCi	Sealed source	Check source	unknown
Ce 68 Cobalt 68	10 mCi	Activated target body	Byproduct activation	unknown
Ce 64 Cobalt 64	10 mCi	Activated magnet coils	Byproduct activation	unknown
Cu 60 Copper 60	50 mCi	Activated foils	Byproduct activation	unknown
Cu 61 Copper 61	25 mCi	Activated foils	Byproduct activation	unknown
F 18 Fluorine 18	10 Ci	Any	Radiopharmacy	unknown
Hf 181 Hafnium 181	50 mCi	NRC- Activated target body	Byproduct activation	unknown
Mn 47 Manganese 47	10 mCi	Activated magnet coil	Byproduct activation	unknown
Mn 52 Manganese 52	200 mCi	Activated foils	Byproduct activation	unknown
Mn 52m Manganese 52m	200 mCi	Activated foils	Byproduct activation	unknown
Mn 54 Manganese 54	10 mCi	Activated magnet coils	Byproduct activation	unknown
Mn 56 Manganese 56	10 mCi	Activated magnet coils	Byproduct activation	unknown
N 13 Nitrogen 13	200 mCi	Any	Radiopharmacy	unknown
Na 22 Sodium 22	500 uCi	Sealed source	Check source	unknown
Na 24 Sodium 24	10 mCi	NRC regulated- magnet coil	Byproduct activation	NRC Material
O 15 Oxygen 15	5 Ci	Any	Radiopharmacy	unknown
Ta 182 Tantalum 182	50 mCi	Activated target body	Byproduct activation	unknown
V 47 Vanadium 47	10 mCi	Activated foils	Byproduct activation	unknown
V 48 Vanadium 48	75 mCi	Activated foils	Byproduct activation	unknown
W 181 Tungsten 181	100 mCi	Activated target body	Byproduct activation	unknown
Zn 63 Zinc 63	2500 mCi	Activated target body	Byproduct activation	unknown
Zn 65 Zinc 65	25 mCi	Activated target body	Byproduct activation	unknown

Signature of Facility Representative: *[Handwritten Signature]* RPH Title: *Facility RSO, Physicist* Date Signed: *8-13-07*

Wednesday, August 08, 2007

Page 1 of 1

ATTACHMENT D: Training and Experience for Authorized Users

Notes: Agreement State licenses listing individual Authorized Nuclear Pharmacists/Authorized Users are considered evidence of having achieved the training and experience requirements of 10 CFR 35.55

COPY

Training Certificate

This certificate is awarded to

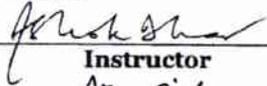
John Beyer

In recognition of successful completion of

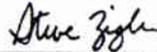
Radiation Protection Training

Ashok Dhar

Instructor



Instructor



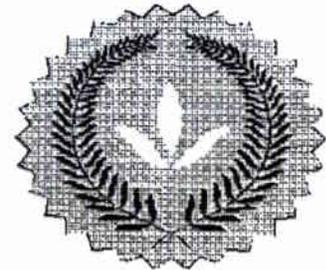
Training Manager

April 29, 2002

Date Issued

02/21/2002;02/22/2002

Dates of Training



Pharmaceuticals, Inc.

Fueling the Power of PET

COPY

Training Certificate

This certificate is awarded to

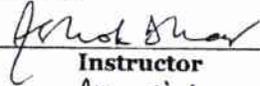
John Beyer

In recognition of successful completion of

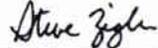
DOT Training

Ashok Dhar

Instructor



Instructor



Training Manager

April 29, 2002

Date Issued

02/22/2002

Dates of Training



PET.Net[®]

Fueling the Power of PET

Pharmaceuticals, Inc.

Mr. Beyer's Pharmacist license

Missouri Division of Professional Registration

Page 1 of 1

Detail

Licensee Name:	Beyer, John J
Profession Name:	Pharmacist
Address:	
Address Con't:	
City, State Zip:	Brentwood, MO 63144
County:	St. Louis County
Practitioner DBA Name:	
Certification Type:	
Classification:	
Licensee Number:	045306
Original Issue Date:	8/24/1999
Expiration Date:	10/31/2010

Current Discipline Status: None



Missouri Division of Professional Registration

3605 Missouri Boulevard
P.O. Box 1335
Jefferson City, 65102-1335
573.751.0293 Telephone
800.735.2966 TTY
800.735.2466 Voice Relay
profreg@pr.mo.gov
<http://pr.mo.gov/>

<https://renew.pr.mo.gov/licensee-search-detail.asp?passkey=1289543>

2/9/2009

Ranjit Bera, Ph. D.

Resume

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LANAJIT K. BERA

1405 Cedar Bluff Dr. Ballwin, MO 63021. Ph. (314) 861-2160

Office: PETNet Pharmaceuticals, Inc. Saint Louis University
Hospital, 1325 South Grand Blvd. Saint Louis, MO 63110

EDUCATION

Honores Hindu University, Varanasi, India; Ph.D. Nuclear & Radiochemistry: 1976.
I. I. T., India, M.S. Inorganic & Analytical Chemistry: 1970.
Calcutta University, India, B.S. Chemistry, Physics & Mathematics: 1968.

PROFESSIONAL AND RESEARCH EXPERIENCE

1/2001 - Present PETNet Pharmaceuticals at Saint Louis University Hospital,
St. Louis, MO
Chemist

Large scale manufacturing of F-18 FDG including cyclotron operation,
radiosynthesis and quality control following SOP's, GMP's, GDP's. Also, worked
on F-18 Fluoride production and quality control.

07/91 - 6/2001 Saint Louis University Medical Center, St. Louis, MO
Assistant Research Professor

Principal job included running the cyclotron/radiochemistry facility for
cyclotron isotope production, conversion to radiopharmaceuticals (mainly F-18
FDG, N-13 Ammonia, O-18 Water) and quality control for diagnostic imaging of
oncology, cardiology, epilepsy patients. Major accomplishments are designing the
radiochemistry facility, remote techniques for production and handling of high
level radioactivity and developing a course on PET radiopharmaceuticals to teach
Nuclear Medicine Technology students and Nuclear Medicine, Cardiology, and
Radiology residents. Also, worked on F-18 cyclooxy synthesis and quality
control for breast cancer imaging.

07/90 - 06/91 Washington Univ. School of Medicine, Mallinckrodt Institute of
Radiology, St. Louis, MO
Research Instructor

Worked on production and quality control of PET radiopharmaceuticals.
Designed remote synthetic techniques.

08/87 - 06/90 University of Kentucky, Lexington, KY
Isotope Scientist

Worked on targetry and target chemistry. Designed targets for isotope production
and labelled several PET radiopharmaceuticals.

06/81 - 08/87 University of Florida, Gainesville, FL
Post Doctoral Fellow

Worked on fast kinetics and computer modelling. Developed electrooptic
techniques to study fast reactions.

RAJAT K. BERA

1405 Cedar Bluff Dr. Ballwin, MO 63021. Ph. (314) 861-2160

PROFESSIONAL AND RESEARCH EXPERIENCE contd.

01/80 - 05/81 Kernforschungsanlage, Juelich, West Germany
Research Associate

Worked on PET isotopes, their precursors and radiopharmaceuticals production.

09/75 - 11/89 Indian Institute of Technology, Kharagpur, India
Assistant Professor and Research Associate

Taught undergraduate chemistry and researched in catalysis.

01/72 - 08/75 Banaras Hindu University, Varanasi, India
Research Associate

Researched on solid and solution chemistry associated with nuclear reactions.

10/70 - 08/71 Midnapore Town School, India
Chemistry Teacher

Taught chemistry in higher secondary classes.

HONORS & SOCIETIES

Member of American Chemical Society.

RANAJIT K. BERA

1405 Cedar Bluff Dr. Ballwin, MO 63021. Ph. (314) 861-2160

PUBLICATIONS

- Book Chapter: RK Bera, P Yost, TR Hendershott, R Gentilecore, D Phogley and JW Fletcher, "Layout and planning of a University Hospital clinical cyclotron/PET facility" in Chemists' Views of Imaging Centers Ed. A. M. Emran, 1995, pp 35-38.
- ¹⁵M Moerlein, GG Gaelele, KR Lechner, RK Bera and MJ Welch, Automated Production of Oxygen-15 Labelled Butanol for PET Measurement of Regional Cerebral Blood Flow. Appl. Radiat. Isotopes, 1993.
- ¹⁴NG Hartman, M Jay, D Hill, RK Bera, CJ McClain and UY Ryo, Noninvasive detection of Helicobacter pylori colonization in the stomach using ¹¹C-urea. Dig. Diseases & Sci., 1992, 37, 618.
- ¹¹RK Bera, JL Weil, SW Yates and M Jay, Production of ¹¹C-carbon dioxide via the ¹¹B(p,n)¹¹C reaction and ¹⁸F-fluoride via the ¹⁸O(p,n)¹⁸F reaction for radiopharmaceutical development. Appl. Radiat. Isotopes, 1991, 42, 683.
- ¹¹RK Bera, NG Hartman and M Jay, Continuous production of ¹¹C-urea for medical application. Appl. Radiat. Isotopes, 1991, 42, 407.
- ¹¹NG Hartman, M Jay, UY Ryo, RK Bera, D Hill and CJ McClain, Carbon-11 urea for detection of Helicobacter pylori infection using dynamic imaging. European J. Nucl. Medicine, 1990, 16, 536.
- ¹⁴G Vaidyanathan, M Jay, RK Bera, PF Mayer and RK Brazzell, Scintigraphic evaluation of the ocular disposition of [¹⁸F]-imirestat in rabbits. Pharmaceutical Research, 1990, 7, 1190.
- ¹⁹RK Bera and RJ Hanrahan, Investigation of gas phase hydroxyl radical reactions with fluoromethane and difluoromethane using argon sensitized pulse radiolysis. Radiation Physics and Chemistry, 1988, 32, 579.
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CONTRIBUTIONS TO CONFERENCES contd.

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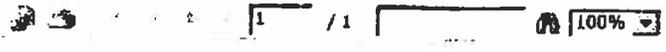
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Ranajit Bera, Ph.D

Dr. Ranajit Bera received PETNET's initial radiation safety and DOT training; however, records of his initial training cannot be located. PETNET's Corporate Radiation Protection Department acknowledged that Dr. Bera was given initial radiation safety and DOT training in 2001 when he became a PETNET employee for the St. Louis facility. Dr. Bera has been given annual radiation safety and DOT refresher training every year since his initial training. A copy of his latest radiation safety and DOT refresher training certificates are included.



