union HOSPITAL

1606 North Seventh Street
Terre Haute, IN 47804-2780
(812) 238-7000

May 28, 2008

Nuclear Materials Licensing Branch
Attn: Mr. William P. Reichhold
United States Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: NRC Material License
No. 13-16457-01

Dear Mr. Reichhold:

This is to inform you that the Union Hospital wishes to amend its' Nuclear Regulatory Commission License to include the Terre Haute Medical Laboratory's activities at their PET Imaging Center located at 1532 North Seventh Street, Suite 100, Terre Haute, Indiana 47807-1008 on the Union Hospital Campus. The genesis for this request is Energy Policy Act of 2005 which requires the NRC to extend its oversight to include accelerator produce radioisotopes.

The PET Imaging Center was opened in September 2004 under Indiana Radioactive Material Registration Number NX000156, and has be in continuous operation since that time. Attached, please find the supporting documentation necessary to aid in your action on our request.

If you have any questions regarding this request please contact our Radiation Safety Officer, Rasiklal Ganatra, MD at (812) 238-7581 or Dean Taylor our Radiation Safety Consultant at (812) 238-7184.

Sincerely,

Scott Teffeteller
Senior Vice President/Chief Operating Officer

RECEIVED MAY 2 9 2008

Attached

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

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

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.

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
- [x] B. AMENDMENT TO LICENSE NUMBER **13-16457-01**
- [ ] C. RENEWAL OF LICENSE NUMBER

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

Union Hospital, Inc.
1606 North Seventh Street
Terre Haute, Indiana 47804-2780

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

additional location: PET Imaging Center
1532 North Seventh Street, Suite 100
Terre Haute, Indiana 47807-1008

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Rasiklal B. Ganatra, M.D.

TELEPHONE NUMBER

(812) 238-7000

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. maiximum 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 **7.c.** AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Scott Teffeteller, Chief Operating Officer	Scott L	**05/28/2008**

FOR NRC USE ONLY

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

Index of Attachments		
Attachment Number	Description	No. of Pages
Table C.2.	Summary of Item 5 and Item 6 Information	3
Table C.3.	Summary of Items 7 Through 11 Information	4
Attachment 9.1	Floor Plans for Areas of Use/Storage Structural Shielding Plan Structural Shielding Evaluation Report	8
Attachment 9.2	Description of Pet Scanner and Survey Meters	4
Attachment 9.4	Description of Additional Associated Equipment	
Attachment 10.2	Examples of Area Survey Forms	2

Table C.2 - Items 5 and 6 on NRC Form 313: Radioactive Material And Use				
☐ Yes ☒ No	This response includes security-related sensitive information (see Section 5.2) which is included in Attachment ____ and marked "Security-related information - withhold under 10 CFR 2.390"			
Yes	*Radionuclide*	*Form or* Manufacturer /Model Number	*Maximum* Quantity	Purpose of Use
	Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100
X	Any byproduct material permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200
	F-18	Any	____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j)
	O-15	Any	____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j)
	C-11	Any	____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j)
	Any byproduct material permitted by 10 CFR 35.300	Any	As needed	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300
	Iodine-131	Any	____ millicuries	Administration of I-131 sodium iodide
	Byproduct material permitted by 10 CFR 35.400 (Xx-000)	Sealed Source Manufacturer ______ Model: ___________	____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400
	Byproduct material permitted by 10 CFR 35.400 (Xx-000)	Sealed Source Manufacturer ______ Model: ___________	____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400
	Byproduct material permitted by 10 CFR 35.400 (Xx-000)	Sealed Source Manufacturer ______ Model: ___________	____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400
	Byproduct material permitted by 10 CFR 35.400 (Xx-000)	Sealed Source Manufacturer ______ Model: ___________	____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400
	Byproduct material permitted by 10 CFR 35.400 (Xx-000)	Sealed Source Manufacturer ______ Model: ___________	____ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400

Table C.2 Continued - Items 5 and 6 on NRC Form 313: Radioactive Material And Use				
Yes	Radionuclide	Form or Manufacturer /Model Number	Maximum Quantity	Purpose of Use
	Strontium-90	Sealed Source Manufacturer_____ Model: _____	____ millicuries	Tx of superficial eye conditions using an applicator distributed pursuant to 10 CFR 32.74 and permitted by 10 CFR 35.400
X	Byproduct material permitted by 10 CFR 35.500 ☒ Germanium-68	Sealed source Manufacturer: Siemens Models. LS-ACCEL CS-20-3 CS-20-1 LS-LA	0.006 curies/source 0.060 curies total	Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g)
	Iridium-192	Sealed Source Manufacturer _____ Model: _____	__ curies/source __ curies total	One source for medical use permitted by 10 CFR 35.600 in a Manufacturer _____ Model No. _____ remote afterloading brachytherapy device. One source in its shipping container as necessary for replacement of source in the remote afterloader.
	Cobalt-60	Sealed Source Manufacturer _____ Model: _____	__ curies/source __ curies total	One source for medical use permitted by 10 CFR 35.600 in a Manufacturer _____ Model No. _____ teletherapy unit. One source in its shipping container as necessary for replacement of source in the teletherapy unit.
	Cobalt-60	Sealed Source Manufacturer _____ Model: _____	__ curies/source __ curies total	One source for medical use permitted by 10 CFR 35.600 in a Manufacturer _____ Model No. _____ stereotactic radiosurgery device. Sources in the shipping container as necessary for replacement of the sources in the stereotactic radiosurgery device.