CERTIFICATE *of* COMPI

This is to certify that:

Ranajit Bera

successfully completed

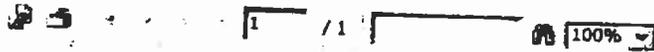
PETNET RAD Protection Refresher Quiz

01

Completion Date: 01/05/2009

Need score: 89%

SIEMENS



CERTIFICATE *of* COMPI

This is to certify that:

Ranajit Bera

successfully completed

PETNET - DOT/Hazardous Material Refresh

01

Completion Date: 01/05/2009

Score - 99 %

SIEMENS

4 4 4 3 1/1

License listing Alan Bilbrey, RPh, as an ANP

STATE OF COLORADO RADIOACTIVE MATERIALS LICENSE



Colorado Department
of Public Health
and Environment

Pursuant to the *Colorado Radiation Control Act*, Title 25, Article 11, *Colorado Revised Statutes*, and the State of Colorado *Rules and Regulations Pertaining to Radiation Control* (the Regulations), and in reliance on statements and representations heretofore made by the licensee designated below; a license is hereby issued authorizing such licensee to transfer, receive, possess and use the radioactive material(s) designated below; and to use such radioactive material(s) for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders now or hereafter in effect of the Colorado Department of Public Health and Environment and to any conditions specified below.

1. **Licensee:** PETNET Solutions, Inc.
2. **Mailing Address:** Radiology / Mailstop F726
A.O.P. 1635 North Ursula Street
P.O. Box 6510
Aurora, Colorado, 80045
3. **License Number:** Colo. 990-02, Amendment Number 8
4. **Expiration date:** July 31, 2009
5. **Authorized Storage/Use Location:** 1635 N. Ursula Street, Aurora, Colorado, 80045
6. **Designated Radiation Safety Officer:** Albert J. Roybal, R.Ph.
Designated Alternate Radiation Safety Officer: Roger Moroney (Corporate)
7. **Radiation Safety Officer Contact Number:** 720-848-1189
8. **Fee Category:** 3.C
9. **Reference Number:**

CONDITIONS

10. Authorized Radioactive Material and Uses:

- A. The licensee is authorized to possess and use any radioactive materials with atomic numbers 6 through 9 inclusive, in any form, for the preparation of radiopharmaceuticals for transfer to licensed recipients. The total activity of these materials shall not exceed 1073 GBq (29 Ci).

Training Certificate

This certificate is awarded to:

Alan Edward Bilbrey

**Radiation Protection Training
for Nuclear Pharmacy Employees**

June 11 - 13, 2008

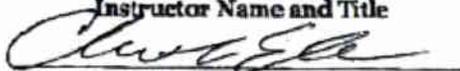
*This training is designed to satisfy the General Awareness, Function-Specific and Safety Training Requirement of 49 CFR 179.704(a).
Training was conducted by Siemens Medical Solutions Molecular Imaging Radiological Compliance Department for
PETNET Pharmaceuticals, Inc. in Knoxville, Tennessee.*

SIEMENS

PETNET Solutions

Christi Elam, Regional Health Physicist

Instructor Name and Title



Instructor Signature

July 9, 2008

Date Issued



Training Certificate

This certificate is awarded to:

Alan Edward Bilbrey

*In recognition of successful completion of the Transportation of Radioactive Materials Class
and receipt of a copy of the Federal Safety Report as a result of this training, conducted by the expert
instructors of the PETNET Solutions, Inc. in Knoxville, Tennessee.*

D.O.T./Hazardous Materials Training

June 13, 2008

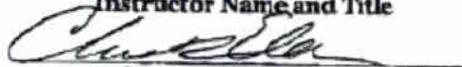
*This training is designed to satisfy the General Awareness, Function-Specific and Safety Training Requirement of 49 CFR 172.704(A).
Training was conducted by Siemens Medical Solutions Molecular Imaging Radiological Compliance Department
for PETNET Pharmaceuticals, Inc. in Knoxville, Tennessee.*

SIEMENS

PETNET Solutions

Christi Elam, Regional Health Physicist

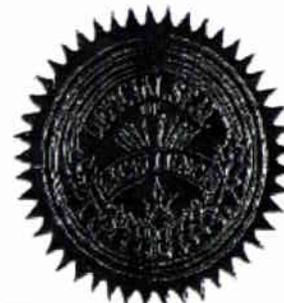
Instructor Name and Title



Instructor Signature

July 9, 2008

Date Issued





State of Missouri

Department of Insurance, Financial Institutions and Professional Registration
Division of Professional Registration
Missouri Board of Pharmacy
Pharmacist



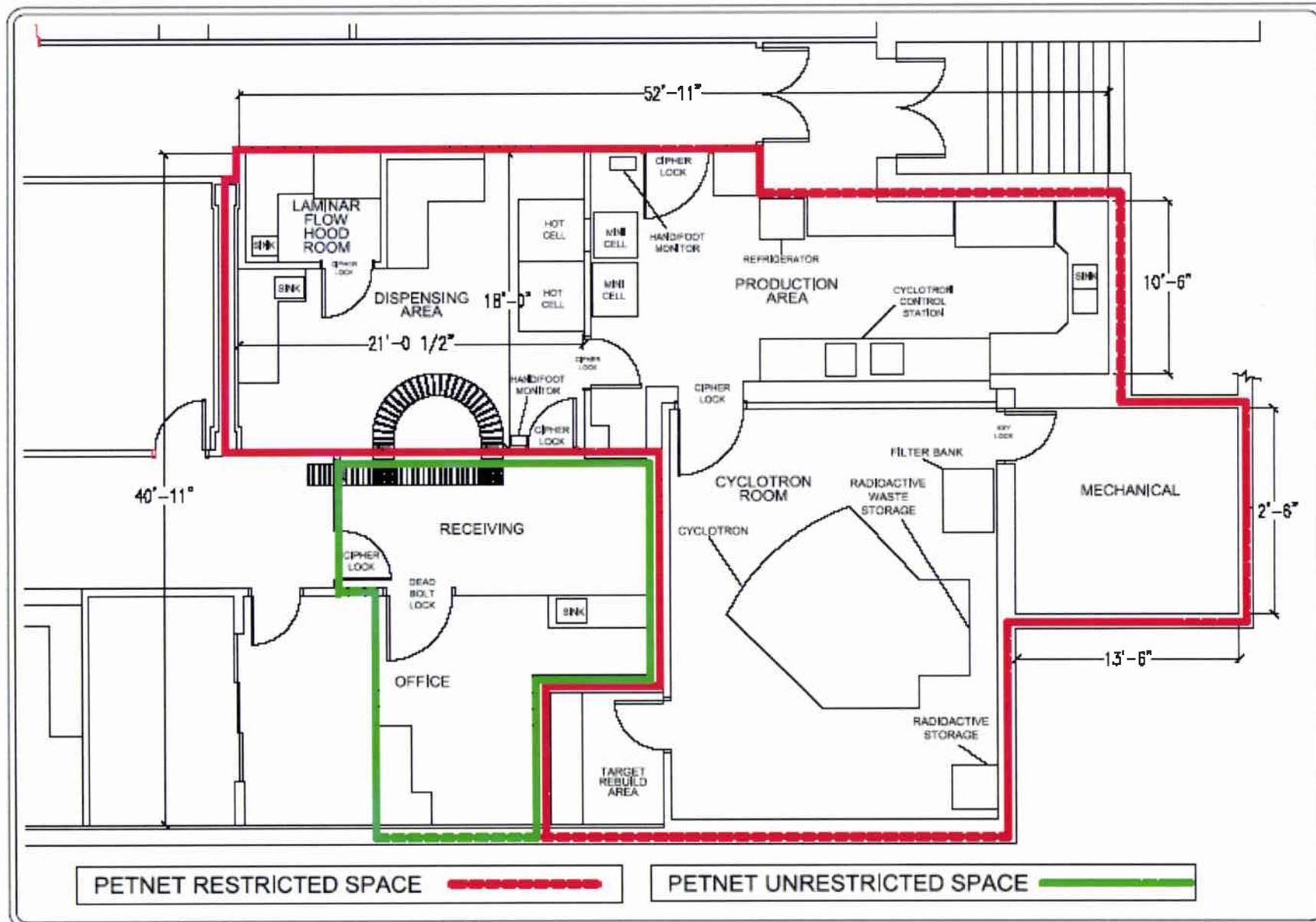
VALID THROUGH OCTOBER 31, 2010
ORIGINAL CERTIFICATE/LICENSE NO. 2005083258