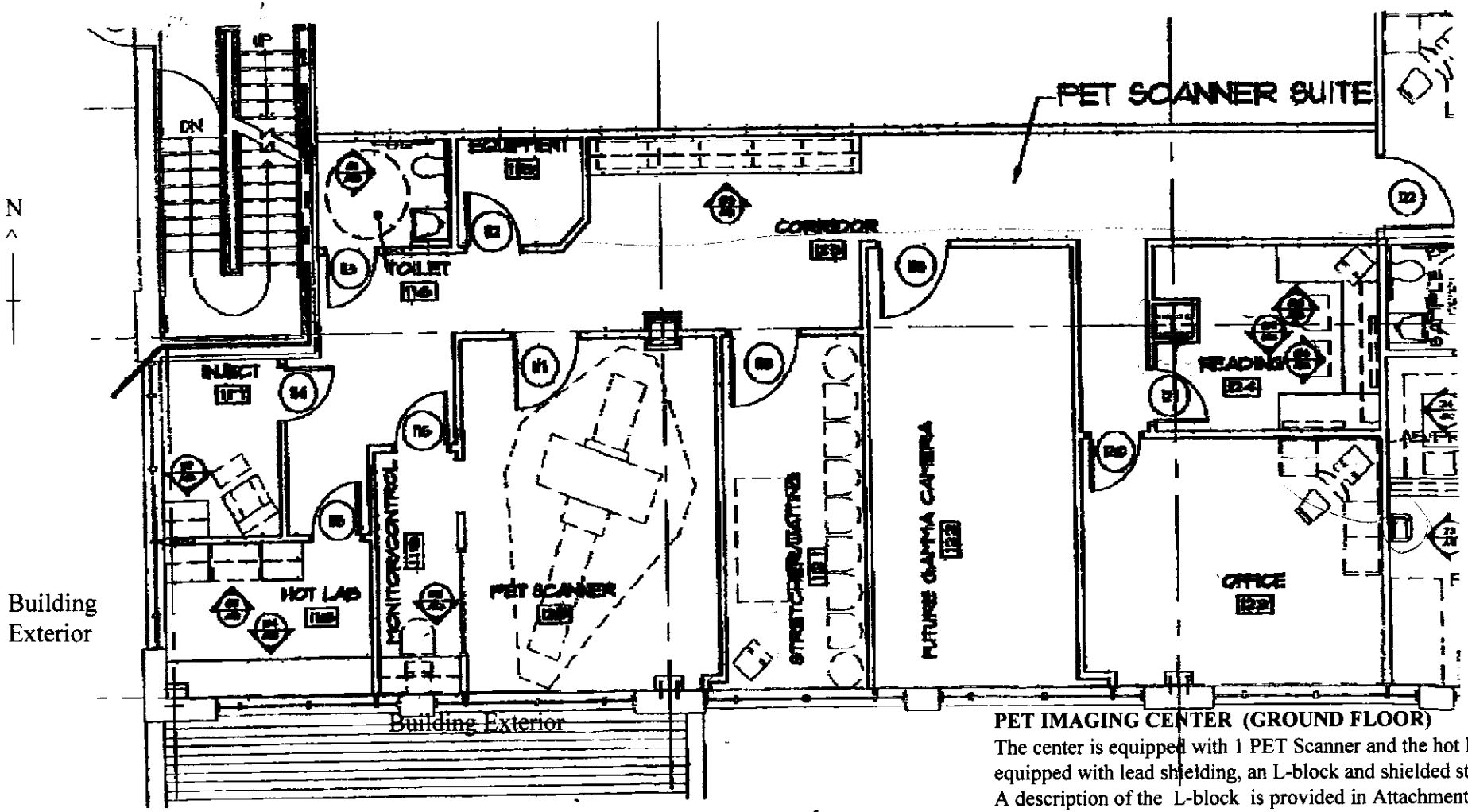
Table C.2 Continued - Items 5 and 6 on NRC Form 313: Radioactive Material And Use				
Yes	Radionuclide	Form or Manufacturer /Model Number	Maximum Quantity	Purpose of Use
	Any byproduct material permitted by 10 CFR 31.11	Prepackaged kits	___ millicuries	*In vitro* studies
	Depleted uranium	Metal	___ kilograms	Shielding for teletherapy unit
	Depleted uranium	Metal	___ kilograms	Shielding in a linear accelerator
	Any radionuclide in excess of 30 millicuries for use in calibration, transmission, and reference sources	Sealed Source Manufacturer _____ Model: _____	___ millicuries	For use in a Manufacturer _____ Model No. _____ calibration and checking of licensee's survey instruments
	Americium-241	Sealed source or device (Manufacturer:_____ Model #_____)	___ millicuries/source ____ millicuries total	Used as an anatomical marker
	Plutonium (Pu-238)	Sealed source	___ millicuries/source ____ grams total	As a component of Manufacturer_____ Model No. _____ nuclear powered cardiac pacemakers for clinical evaluation in accordance with manufacturer's protocol dated_____. This *includes: follow-up*, recovery, disposal, and implantation.
X	Other: Cs-137	Manufacturer: RadQual, LLC BM0837-000-8 Spectrum Techniques 2568	0.0011 millicuries total	Calibration reference sources

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal		
Item Number and Title	Suggested Response	Indicate material included in application
Item 7: Radiation Safety Officer Name: Rasiklal B. Ganatra, MD	Currently on license number: 13-16457-01	
Item 7: Authorized User Name and Requested Uses Name: Betty Jo Mills, MD	Currently on license number: 13-16457-01 Requested Uses: 10 CFR 35.100 and 35.200	
Item 7: Authorized User Name and Requested Uses Name: Upendra C. Shah, MD	Currently on license number: 13-16457-01 Requested Uses: 10 CFR 35.100 and 35.200	
Item 7: Authorized User Name and Requested Uses Name: Gerald J. Longa, MD	Currently on license number: 13-16457-01 Requested Uses: 10 CFR 35.100 and 35.200	
Item 7: Authorized User Name and Requested Uses Name: Dennis J. Cavanaugh, MD	Currently on license number: 13-16457-01 Requested Uses: 10 CFR 35.100 and 35.200	
Item 7: Authorized User Name and Requested Uses Name: M. Bashar Kashlan, MD	Currently on license number: 13-16457-01 Requested Uses: 10 CFR 35.100 and 35.200	
Item 7: Authorized Nuclear Pharmacist Name: NA		
Item 7: Authorized Medical Physicist Name: NA		