ALAN E BILBREY

Shirley A. Smith
EXECUTIVE DIRECTOR

James A. Packard
DIVISION DIRECTOR

ATTACHMENT E: Facility Floor Plan and Location of Equipment

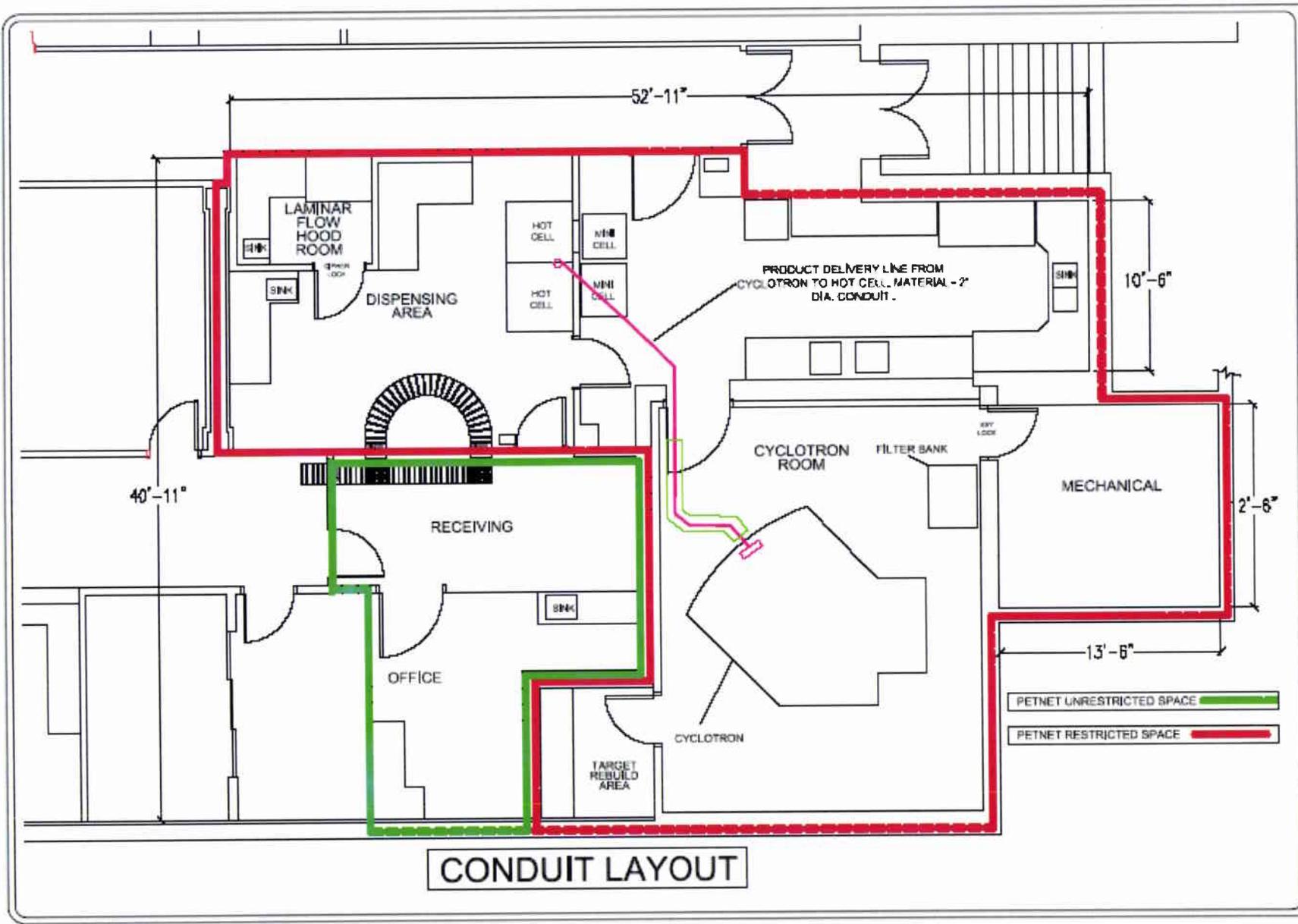


PETNET Solutions
 4710 Breckwood Drive
 Kansasville, Tennessee 37057 USA
 888.278.2000

PETNET
 ST. LOUIS

PROJECT NUMBER	
DRAWING TITLE	
REGULATORY PERMITS	
PROJECT NUMBER	
SCALE	
DESIGNED BY	DATE
CHECKED BY	DATE
APPROVED	
REVISION	DATE
1	00

Security-Related Information -
 Withhold under 10 CFR 2.390



PETNET Solutions

815 Innovation Drive
 Kennett, Tennessee 37052 USA
 663.713.0000

PETNET
 ST. LOUIS

PROJECT NAME

PROJECT INFORMATION
 APPROVED BY: [Signature]
 DATE: [Date]
 PROJECT NUMBER: [Number]

CONDUIT LAYOUT
 PROJECT NUMBER: [Number]
 SCALE: NTS
 DRAWN BY: [Name] DATE: [Date]
 CHECKED BY: [Name] DATE: [Date]
 REVISIONS

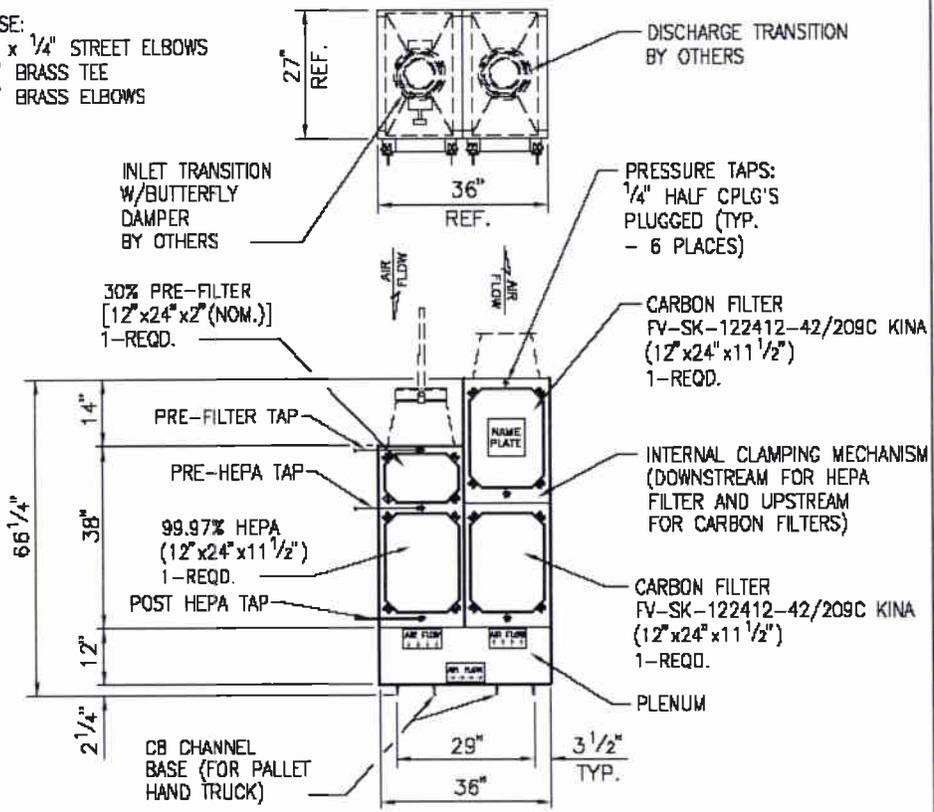
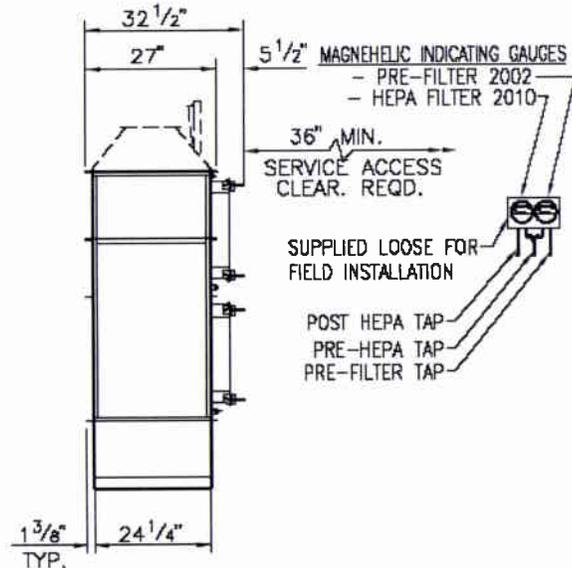
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Security-Related Information -
 Withhold under 10 CFR 2.390

ATTACHMENT F: Details on the KEP3S Filter, Carbon and Lab Impex Stack Monitor

- NOTES:**
- HOUSING MATERIAL - 304 SST
CHANNEL BASE MATERIAL - PAINTED C.S.
 - EMPTY WEIGHT (APPROX.) - 550 lbs.
INSTALLED WEIGHT (APPROX.) - 785 lbs.
 - DESIGN PRESSURE: $\pm 10''$ W.C.
 - HEPA AND CARBON FILTERS TO BE OF GEL SEAL DESIGN.
 - MAGNEHELIC GAUGES TO BE SHIPPED LOOSE TO BE INSTALLED IN THE FIELD BY OTHERS.

- NOTES CONT'D:**
- ALSO SHIP LOOSE:
 - (4) - $\frac{1}{8} \times \frac{1}{4}''$ STREET ELBOWS
 - (1) - $\frac{1}{4}''$ BRASS TEE
 - (3) - $\frac{1}{4}''$ BRASS ELBOWS



<table border="1"> <tr> <td>7-25-05</td> <td>JDV</td> <td>MD</td> <td>MD</td> <td>REVISED HEPA FILTER GAUGE FROM 2004 TO 2010</td> </tr> <tr> <td>6-21-05</td> <td>JDV</td> <td>MD</td> <td>MD</td> <td>ADDED GAUGES, NOTES #5 & #6 AND DIRECTIONAL ARROWS.</td> </tr> <tr> <th>REVISION</th> <th>DATE</th> <th>DWN</th> <th>CHK</th> <th>APPV</th> <th>DESCRIPTION</th> </tr> </table>					7-25-05	JDV	MD	MD	REVISED HEPA FILTER GAUGE FROM 2004 TO 2010	6-21-05	JDV	MD	MD	ADDED GAUGES, NOTES #5 & #6 AND DIRECTIONAL ARROWS.	REVISION	DATE	DWN	CHK	APPV	DESCRIPTION	<table border="1"> <tr> <td>DRAWN</td> <td>JDV</td> <td>8/24/04</td> </tr> <tr> <td>CHECKED</td> <td>MD</td> <td>8/24/04</td> </tr> <tr> <td>APPROVED</td> <td>MD</td> <td>8/24/04</td> </tr> </table>		DRAWN	JDV	8/24/04	CHECKED	MD	8/24/04	APPROVED	MD	8/24/04	<p>CALGON CARBON CORPORATION</p>																
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<p>THIS DRAWING REMAINS THE EXCLUSIVE PROPERTY OF THE CALGON CARBON CORPORATION. ALL AUTHORIZED COPIES ARE LOANED IN GOOD FAITH AND SUBJECT TO RETURN UPON REQUEST. ANY FURTHER REPRODUCTION WITHOUT THE CONSENT OF CALGON CARBON CORPORATION IS THEREBY PROHIBITED.</p>					<table border="1"> <tr> <td>P#</td> <td>CUSTOMER:</td> <td>ALLIED TECH. OF KY.</td> <td>ORDER NO.</td> <td>C01111</td> </tr> <tr> <td>TAG:</td> <td colspan="4">TITLE</td> </tr> <tr> <td colspan="2">TOLERANCES</td> <td colspan="3">GENERAL ARRANGEMENT</td> </tr> <tr> <td colspan="2">FRACTIONAL</td> <td colspan="3">KEP3S-3-1/2x1-V-P2/H12-C12-C12</td> </tr> <tr> <td colspan="2">ANGULAR</td> <td>SCALE</td> <td>SIZE</td> <td>DRAWING NUMBER</td> </tr> <tr> <td colspan="2"></td> <td>1/2"-1"-0"</td> <td>B</td> <td>31999</td> </tr> <tr> <td>FILE:</td> <td>31999</td> <td>PLOT:</td> <td>14.75,9.75</td> <td>ORIGIN:</td> <td>0,0</td> <td>FACTOR:</td> <td>1-24</td> <td>SHEET</td> <td>1 of 1</td> <td>REV.</td> <td>B</td> </tr> </table>		P#	CUSTOMER:	ALLIED TECH. OF KY.	ORDER NO.	C01111	TAG:	TITLE				TOLERANCES		GENERAL ARRANGEMENT			FRACTIONAL		KEP3S-3-1/2x1-V-P2/H12-C12-C12			ANGULAR		SCALE	SIZE	DRAWING NUMBER			1/2"-1"-0"	B	31999	FILE:	31999	PLOT:	14.75,9.75	ORIGIN:	0,0	FACTOR:	1-24	SHEET	1 of 1	REV.	B
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Activated Carbon 209C KINA

Specialty Activated Carbon

209C KINA is a specialty impregnated activated carbon specifically developed for the removal of acid gases from air. The 12x20 mesh product is designed for use in gas respirators. The carbon is manufactured by high-temperature steam activation followed by impregnation. 209C KINA is a proven product for respirator applications and other applications including indoor air quality and industrial processes. It provides very high capacity for compounds that are not strongly adsorbed by other carbons (such as, hydrogen sulfide, mercaptans, sulfur dioxide, chlorine, hydrogen chloride, nitrogen oxides, etc.). Carbon canisters containing 209C KINA pass stringent NIOSH requirements for acid gas respirators.