Table C.3 Continued - Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal		
Item Number and Title	Suggested Response	Indicate material included in application
Item 9: Facility Diagrams	Diagrams are enclosed that describe the facilities and identify activities conducted in all contiguous areas surrounding the areas of use. The following information is included: • Drawing are to scale and the scales are indicated. • Location, room numbers, and principal use of each room and area where byproduct material is prepared, used or stored, as provided above under the heading "Discussion" • Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and • Shielding calculations, including information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shielding, if one is used; source storage safe, etc.). In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.	☒ ☒ ☒ ☒ N/A
Item 9: Radiation Monitoring Instruments	Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations. AND/OR We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 ant that meet the requirements of 10 CFR 35.61. AND A description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys. AND We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.	☒ N/A ☒ ☒

Table C.3 Continued - Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal		
Item Number and Title	Suggested Response	Indicate material included in application
Item 9: Dose Calibrator and Other Dosage Measuring Equipment	Equipment used to measure dosages:	*1
Item 9: Therapy Unit - Calibration and Use	We are providing the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.	N/A
Item 9: Other Equipment and Facilities	Attached is a description identified as Attachment 9.4, of additional facilities and equipment.	☒
	For manual brachytherapy, we are providing a description of the energy response equipment.	N/A
	For teletherapy, GSR, and remote afterloader facilities, we are providing a description of the following:	N/A
	• Warning systems and restricted area controls	N/A
	• Area radiation monitored equipment	N/A
	• Viewing and intercom systems	N/A
	• Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment are in the treatment room	N/A
	• Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons	N/A
	• Emergency response equipment	N/A
Item 10: Safety Procedures and Instructions	Attached procedures required by 10 CFR 35.610	N/A
Item 10: Occupational Dose	Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR 20 or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG 1556, Vol. 9, Rev 2, Consolidated Guidance About Medical Use Licensees: Program-Specific Guidance About Medical Use Licensees,"	*2
	OR	
	A description of an alternative method for demonstrating compliance with the referenced regulations.	N/A
Item 10: Area Surveys	We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.	☒

Table C.3 Continued - Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal		
Item Number and Title	Suggested Response	Indicate material included in application
Item 10: Safe Use of Unsealed Licensed Material	We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.	*2
Item 10: Spill Procedures	We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101.	*2
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	Name of the proposed employee and types of activities requested:_____ AND Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested. AND Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.	N/A N/A N/A
Item 10: Minimization of Contamination	A response is not required under the following condition: the NRC will consider that the above criteria have been met if the information provided in the applicant's responses satisfy the criteria in Sections 8.14, 8.15, 8.20, 8.24, 8.26, and 8.28, on the topics: Facility and Equipment; Facility Diagram; Radiation Protection Program; Safety Program; and Waste Management.	N/A
Item 11: Waste Management	We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR 20 and 10 CFR 35.92.	*2
*1 Unit doses are used exclusively. All doses are measured by the Nuclear Pharmacy (Cardinal Health) and are adjusted at the time of administration for physical decay only, in accordance with 10 CFR 35.63(b)(2).		
*2 These items were provided as part of our license renewal application dated March 23, 2005		



NEW LAYOUT ARCHITECTURAL PLAN
PET SCANNER SUITE
SCALE: 1/8" = 1'-0"
REVISED 07-16-04

PET IMAGING CENTER (GROUND FLOOR)

The center is equipped with 1 PET Scanner and the hot lab is equipped with lead shielding, an L-block and shielded storage A description of the L-block is provided in Attachment 9.4. Environmental monitoring is done daily in all use areas. Immediately below the center are mechanical equipment rooms. Above the center are doctors' offices and examination rooms (14' separation between floors with a minimum of 4"of concrete over a steel frame in each floor).

MEDICAL PHYSICS CONSULTANTS, INC.
70 East 91st Street, Suite 106
Indianapolis, IN 46240
(877) 317-5811

Attachment 9.1

Gerald J. Longa, M.D., FACP
Terre Haute Medical Laboratory, Inc.
1625 North Seventh Street
PO Box 1468
Terre Haute, IN 47808

July 22, 2004

SHIELDING EVALUATION FOR TERRE HAUTE MEDLAB PET FACILITY

These are revised calculations based on the attached revised PET Scanner Suite architectural plan dated 7/16/04.

Assumptions:

- F-18 only
- 12 mCi average injected activity
- 8 patients per day
- 60 minute uptake time
- 45 minute imaging time
- An attenuation factor of 0.34 is assumed for the F-18 in the patient
- Attenuation by the scanner is not taken into consideration

Pb HVL (broad beam) = 0.6 cm or 0.236 inches
Concrete HVL (broad beam) = 7 cm or 2.8 inches

Barrier Calculations for Layout Option #1 (See attached)

Room	Barrier	Distance(ft)	Allowed dose (mrem/year)	Occupancy	Added lead necessary (inches)
Uptake	Floor	13	100	0.125	none
Uptake	Ceiling	16	100	0.125	none
Uptake	West Wall	6	100	0.025	none
Uptake	North Wall	6	100	0.025	none
Uptake	East Wall	12	250	1	0.25 (1/4)
Uptake	South Wall	6	250	0.125	0.125 (1/8)
Imaging	Floor	13	100	0.125	none
Imaging	Ceiling	16	100	0.125	none

Structural Shielding Plan

MEDICAL PHYSICS CONSULTANTS, INC.
70 East 91st Street, Suite 106
Indianapolis, IN 46240
(877) 317-5811

Attachment 9.1

Room	Barrier	Distance(ft)	Allowed dose (mrem/year)	Occupancy	Added lead necessary (inches)
Imaging	West Wall (Control)	8	300	1	0.25 (1/4)*
Imaging	North Wall	10	100	0.125	none
Imaging	East Wall	16	100	1	0.125 (1/8)
Imaging	South Wall	12	100	0.025	none

* See comment 2 below

The barriers to be shielded are indicated on the attached drawing. Added shielding should extend to a height of eight (8) feet.

Comments:

1. From a design standpoint, the rearrangement of the control room is not particularly ideal. Moving the doorway between the control room and the imaging room to the north end of the barrier provides a greater opportunity for someone to stand in the doorway exposed to direct line radiation from the patients. Although it seems intuitive, your radiation safety guidelines for the technologist should include an instruction not to stand in the doorway. A portable barrier could also be used in the imaging room to minimize the exposure rate in the doorway.

2. The viewing window in the Control room barrier should have the same protective equivalence as the barrier. The size of the viewing window should be determined by the availability of standard sizes of leaded acrylic or leaded glass of the appropriate lead equivalence.

   Based on the calculations using the stated assumptions, the control room barrier requires 0.25 (1/4) inch of lead equivalence. The calculations assume 8 patients per day; if only 4 patients per day turns out to be a more realistic workload, 0.125 (1/8) inch lead equivalence in this barrier would be sufficient. Also, there is additional conservatism built into the stated assumptions. Your average administered activity may be closer to 10 mCi than 12 mCi. I have assumed an attenuation factor for the patient of 0.34, based on MIRD internal dosimetry absorbed fraction data; based on some measured exposure rates from patients, the attenuation factor may actually be closer to 0.5 or 0.6. Also, it is reasonable to assume that the patient will excrete some of the F-18 when they use the restroom immediately prior to imaging; again, some measured data for patients suggests that this could be as much as about 1 mCi. The PET imaging system gantry will also provide some unknown (and directionally variable) amount of exposure rate reduction. All of the above would reduce the potential exposure rates from the patient during imaging and thus reduce the required shielding in the walls. Even for workloads up to 8 patients per day, 0.125 (1/8) inch lead equivalence in the control room barrier may provide adequate protection.

Structural Shielding Plan

MEDICAL PHYSICS CONSULTANTS, INC.
70 East 91st Street, Suite 106
Indianapolis, IN 46240
(877) 317-5811

Attachment 9.1

3. The shielding specified for the Injection (Uptake) room assumes that the patient will sit in a chair in the southeast corner of the room. The door to this room does not require lead shielding. A dosage pass-through (unshielded) can be located at the west end of the wall between the Hot Lab and the Injection room as indicated on the drawing.

4. The shielding in the Control room barrier (west wall of the Scanner room) does not need to extend beyond the end of the Control room.

5. For the exterior walls of the Scanner room and the Injection room, I have assumed an occupancy factor of 1/40 (i.e., one person spending one hour a week adjacent to the building when patient studies are being performed). This is sufficiently conservative that no modifications are required outside the building. If future utilization of the outside areas adjacent to these rooms changes, the need for shielding (or shrubbery to discourage people standing or sitting within several feet of the building) should be evaluated.

6. After the facility is operational, I would recommend using film badges to assess the actual exposures in selected areas. If necessary, portable shield(s) can be utilized to supplement the fixed barrier shielding.

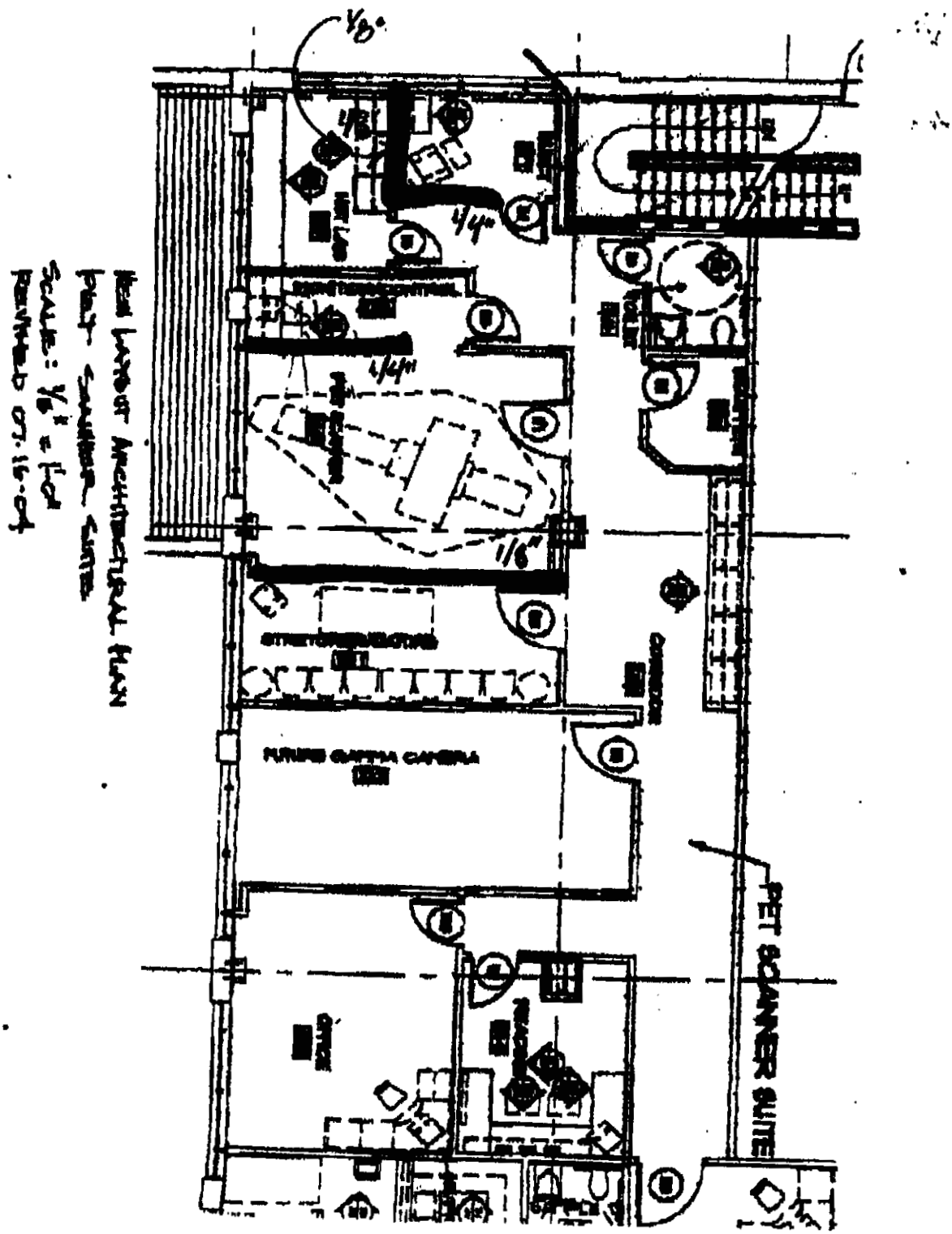
Thank you for the opportunity to work with you on this project. If you have any questions regarding this information, please let me know.