Specifications

Iodine Number [BSC 90-032]	70% w/w Minimum
Moisture Content [ASTM D-2867]	20 % w/w Maximum
Particle Size [ASTM D-2862]	12x20 US Mesh

Typical Properties

Ball Pan Hardness [ASTM D-3802]	98
Ash Content [ASTM D-2866] (Base Material)	3% w/w
Bulk Density [ASTM D-2854]	0.51 g/cm ³

Packaging Options

50 Pound bags	Bulk tanker	15 Gallon drum
55 Gallon drum	1,000 Pound bulk sacks	

Unless otherwise specified, particle size distribution will be 5% maximum on the top screen and 5% maximum through the bottom screen. An MSDS is available for all BSC activated carbon products. If the moisture exceeds the referenced value, BSC weight adjusts to the referenced value.

835 N.Cassady Ave. • Columbus, OH 43219 • 800-886-2272 • 614-258-9501 • Fax 614-258-3464 • Email: activated_carbon@waterlink.com • www.bsccarbons@waterlink.com
Rocky Mountain Office • Reno, NV • 775-355-7770 • Fax 775-355-7785 • Western Regional Office • Los Angeles, CA • 562-802-3400 • Fax 562-802-3480
Gulf Coast Office • Sulphur, LA • 337-527-0084 • Fax 337-527-0087 / Northeast Regional Office • Downingtown, PA • 610- 870-3070 • Fax 610-870-3072

Type FV-Bed Carbon Adsorbers

The Barnebey Sutcliffe Corporation. (BSC) Type FV Activated Carbon Adsorber provides high-efficiency, single-pass filtration of gaseous contaminants for the cleanup of nuclear ventilation airstreams; labs utilizing radioactive isotopes; destruction, testing or collective protection from chemical/biological warfare agents.

The adsorbers can be customized to remove radioactive gases such as elemental iodine and organic iodides, mercury vapors, acid gases, organic vapors, odors and various other contaminants.

Carbon types available include; coconut shell, coal, and wood based products as well as a large variety of specially impregnated carbons.



The BSC Type FV-Bed Adsorber is designed with either a 1" or 2" thick carbon bed arranged in a V-Bank configuration. This design allows a high airflow with relatively low pressure drop. Adsorber frames are constructed of 18 gauge T-304 stainless steel with 26 gauge perforated screens. The adsorbers are designed for use in the BSC "CM" Series Bag-In/Bag-Out Housings and "KE" series Liquid Seal Knife-Edge Housing.

These adsorbers are manufactured under stringent quality control procedures. Each adsorber is filled, tested, and packaged in accordance with IEST Designation: IEST-RP-CC-008-84. Each adsorber is tested in accordance with this standard to assure a minimum mechanical efficiency of 99.9% prior to shipment.

Features

- Minimum mechanical efficiency of 99.9% when tested in accordance with IEST-RP-CC-008-84.
- Available in several standard sizes.
- Can be filled with the appropriate adsorbent to capture any absorbable contaminant.
- Available with Army chemical warfare (DMMP tested) approval for extremely critical applications.

835 N. Cassidy Ave • Columbus, OH • 43219 • 1-800-886-2272 • 614-258-9501 • Fax 614-258-3464 • E-mail: activated_carbon@waterlink.com • www.bsccarbons.com
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Gulf Coast Office • Sulphur, LA • 337-527-0084 • Fax 337-527-0087 • Northeast Regional Office • Downingtown, PA • 610-870-3070 • Fax 610-870-3072

The Lab Impex Systems Stack Monitoring Solution for
Continuous Effluent Measurement from a PET
Radionuclide Production Facility



- a. Introduction
- b. System Configuration
 - 1) *Pet Gas Monitoring Panel*
 - 2) *Stack Flow Measurement*
 - 3) *Stack Sample Probes*
 - 4) *CMS-1 Continuous Monitoring Station*
 - 5) *9205-PET Data Management System*

a) Introduction

The document describes a monitoring system for the on line continuous measurement of positron gas emissions from a PET production facility.

Founded in 1976, Laboratory Impex Systems Ltd (LIS) has had many years of experience working with gamma dose, radioiodine and positron gas detection. Our work in PET facilities coupled with our expertise in environmental, workplace and stack monitoring within nuclear facilities puts LIS at the forefront in this aspect of measurement technology.

The offered equipment is based on the innovative, flexible Continuous Monitoring Station (CMS) range of instrumentation, a tried and tested system operating in numerous nuclear and industrial establishments throughout Europe, the USA and the rest of the World.

With over twenty years experience in the field of continuous monitoring systems, the proposed system will be manufactured, tested and serviced by LIS personnel with unrivalled experience in the field of emissions monitoring within PET facilities.

The key points of our the LIS Stack Monitoring solution are

- Turnkey system – including stack concentration and stack flow measurement
- System configured specifically for client measurement requirements and working needs
- Simple and inexpensive to maintain and service
- ISO9001:2000 / NQA-1 accredited supplier, experienced with working with subcontractors on major projects
- Unsurpassed levels of detection sensitivity and accuracy
- High levels of company experience in cyclotron monitoring and continuous measurement systems for PET facilities

b) System Configuration

A system schematic for LIS stack monitoring system is shown in figure 1, overpage and can be summarised as follows:

Stack Monitoring Instrumentation

- a) 1 x PET gas monitoring panel
- b) 1 x PMP-6 vacuum pump
- c) 1 x DP2001 Differential Pressure Transmitter
- d) 1 x CMS-1 Continuous Monitoring Station

Stack Probes

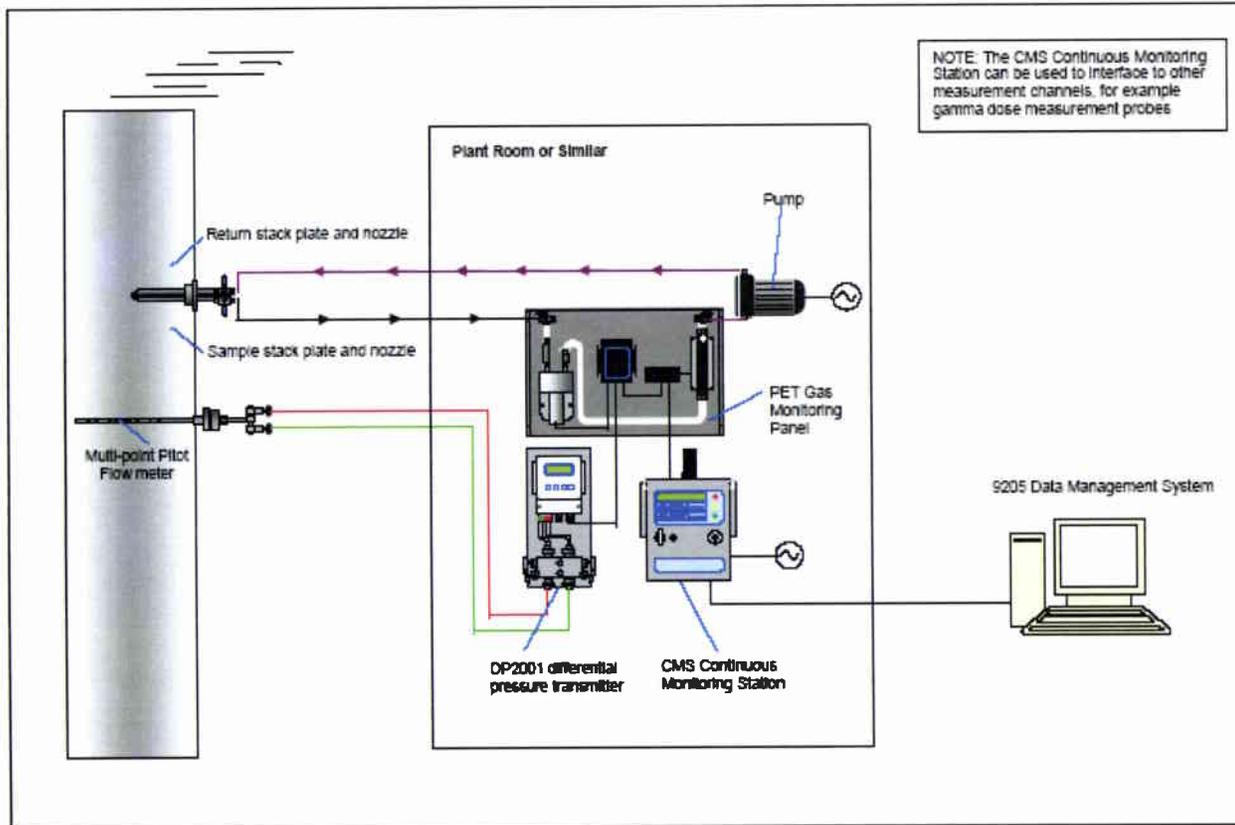
- e) 1 x Stack penetration plate and nozzle (Sample)
- f) 1 x Stack penetration plate and nozzle (Return)
- g) 1 x insertable Pitot (flow sensor)