Sincerely,

Robert T. Anger, Jr., M.S., M.P.H., FACR
ABR Certified Medical Nuclear Physicist
ISDH approved Diagnostic Imaging Physicist

Structural Shielding Plan

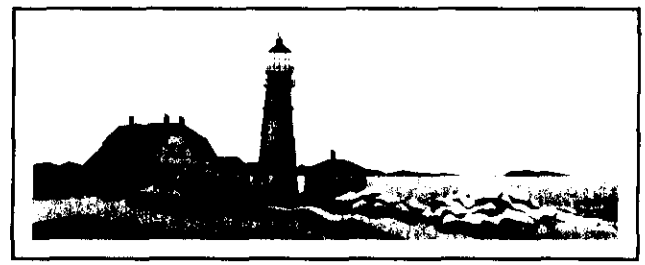
Attachment 9.1



Structural Shielding Plan

Attachment 9.1

Beacon X-Ray Testing, Inc.
5696 South Ernest Street
Terre Haute, IN 47802-9499



Mr. Rex J. Bowser, Radiation Specialist
Radioactive Materials Program
Indiana State Department of Health
(Fifth Floor)
2 North Meridian Street
Indianapolis, IN 46204-3003

October 29, 2004

Regarding:
Facility #R0156-84

Dear Mr. Bowser:

Pursuant to the provisions of 410 IAC 5-4-6(a), I am submitting the enclosed ambient area radiation survey on behalf of the Terre Haute Medical Laboratory for their new PET Imaging Center located at 1532 North Seventh Street, Suite 100, Terre Haute, Indiana 47807-1008. The clinic opened for business on October 27, 2004, the date of the survey.

Please call me if you have any questions about these results or radiation protection in general. Phone: 894-2554 (office) or 238-7184 (Union Hospital).

Thank you,

Dean A. Taylor, M.S.
Diagnostic Imaging/Health Physicist

Enclosed

cc:
THML

Structural Shielding Evaluation Report

Ambient Area Radiation Survey

Facility :	THML PET Imaging Center 1532 North Seventh Street, Suite 100 Terre Haute, Indiana 47807-1008	Date: October 27, 2004 Time 0930 - 1030

Survey Conditions: At 0930 a patient received a 15.0 mCi dose of ^{18}FDG by I.V. injection for a PET scan. The patient remained in the dosing room chair for approximately 40 minutes and then proceeded to the scanning room to begin the scan. Ambient area radiation readings were taken around the injection room during the first 15 minutes following dose administration. Ambient area radiation readings were taken around the scanning room during the first 15 minutes of the scan. Survey points *1 through *8 are for the injection room and the balance are for the scanning room.

Survey Results (see attached survey map for survey point locations):

Location	Reading(mR/hr)	Location	Reading (mR/hr)
*1	0.10	*8	0.15
*2	1.50	*9	0.05
*3	0.05	*10	0.60
*4	0.03	*11	0.40
*5	2.00	*12	0.30
*6	1.50	*13	0.20
*7	0.05	*14	0.30

Background Reading:	0.03 mR/hr	Survey Instrument:	Ludlum Model 14-C
Instrument Calibration Date:	April 26, 2004	Serial Number:	4297

Comments: It was indicated by the Center Manager that 15 mCi of ^{18}FDG will be the standard dose. Based on the survey results a "Caution - Radiation Area" sign must be posted on the left side of the sink in the hallway leading to the "Hot Lab". The shielding design for the facility is considered satisfactory to support of the requirements of 410 IAC 5-4-6(a) as long as only one patient is in the dosing room and the scanning room at any one time.

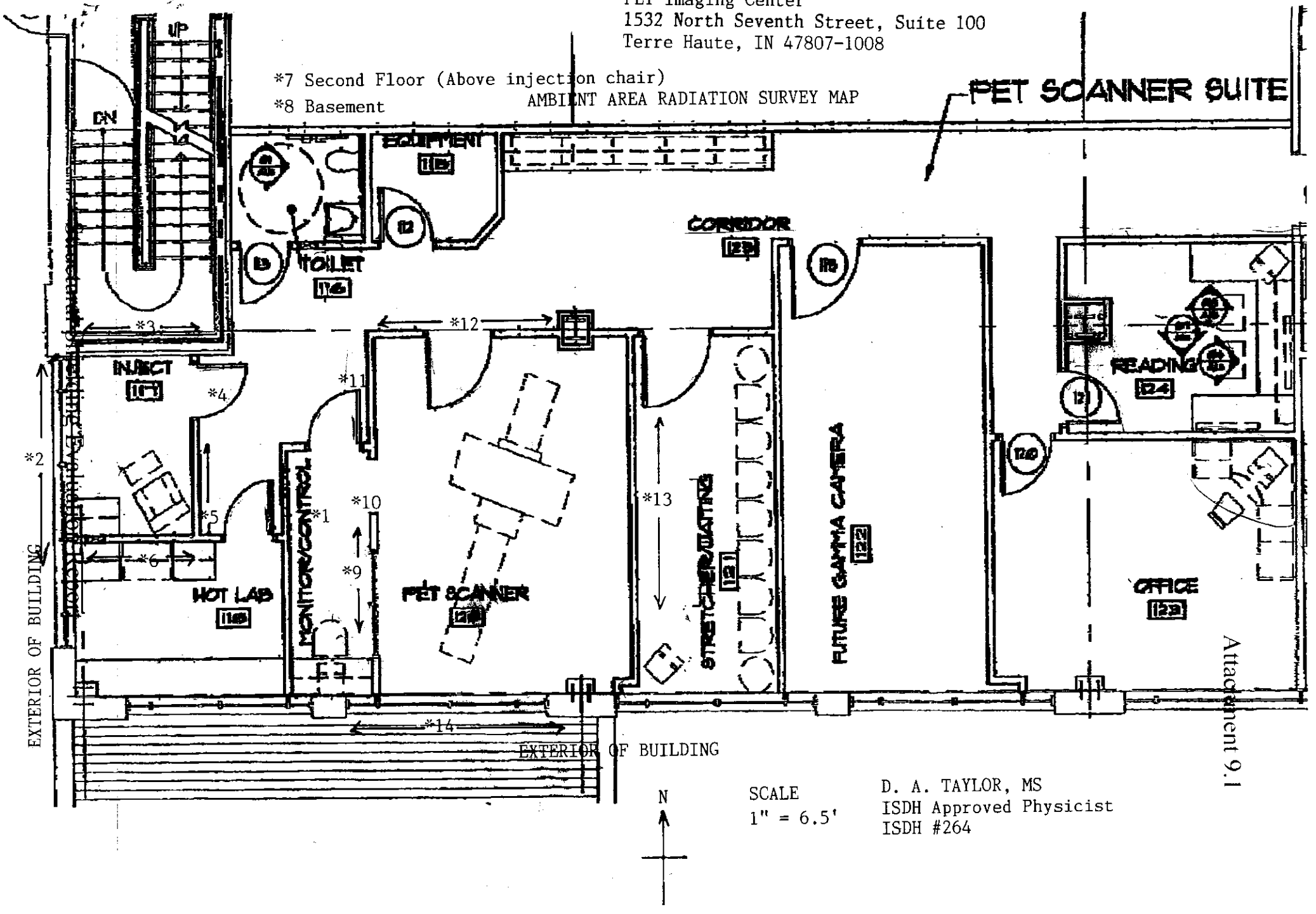
Surveyor/Report Prepared by:	Signature: Dean A Taylor	
	Dean A. Taylor, MS, Radiation Safety Officer	Date: October 27, 2004

Details of: Terre Haute Medical Laboratory
PET Imaging Center
1532 North Seventh Street, Suite 100
Terre Haute, IN 47807-1008

October 27, 2004

*7 Second Floor (Above injection chair)
*8 Basement

AMBIENT AREA RADIATION SURVEY MAP



D. A. TAYLOR, MS
ISDH Approved Physicist
ISDH #264

Attachment 9.1

Union Hospital, Inc.
USNRC Material License Amendment Application
License #13-16457-01
Date: May 28, 2008

Attachment 9.2

Positron Emission Tomography Scanner

Manufacturer	Description	Number
Siemens	ECAT ACCEL	1

Survey Meters: the following is a list of survey meters, one of which is always on hand and in use at the PET Imaging facility.

Manufacturer & Model	Description	Range	S/N
Ludlum 14C	GM Survey Meter, End Window	0-2000 mR/hr	201402
Ludlum 14C	GM Survey Meter, End Window	0-2000 mR/hr	70274
Ludlum 14C	GM Survey Meter, End Window	0-2000 mR/hr	68141

Attachment 9.4

Other Equipment:

Capintec Caprac Well Counter
Syringe Shields*
Lead-lined Storage Cabinets & Waste Container*
Lead-lines Syringe Holder
Lab Coats & Disposable Gloves
Lead Bricks (>30)
L-Block With Leaded Glass Window*
Cs-137 Reference Sources (<1 μCi each)

(* Manufacturers' description of item attached)

Attachment 9.4

PRO-TEC®
PET SYRINGE SHIELD

- *Constructed of .34" thick (9 mm) tungsten, attenuates FDG F-18 by 88%*
- *Available with or without a high density lead glass window*
- *Fits most disposable syringes*

The Pro-Tec® PET Syringe Shield reduces hand exposure from syringes containing 511 keV radionuclides. The barrel of the shield is constructed of .34" thick (9 mm) tungsten that attenuates FDG F-18 by 88%.

The syringe shield is offered with or without a high density (5.6) flush mounted lead glass window that provides protection and visibility. A white reflective surface on the shield interior improves viewing of the syringe's markings and fluid content. A thumbscrew holds syringes firmly in place.

Pro-Tec® PET Syringe Shields accommodate the standard sized 1 cc, 3 cc, 5 cc and 10 cc syringes. The Manual Dose Injector is an ideal companion, providing both additional shielding and distance.