Network Station

- h) 9205-PET Data Management System

The Lab Impex PET stack monitoring system is designed to provide the client with the best mix in terms of operational needs and possible future requirements. The key design criterion of the system has been:-

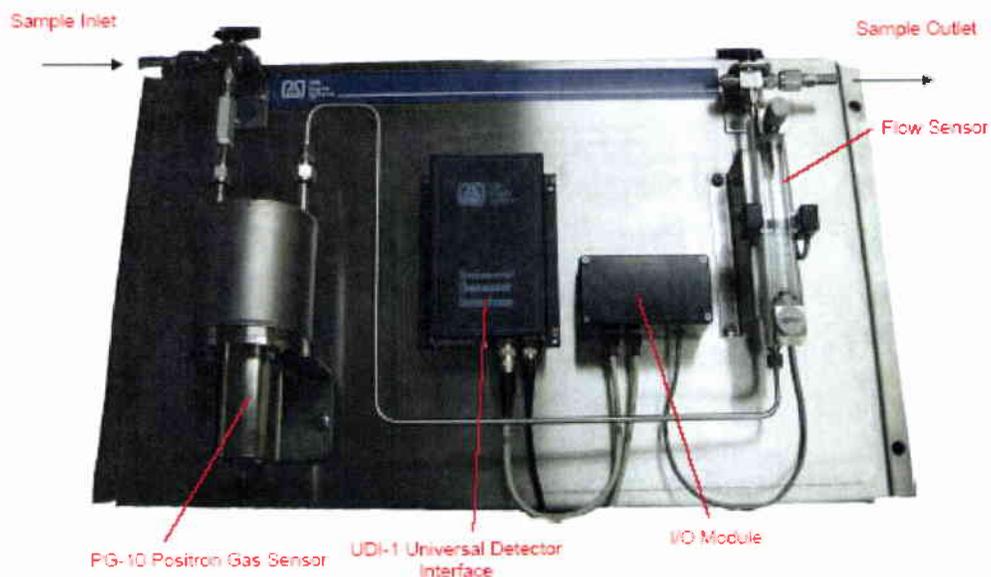
- a) To offer instrumentation with fail safe characteristics
- b) To maximise sensitivity and accuracy of effluent emission measurement in terms of flow and concentration
- c) To simplify instrument calibration and system maintenance
- d) To provide result data and reporting facilities in a form to aid and assist the licensor and the licensee
- e) To offer full expansion opportunities in the future (i.e. additional gamma measurement points and/or gaseous area monitors)



1) PET Gas Monitoring Panel

The PET gas monitoring panel is used to mount the following components

- PG10 Positron Gas Detector
- VA Flow Sensor and Flow Control Valve
- UDI-1 Universal Detector Interface
- Sample Inlet and Outlet with Isolation valves



The PET gas monitoring panel is stainless steel, of dimensions of 30" x 18" (750 x 450 mm), and intended for wall mounting.

The PG-10 Positron Gas Detector is an advanced sensor for the accurate, sensitive measurement of PET radionuclide gas concentration. The culmination of over 15 years research and operation in PET facilities, the PG-10 is a unique solution offering unparalleled performance in terms of detectable limit, accuracy and range of operation.

The PG-10 comprises a 0.75 litre measurement chamber and plastic scintillation detector. The assembly incorporates a mounting flange into which is fitted a light tight window, plastic phosphor scintillant and photomultiplier. The sample gas is drawn into the chamber via a 0.4" outer diameter pipe-stub and exhausted via a similar pipe in a laterally displaced position.

The PG-10 provides real operational benefits. The thin plastic scintillant ensures an efficient response to positron emissions in the chamber – but possesses a very low inherent background and minimal response to 511 KeV gamma's which can be highly beneficial if the system is located near to stack filters or other sources of background. Furthermore the system is small, compact and easily installed and serviced.

The PG-10 provides a measurement range of 5E-8 uCi/ml to 1 E-2 uCi/ml (normalised to C-11) and can be easily calibrated in-situ by a unique calibration jig that allows the system to be calibrated without making a controlled release to the environment.

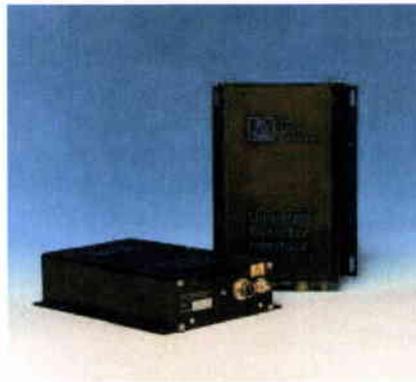
The PG-10 has shown stable long term performance in many facilities around the World and is recognised as the most accurate, sensitive system commercially available.

PG-10 Specifications	
<u>Scintillation Detector</u>	
Unshielded scintillation counter consisting of a plastic phosphor scintillator with light guide, PMT and dynode chain.	
<u>Measuring Chamber</u>	
Type:	0.75 litre s.s
Air Connections:	2 x 10 mm O.D. pipe
Dimensions:	100mm diameter, 100mm height
<u>Detector Characteristics</u>	
Length:	280mm
Diameter:	65mm
Efficiency:	Positron efficiency greater than 30% (At contact)

Temperature range: -10C to 50C
Weight: 2kg
Detectable Limit: Better than $5 \text{ E-}8$ uci/ml (C-11), given suitable background and measurement time

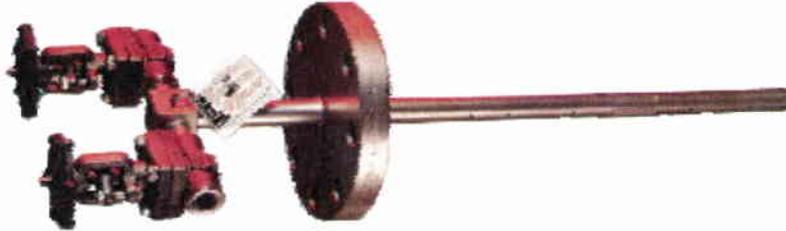
The PG-10 system is factory calibrated with a solid source cross-related to a previous gas calibration report for the PG-10

The Universal Detector Interface (or UDI) is an electronics module that provides the high voltage supply to the PG-10 sensor and also the necessary amplifier electronics for the detector pulses. After amplification and discrimination pulses are transmitted to the I/O module on the PET panel through to a local CMS Continuous Monitoring Station for result display and alarm.



2) Stack Flow Measurement

Lab Impex Systems offer a range of flow measurement devices to accurately measure stack flow.



For most installations, a multi point insertable pitot is used to provide a measurement of volumetric flow. In a typical installation, where the Pitot is located and installed into a straight duct length of stack 10 hydraulic diameters of more; an accuracy of $\pm 5\%$ will be achieved – significantly improving the accuracy achieved from conventional flow meters such as thermal anemometers.

The pitot is a passive device - where the differential pressure produced across the device is related to a stack flow - and a small local pressure measurement system called the DP2001 is used to monitor and record stack flow.

The DP2001 differential pressure transmitter provides a continually updating measurement of volumetric flow, which will be normalised to standard conditions (25°C and 760 mm Hg as per ANSI N13.1-1999 paragraph 6.2.2.2). A 5-valve manifold is fitted to the instrument, to allow easy isolation and equalisation of the signal differential pressures. From the DP2001, a 2 wire 4-20 mA output is used to transmit flow to the CMS-Continuous Monitoring Station.

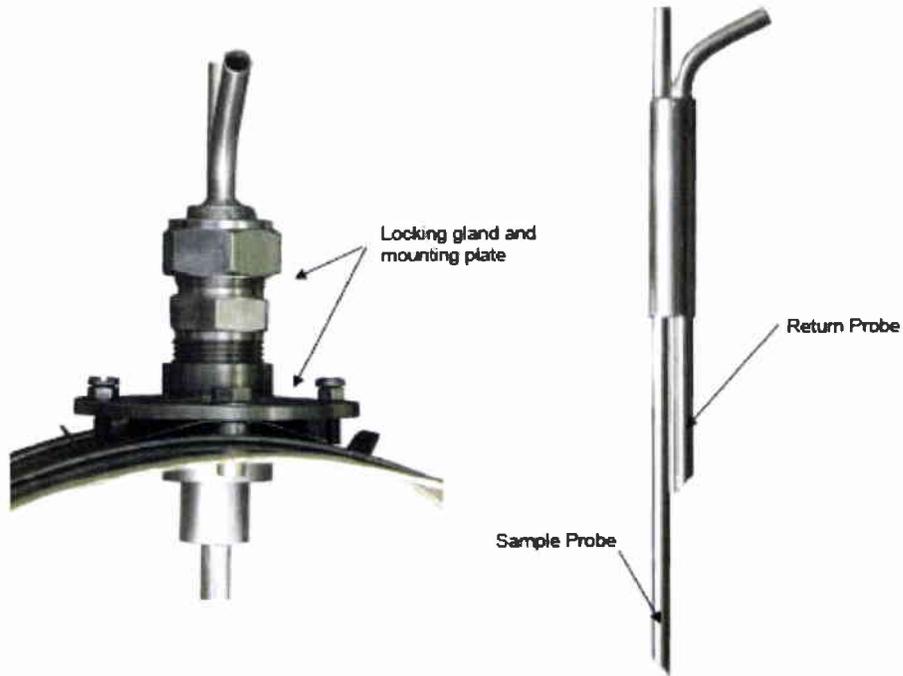


Lab Impex Systems are the only system supplier to offer a complete solution of in-house manufactured stack radiation and stack flow sensors.

3) Stack Sample Probes

The stack sample probes are installed via a locking gland mounted on a plate that is fixed to the outer stack wall. The plate can be easily installed to the stack by means of "Hank bushes" or self tapping screws. A neoprene gasket is supplied with the plate so that a gas tight seal is formed between the stack outer wall and the mounting plate. The plate can be used on circular or rectangular stacks, and both the sample and return probes are inserted and installed through the one plate.

Lab Impex Systems recommend that the connection onto the sample and return probe is made via a full bore ball valve, which facilitates isolation of the stack, should any of the secondary equipment need to be removed for servicing.



The pitot tube is also installed through an identical mounting plate

d) CMS-1 Continuous Monitoring Station

The CMS-1 Continuous Monitoring Station is a data processor and display instrument, which accepts the data inputs from the PG-10, VA flow sensor, DP2001. Using proven and established firmware, the CMS-1 Continuous Monitoring Station provides assured, precise radiation monitoring. Over 500 CMS devices are used in the field. Current analysis gives a MTBF for the system of more than 20 years.



The CMS-1 is housed in a rugged stainless steel box with a front panel and keyboard indicating alarm, status and result data. The system uses three alarm thresholds for stack concentration (high, alert and detector fail) and any occurring alarm or status event is indicated by three multi element indicators (red, amber, green). In addition, operator awareness to alarm, by audible means, is confirmed by an 1800Hz, 80dB sounder with mute facility.

A large 40 character LCD provides a display of result data configured to read in engineering units. Designed to provide fast response to positron gas concentration, the CMS-1 will provide a display of concentration ($\mu\text{Ci/ml}$) and volumetric stack flow (cfm)

Working parameters may be accessed via the keypad, which is passcode and key protected to prevent unauthorised access. Detector count-rate, stack flow (via a 4-20 mA input from the DP2001) and sample flow status will be accepted by the CMS, which at all times will verify the correct operation and functioning of the stack monitoring instrumentation

The CMS-1 generates high intensity audible – visual alarms on the following system statuses

- High positron gas concentration ($\mu\text{Ci/ml}$)
- PG-10 Detector Fail
- Low sample Flow
- Low Stack flow

The CMS-1 can be located adjacent to the Pet Gas Monitoring Panel, or remotely, up to 3000 ft away. In addition, the CMS-1 has the capability to accept other data inputs (eg. gamma dose rate from a Geiger probe) and hence enables the user to expand the stack monitoring system to a complete facility radiation system.

From the CMS-1, an RS-232/485 connection is made to a local PC running 9205-PET application software (see section e).

Specifications

Type of Alarm

The CMS-1 has a comprehensive alarm system to give fast warning of high activity or fault condition.

Any alarm event will trigger an alarm response locally at the CMS-1.

A green OK lamp on the front panel of the CMS-1 gives confidence that the system is performing normally.

The system continuously performs self-tests and malfunctions are indicated by flashing of the green OK lamp.

When the alert threshold is exceeded the amber alert lamp will be activated. Similarly when the alarm threshold is exceeded the red lamp will be activated in addition to an external (top mounted) strobe and siren.

The green, amber and red lamps are 20mm diameter multi-element LED's, clearly visible from 10 m (30 feet).

CMS Microprocessor Type

A 68000 microprocessor with separate hardware counters processes the detector results.

Digital Display

Large, clear 20 mm x 142 mm liquid crystal display with backlighting comprising 2 rows of 20 x 8.5 mm height characters.

Technical Specification and Description

Parameters

A number of internal parameters must be set to give the required operational characteristics. Parameters are accessed by the keypad and are password protected. All system parameters are held in non-volatile memory.

Supply Voltage

85V - 264V, 50/60 Hz

Temp Range (operating)

- 10 + 55°C, 95% RH (non-condensing).

Dimensions and Weight

350 (h) x 256 (w) x 140 (d), 8 kg

EMC Standard

EN50081-2 emission

EN50082-2 immunity

Type Test

The CMS-1 has been fully type tested by the UK NRPB (National Radiological Protection Board) and other international recognised test laboratories



LIS DOCUMENT CONTROL RECORD

TITLE: PG-10 Cs-137 Calibration Check

ISSUE: 1.0

Amendment No.	AMENDMENT RECORD AND DETAILS					
0	New Issue					
1	To provide tolerance statement					
2						
3						
4						
5						
6						
7						
8						
9						
Amendment		0	1	2	3	4
PREPARED	BY	NC	NC			
	DATE	05/10/08	18/8/09			
APPROVED	BY	JR	JR			
	DATE	05/10/08	18/8/09			
Amendment		5	6	7	8	9
PREPARED	BY					
	DATE					
APPROVED	BY					
	DATE					

INTRODUCTION

A ¹¹CO₂ Gas Calibration at WMIC gave the following correlation between detector gas response and the response to a Cs137 check source. (see Annex A)

Gamma Source Strength	PG-10 Count Rate (Background subtracted)	Source Activity to Count Rate Ratio	Equivalent Conversion Factor
8176757 pCi	237.7 cps	34397 pCi per cps	0.213 pCi/ml per cps

CS-137 CALIBRATION CHECK

The PG-10 can be calibrated on-site using a Cs137 check source using the the following calculation

$$\text{NEW CONVERSION FACTOR} = (\text{Site Source (pCi)} / 34397) * (1 / X) * 0.213$$

Where X = the background subtracted source count-rate

PROCEDURE

- 1.1 With no source present, record the background cps count-rate
- 1.2 Place the Cs-137 check source on the outside of the PG-10 chamber, as detailed in the photograph below, and record cps count-rate





	LIS Job No:	Customer Ref:
PG-10 CERTIFICATE OF CALIBRATION TESTS		
<u>INSTRUMENT</u>		
Serial No.	Channel	
Type	Description	
<u>SOURCE.</u>		
Ref. No.	_____	
Isotope.	_____	
Half Life Corrected	_____ pCi (A1)	
Activity	_____	
<u>BACKGROUND TEST</u>		
	Background (no source present)	
	_____ cps (A2)	
<u>SOURCE TEST</u>		
	Source in position	
	_____ cps (A3)	
<u>CONVERSION FACTOR CALCULATION</u>		
Conversion Factor =	$(A1 / 34397) * (1 / A3 - A2) * 0.213 =$ _____	
<p>If the new calculated conversion factor is within +/- 10% of the existing conversion factor, LIS advise the existing conversion factor is retained and no adjustment is made.</p> <p>Note: It is the obligation of the client to gain approval for the acceptability of this calibration method from local radiation protection staff and the site regulator and LIS take no liability in this regard.</p>		
Completed By:-	_____	Date: _____

ANNEX A: CALIBRATION OF PG-10 GAS DETECTOR

Method

The panel detector connected in series to previously calibrated detector LG12 via a closed-loop system. The method for calibration has been established previously with this model of detector and is as follows:

- A gaseous radioisotope ($^{11}\text{CO}_2$) is injected into the closed-loop system and is circulated by a pump until mixed
- A sample of the gas is then taken and measured in the highly sensitive bismuth germinate (BGO) scintillation detector
- The decays of the BGO sample and the gas in the closed-loop are observed and compared, and a calibration factor inferred

Three samples were taken after different mixing times, in order to ensure that the gas in the closed-loop was sufficiently mixed.

As the detector has known volume $\sim 750\text{ml}$ and the BGO has previously been calibrated (see report Hughes and Robinson, 2006), the coefficient κ can be calculated from the equation

$$\kappa = \frac{A_0^{\text{BGO}}}{C_0^{\text{U}}} \cdot \frac{V^{\text{U}}}{V^{\text{BGO}}} \quad [\text{Eq. 1}]$$

where A_0^{U} , C_0^{U} and V^{U} are the activity and CPS at time $t = 0$, and volume of detector x , respectively. This coefficient is related to the efficiency of the detector by the equation

$$\text{eff} = \frac{1}{\kappa} \quad [\text{Eq. 2}]$$

The calibration factor for the detector, K , can then be calculated using

$$K = \frac{1}{\text{eff} \cdot V^{\text{U}}} \quad [\text{Eq. 3}]$$

and has units of activity \cdot volume $^{-1} \cdot$ cps $^{-1}$. This calibration factor relates the activity in the detector, A^{U} , to the CPS, C^{U} via the equation

$$A^{\text{U}} = KC^{\text{U}} \quad [\text{Eq. 4}]$$

**Figure 1
Results**

	Sample 1		Sample 2		Sample 3	
	Calibration Factor (r^1)	Efficiency (%)	Calibration Factor (r^1)	Efficiency (%)	Calibration Factor (r^1)	Efficiency (%)
LG12	8.2 ± 0.2	16.4 ± 0.4	7.8 ± 0.1	17.2 ± 0.2	7.9 ± 0.1	17 ± 0.2
Panel Detector	7.2 ± 0.2	18.6 ± 0.5	6.8 ± 0.1	19.9 ± 0.2	6.8 ± 0.2	19.7 ± 0.5

Detector LG12 had previously been found to have a calibration factor of 8.2 r^1 , providing a secondary confirmation for the calibration of the panel detector. The results from this experiment give a calibration factor of (7.9 ± 0.1) r^1 .

Combining the results for the panel detector using a weighted mean gives a calibration factor of (6.8 ± 0.1) r^1 and an efficiency of (19.7 ± 0.2)%

Conclusion

The panel detector has a calibration factor of (6.8 ± 0.1) r^1 and an efficiency of (19.7 ± 0.2)%

This is confirmed by the close agreement of the calibration factor for LG12 to its previously measured value.

Equipment List

Panel Detector

Detector serial number: B0315/008
 CMS Model number: CMS 1L/4
 CMS serial number: B0250/12

Detector LG12

Detector serial number: B0245/020
 CMS Model number: CMS 1L/4
 CMS serial number: B0250/13

BGO well chamber part number. Scionix detector 80 BP 90 / 3.5M-BGO-X

Serial number: SAH504.

- Photomultiplier base and pre-amp (Ortec Model 296).
- A Minibin and power supply (Ortec Model 4006).
- A shape amplifier with timing SCA (Ortec Model 590A).
- Delay electronics (Ortec Model 427A).
- A data logger (Measurement Computing - PMD-1208LS).

Calibration date: February, 2006

Calibrated by: Neil Hughes
Niall Robinson

Dose Calibrator Model: Isomed 2000

Location: G09

Calibration: yearly against NPL/NWMP

Calibration: Michael Green

Calibration checks: weekly against check source

Test Performed at: Wolfson Molecular Imaging Centre
The University of Manchester
27 Palatine Road
Withington
Manchester
M20 3LJ

Test date: 6th June 2006

Test performed by Neil Hughes
Niall Robinson

Cross Reference to Original Results for Detector B0245-020

LIS source no.2, ¹³⁷Cs, Emission Rate: 302,540 Bq 01/10/03.