SPECIFICATIONS:
Shielding: .34" thick (9 mm) tungsten
Lead Glass: 5.6 density
Weight:
007-973 & 007-985: 1.4 lb (.64 kg)
007-975 & 007-990: 1.7 lb (.83 kg)
007-980 & 007-995: 2.3 lb (1.05 kg)

Pro-Tec® PET Syringe Shields with lead glass window:

007-973 Syringe Shield, 3 cc $325.00
007-975 Syringe Shield, 5 cc 360.00
007-980 Syringe Shield, 10 cc 395.00

Pro-Tec® PET Syringe Shields without lead glass window:

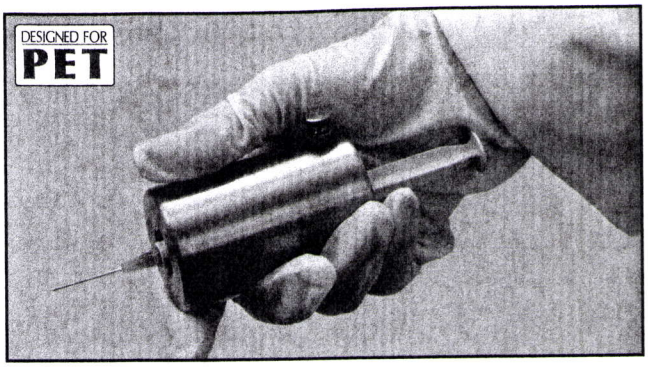
007-983 Syringe Shield, 1 cc $275.00
007-985 Syringe Shield, 3 cc 300.00
007-990 Syringe Shield, 5 cc 325.00
007-995 Syringe Shield, 10 cc 375.00

Replacement Glass:

007-974 Glass, Replacement **$80.00**
For Pro-Tec PET and Gaard Lock PET Syringe Shields 007-973, 007-975, 007-980, 007-716, 007-717 and 007-718

Note: Syringe Shields available for a selection of international syringes. Contact Biodex at 631-924-9000 or e-mail sales@biodex.com.

Z-PET SYRINGE SHIELD



Extra thick wall for extra protection

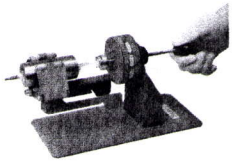
- *Constructed of .55" thick (14 mm) tungsten, attenuates FDG F-18 by 97%*

The Z-PET Syringe Shield greatly reduces hand exposure from syringes containing 511 keV radionuclides. The barrel of the shield is constructed of .55" thick (14 mm) tungsten that attenuates FDG F-18 by 97%. The shield accommodates standard 5 cc syringes. The Manual Dose Injector is an ideal companion, providing both additional shielding and distance.

SPECIFICATIONS:
Dimensions: 2.75" l x 1.7" dia (7 x 4.3 cm)
Shielding: .55" thick (14 mm) tungsten
Weight: 3.7 lb (1.7 kg)

007-945 Syringe Shield, Z-PET, 5 cc*..... **$550.00**

**Z-PET Syringe Shield was conceived by Michael Zimmer, Ph.D.*



REDUCE HAND EXPOSURE - *Manual Dose Injector is an ideal companion, adding shielding and distance to further reduce hand exposure.* ***See page 17 for details.***

CIRCLED ITEMS ARE ON HAND

Attachment 9.4

LEAD-LINED
PET UNIT DOSE CABINET

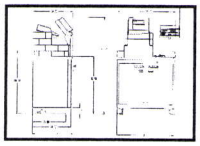
KEY-LOCKED

Designed for PET hot labs with limited space, the PET Unit Dose Cabinet provides a space-efficient work area over a fully shielded storage cabinet.

The cabinet supports the 042-433 Biodex Compact L-Block with Built-in Dose Calibrator Shield, the 039-412 Sharps Container Shield, the 042-434 Lead Brick Cave, and the 086-250 Atomlab 100 Dose Calibrator. The dose calibrator display unit mounts on a stand above the countertop to maximize work space.

The lower cabinet has key-locking doors, two sliding bottom shelves, and two sliding upper shelves. The bottom shelves will accommodate PET shipping containers. The top shelves conveniently store syringes, syringe shields, and other small items. This cabinet is completely shielded on all six sides with 0.25" lead, and can stand alone or be grouped with other cabinets.

All cabinets in this product line are built to the industry standard height of 36.5". All units include a stainless steel countertop incorporating a 0.5" lip and 4" backsplash. When ordering multiple units for grouped configuration, a unified countertop may be ordered to provide a continuous work surface.



Cabinet drawing dimensions can be accessed at www.biodex.com.

SPECIFICATIONS:
Dimensions: 36.5" w x 24.75" depth x 36.5" h (93 x 63 x 93 cm)
Lead Shielding: .25" thick (.64 cm)
Finish: Powder coat
Doors: Key-locked
Countertop: Stainless steel with 4" backsplash and .5" spillproof lip
Weight Capacity: 1550 lb (703 kg)
Weight: 1240 lb (562 kg)

- *Designed for PET hot labs with limited space*
- *Accommodates:*
  - *Compact L-Block Shield with Built-in Dose Calibrator Shield*
  - *PET Sharps Container Shield*
  - *Lead Brick Cave*
  - *Atomlab 100 Dose Calibrator*
- *Sliding shelves for:*
  - *PET shipping containers*
  - *Small items*
- *Lead shielded on all six sides*
- *Key-locked doors*

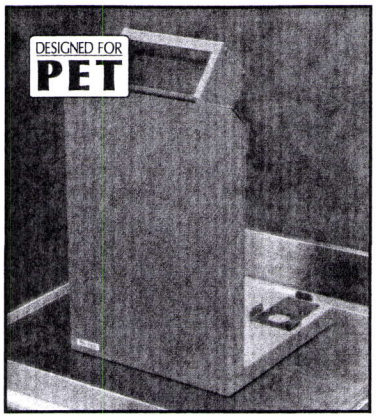
244-200 Cabinet, PET, Unit Dose, .25" lead **$11,220.00**
Does not accommodate Lead Brick Cave
244-205 Cabinet, PET, Unit Dose, .25" lead **11,220.00**
Accommodates Lead Brick Cave 042-434