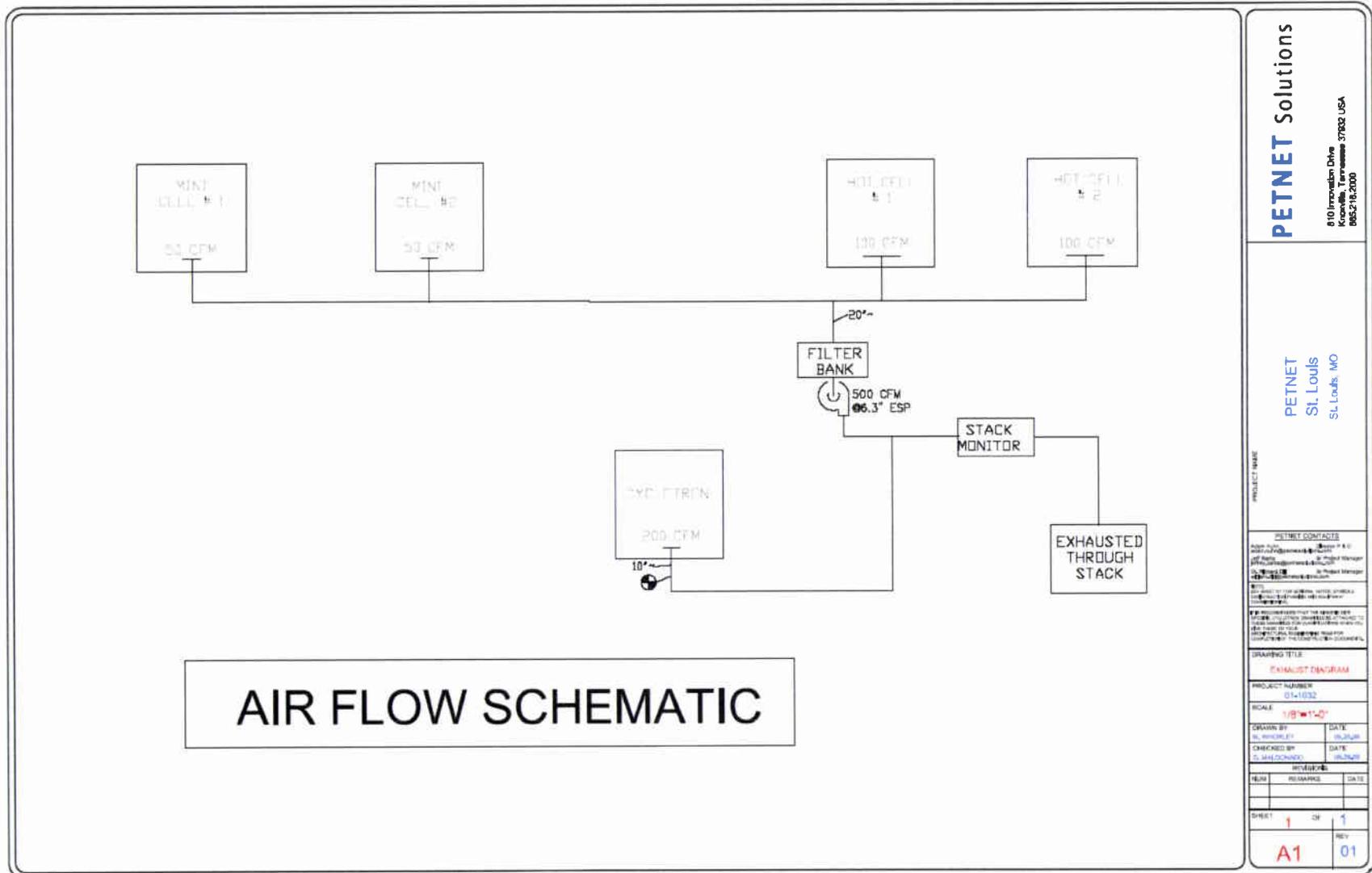
Reading obtained = 237.7 cps (background subtracted).

Therefore 237.7cps should give a conversion factor of 7.9

$\frac{237.7}{x} \times 7.9$ will give future detectors conversion factors, where x is the reading obtained using source LIS 2.

The certificate of calibration has been updated accordingly.

ATTACHMENT G: Schematic of Radioactive Exhaust System



PETNET Solutions

810 Innovation Drive
Knoxville, Tennessee 37902 USA
865.276.2000

PETNET
St. Louis
St. Louis, MO

PROJECT NAME

PETNET CONTACTS

Allen, A. J. | Project Manager
 Allen, A. J. | Project Manager
 Allen, A. J. | Project Manager
 Allen, A. J. | Project Manager

Allen, A. J. | Project Manager
 Allen, A. J. | Project Manager
 Allen, A. J. | Project Manager
 Allen, A. J. | Project Manager

DRAWING TITLE

EXHAUST DIAGRAM

PROJECT NUMBER

014-1032

SCALE

1/8" = 1'-0"

DRAWN BY

SL, RICHLEY

CHECKED BY

SL, RICHLEY

DATE

01/14/2010

REVISION

NO.	REMARKS	DATE

SHEET

1 OF 1

REV

A1 01

ATTACHMENT H: Example of Prescription Labels and Shipping Papers

Doctor: Dr. Peter Arfken # 110030256

F-18 FDG

Pt. Name: PATIENT NAME OMITTED**

Procedure: G I TRACT	Date: 10-09-2008
Lot No.: 938f100908-1	Expires: 10/09/2008 16:45
Qty. Ordered: 15 mCi	As Of: 08:30
Assay: 36.59 mCi/ml	Volume: 0.41ml
Qty. Dispensed: 15 mCi +/- 10% 0.41ml	Processed By: James Kauchak RPh Initials:

Caution: To be used under the direct supervision of a physician.

Directions for use:

PETNET Solutions, Inc. Phone# 800-738-1077

Dr. Dr. Peter Arfken # 110030256

Lot: F-18 FDG 938f100908-1 Expires: 10/09/2008 16:45

Qty. Ordered: 15mCi

Assay: 36.59 mCi/ml As Of: 08:30

Volume: 0.41ml

Qty. Dispensed: 15 mCi +/- 10% 0.41ml

Qty. Admin. By: [Redacted]

G I TRACT

Pt. PATIENT NAME OMITTED**

110030256

CUSTOMER COPY

256

Doctor: Dr. Peter Arfken # 110030256

F-18 FDG

Pt. Name: PATIENT NAME OMITTED**

Procedure: G I TRACT	Date: 10-09-2008
Lot No.: 938f100908-1	Expires: 10/09/2008 16:45
Qty. Ordered: 15 mCi	As Of: 08:30
Assay: 36.59 mCi/ml	Volume: 0.41ml
Qty. Dispensed: 15 mCi +/- 10% 0.41ml	Processed By: James Kauchak RPh Initials:

Caution: To be used under the direct supervision of a physician.

Directions for use:

Lot: F-18 FDG 938f100908-1 Expires: 10/09/2008 16:45

Qty. Ordered: 15mCi

Assay: 36.59 mCi/ml As Of: 08:30

Volume: 0.41ml

Qty. Dispensed: 15 mCi +/- 10% 0.41ml

G I TRACT

Pt. PATIENT NAME OMITTED**

256

Caution: To be used under the direct supervision of a physician.

CONTAINER LABEL

CAUTION 110030256 10-09-2008 08:30
F-18 FDG 15 mCi LOT #: 938f100908-1
pt: PATIENT NAME OMITTED**

CAUTION F-18 FDG 15 mCi 08:30

PETNET Solutions, Inc.
1345 West 16th Street
Room 001
Indianapolis, IN 46202

F-18 FDG 15 mCi 08:30

Bill of Lading

CARRIER BDS	ROUTE NO.	ORIGIN Indianapolis	DATE 10/09/2008
-----------------------	-----------	-------------------------------	---------------------------

TDOT: 06.00

CONSIGNOR

CONSIGNEE NAME AND ADDRESS

PETNET Solutions, Inc.

BOL NBR



10092070

PROPER SHIPPING NAME/CLASSIFICATION
RADIOACTIVE MATERIAL, TYPE A PACKAGE, 7, UN 2915

NO. OF PCE(S)	HAZ	HAZARDOUS CODE	CHEMICAL FORM	PHYSICAL STATE	ACTIVITY	LABEL CATEGORY
1	08:30	F-18	Fluorodeoxyglucose - Liquid - Rm# 110030255		1.430 GBq	RADIOACTIVE WHITE I
Total:					1.43 GBq	RADIOACTIVE YELLOW II

Wipe _____ dpm

Surface Reading _____ mR/hr

T.L. _____

This is to certify that the above named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation.

SHIPPER'S SIGNATURE _____				EMERGENCY CONTACT (800) 255-3924			
PERFORMED BY		CARRIER SIGNATURE		CONSIGNEE SIGNATURE			
DATE	TIME	DATE	TIME	DATE	TIME	DATE	TIME

Bill of Lading

CARRIER BDS	ROUTE NO.	ORIGIN Indianapolis	DATE 10/09/2008
-----------------------	-----------	-------------------------------	---------------------------

TDOT: 06.00

CONSIGNOR

CONSIGNEE NAME AND ADDRESS

PETNET Solutions, Inc.
1745 West 18th Street

BOL NBR



10092070

PROPER SHIPPING NAME/CLASSIFICATION
RADIOACTIVE MATERIAL, TYPE A PACKAGE, 7, UN 2915

NO. OF PCE(S)	HAZ	HAZARDOUS CODE	CHEMICAL FORM	PHYSICAL STATE	ACTIVITY	LABEL CATEGORY
1	08:30	F-18	Fluorodeoxyglucose - Liquid - Rm# 110030255		1.430 GBq	RADIOACTIVE WHITE I
Total:					1.43 GBq	RADIOACTIVE YELLOW II

Wipe _____ dpm

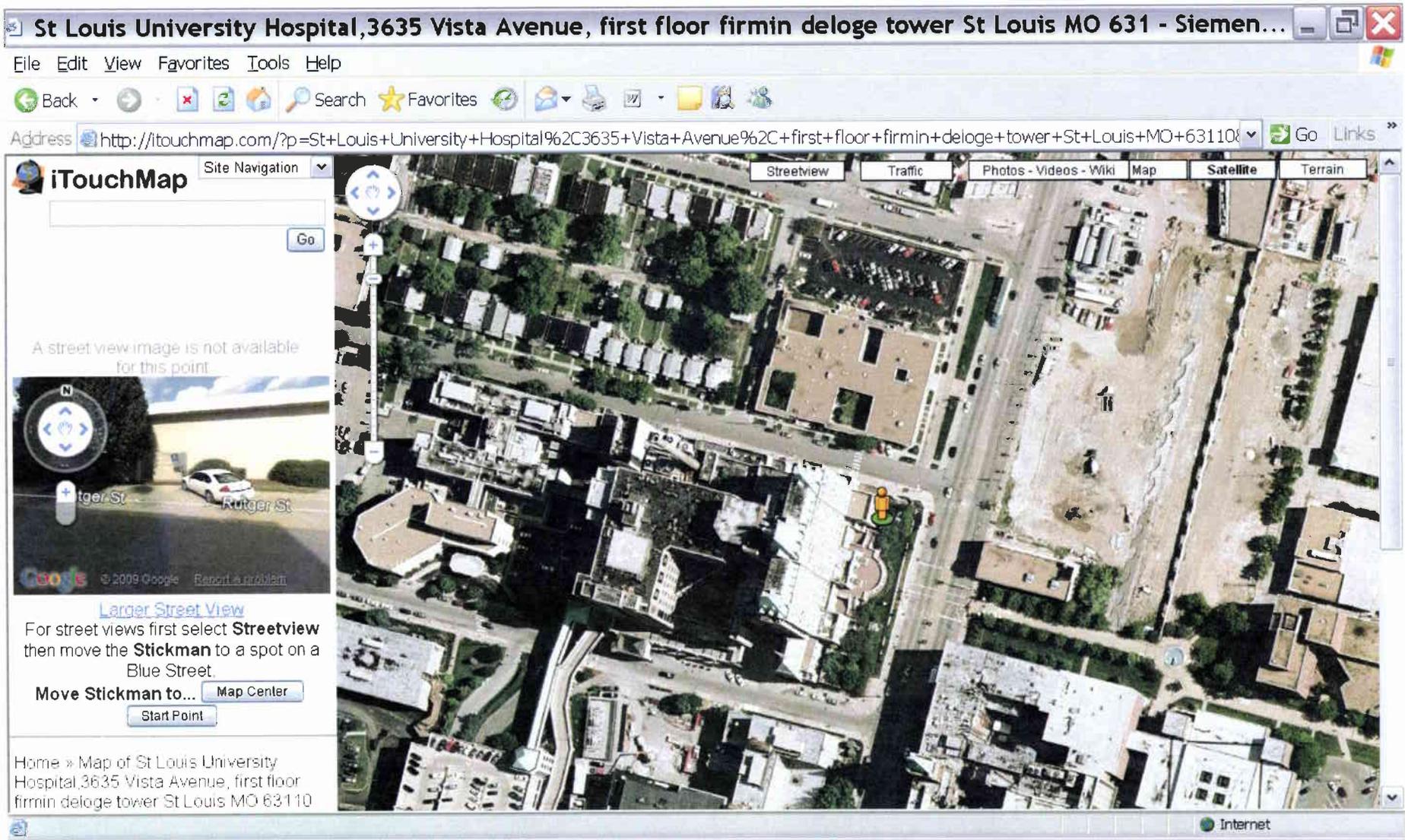
Surface Reading _____ mR/hr

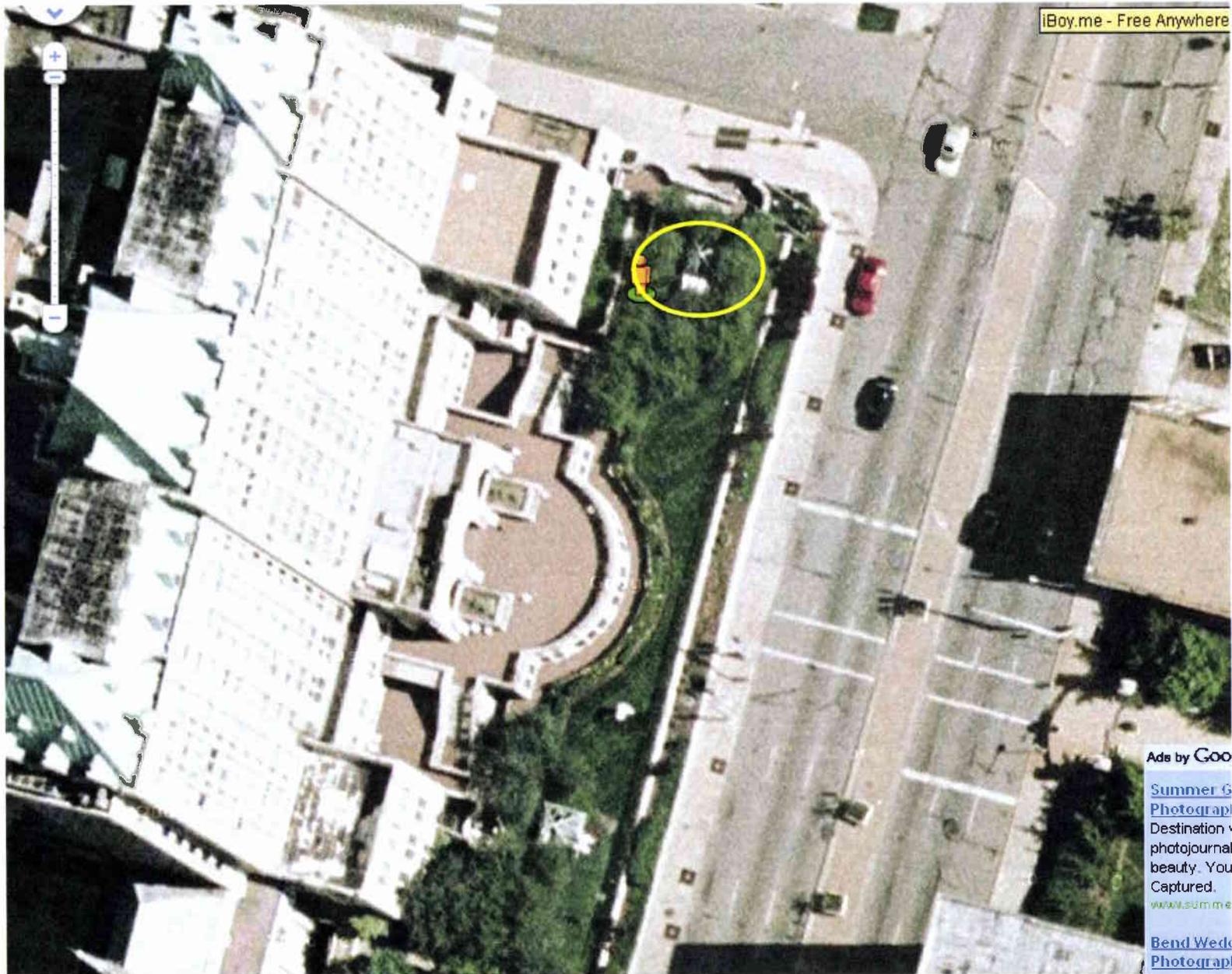
T.L. _____

This is to certify that the above named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation.

SHIPPER'S SIGNATURE _____				EMERGENCY CONTACT (800) 255-3924			
PERFORMED BY		CARRIER SIGNATURE		CONSIGNEE SIGNATURE			
DATE	TIME	DATE	TIME	DATE	TIME	DATE	TIME

ATTACHMENT I: Satellite View of the Building and Environs





**ATTACHMENT J: Microshield, v. 8, 250 mCi
Spill Dose Rate**

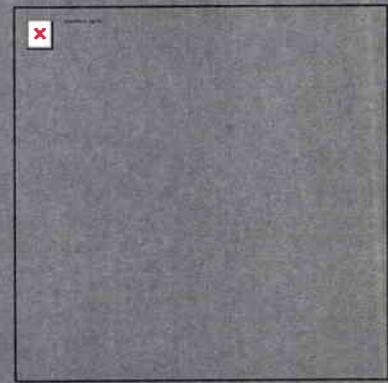
**MicroShield 8.01
Siemens (8.00-0000)**

Date	By	Checked

Filename	Run Date	Run Time	Duration
Case1	September 4, 2009	12:57:20 PM	00:00:00

Project Info	
Case Title	250 mCi F-18
Description	30 cm disk
Geometry	3 - Disk

Source Dimensions			
Radius	30.0 cm (11.8 in)		
Dose Points			
A	X	Y	Z
#1	30.0 cm (11.8 in)	0.0 cm (0 in)	0.0 cm (0 in)
Shields			
Shield N	Dimension	Material	Density
Air Gap		Air	0.00122



Source Input: Grouping Method - Actual Photon Energies				
Nuclide	Ci	Bq	μCi/cm²	Bq/cm²
F-18	2.5000e-001	9.2500e+009	8.8419e+001	3.2715e+006

Buildup: The material reference is Air Gap Integration Parameters	
Radial	20
Circumferential	20

Results					
Energy (MeV)	Activity (Photons/sec)	Fluence Rate MeV/cm²/sec No Buildup	Fluence Rate MeV/cm²/sec With Buildup	Exposure Rate mR/hr No Buildup	Exposure Rate mR/hr With Buildup
0.0005	1.656e+06	4.984e-02	5.060e-02	2.909e-01	2.954e-01
0.511	1.790e+10	5.583e+05	5.603e+05	1.096e+03	1.100e+03
Totals	1.790e+10	5.583e+05	5.603e+05	1.096e+03	1.100e+03

From: Origin ID: RKWA (865) 218-2363
Michael Nazerias
Siemens
810 Innovation Drive
Knoxville, TN 37932



Ship Date: 30SEP09
ActWgt: 5.0 LB
CAD: 100533625/INET9090
Account#: S *****

Delivery Address Bar Code

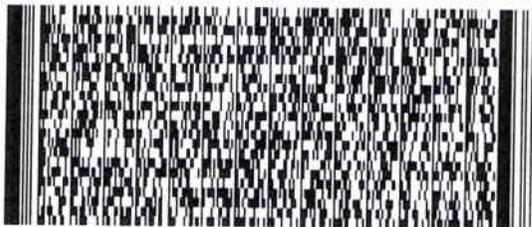


SHIP TO: (865) 712-9161 **BILL THIRD PARTY**
Kevin G. Null
U.S. NRC Region II
2443 WARRENVILLE RD STE 210
MATIERALS LICENSING BRANCH
LISLE, IL 60532

Ref # 919
Invoice #
PO #
Dept #

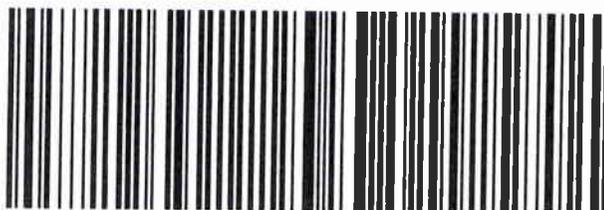
TRK# 7969 9156 2224
0201

THU - 01OCT A1
STANDARD OVERNIGHT



NZ ENLA

60532
IL-US
ORD



After printing this label:

1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.