Related:
042-433 L-Block Shield, Compact, 1.5" lead **$5,795.00**
With built-in Dose Calibrator Shield
042-434 Lead Brick Cave, 3-wall, 2" lead.....**2,550.00**
Fits 042-433 L-Block Shield
042-435 Lead Brick Cave Cover **300.00**
Fits 042-434 Lead Brick Cave
086-250 Dose Calibrator, Atomlab 100,
115 VAC, RS-232 port.....**5,600.00**
Includes: Vial/Syringe Dipper and Well Insert
039-412 Sharps Container Shield, PET, 1" lead **1,300.00**
Uses one 039-413 Sharps Container
039-413 Sharps Container, 3.2 qt., 30/pkg **$175.00**
Fits 039-412

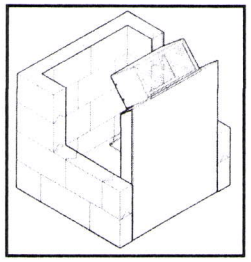
CIRCLED ITEMS ARE ON HAND

L-BLOCK SHIELDS

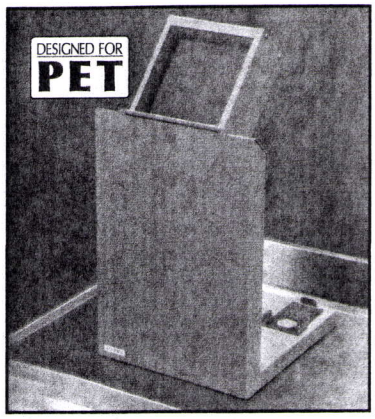
For handling unit doses of high-energy radionuclides

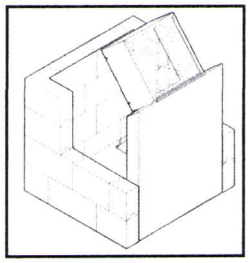


Easy Assembly – no component weighs more than 50 pounds.



042-428 L-Block Shield





042-419 L-Block Shield

- ***Lead shielding:***
  1.5" thickness in front
  1" thickness in base
- ***Lead glass window choices:***
  8" x 4" x 4"
  8" x 8" x 4"
- ***Installs easily***
- ***Optional Lead Brick Cave for complete lateral shielding***

Designed for receiving and preparing unit doses of high-energy radionuclides, these L-Blocks provide 1.5-inch thick lead shielding in front, and 1-inch thick lead in the base. The L-Block may be ordered with either an 8" x 4" x 4" or 8" x 8" x 4" lead glass window. A special plate with a hex-shaped recess is mounted on the base to facilitate one-handed loading and unloading of dose pigs incorporating hex-shaped bottoms. The optional Lead Brick Cave (042-425) may be added to provide lateral shielding around the full perimeter of the L-Block's base. These L-Blocks are shipped in modular form for easy installation without lifting equipment. No component weighs more than 50 pounds. After placing the base frame in its location, pre-cut lead sheets are loaded into the horizontal and vertical portions of the steel frame. The window module is mounted, and assembly is completed by securing window unit and steel end cap with four Phillips head screws. A Phillips screwdriver is the only tool needed. Assembly instructions are provided.

SPECIFICATIONS:

042-428 L-Block Shield (8" x 4" x 4" window)
Dimensions: 14" w x 15" d x 21.6" h (36 x 38 x 55 cm)
Lead Shielding:
Front: 1.5" (3.8 cm) thick
Base: 1" (2.5 cm) thick
Lead Glass Window:
Dimensions: 8" w x 4" h x 4" thick (20 x 10 x 10 cm)
Density: 5.2 g/cm³
Finish: Powder coat
Weight: 270 lb (122 kg)
Shipping Weight: 330 lb (149.6 kg)

042-419 L-Block Shield (8" x 8" x 4" window)
Dimensions: 14" w x 15" d x 24.7" h (36 x 38 x 62 cm)
Lead Shielding:
Front: 1.5" (3.8 cm) thick
Base: 1" (2.5 cm) thick
Lead Glass Window:
Dimensions: 8" w x 8" h x 4" thick (20 x 20 x 10 cm)
Density: 5.2 g/cm³
Finish: Powder coat
Weight: 290 lb (131 kg)
Shipping Weight: 355 lb (161 kg)

042-425 Interlocking Lead Brick Cave
Dimensions:
I.D.: 14" w x 15" depth x 16" h (35 x 38.1 x 40.6 cm)
Lead Shielding: 2" thick (6 cm)
Finish: Paint
Weight: 492 lb (223 kg)
Detailed specifications on page 41

042-426 Interlocking Lead Brick Cave
Dimensions:
I.D.: 14" w x 17.8" depth x 13.8" h (35.5 x 45.3 x 34.6 cm)
Lead Shielding: 2" thick (5 cm)
Finish: Paint
Weight: 532 lb (241 kg)

042-407 Steel Table
Dimensions: 36.75" w x 24" depth x 36" h (93.5 x 61 x 91.5 cm)
Shipping Weight: 195 lb (88 kg)
Detailed specifications on page 41

042-428 L-Block Shield, 1.5" lead $2,995.00
With 8" x 4" x 4" lead glass window
042-419 L-Block Shield, 1.5" lead 3,650.00
With 8" x 8" x 4" lead glass window

Related:
042-425 Lead Brick Cave, 3-wall, 2" lead.....$2,695.00
Fits 042-428 and 042-419 L-Block Shields
042-426 Lead Brick Cave, 3-wall, 2" lead.....3,295.00
Fits 042-428 and 042-419 L-Block Shields
Accommodates 042-466 PET Dose Drawing System
042-407 Table, Steel.....1,295.00

Biodex L-Block Shields incorporate a hex-shaped plate to facilitate one-handed loading and unloading of Biodex PET Pigs.

To order, call Biodex toll free...
1-800-224-6339
Int'l 631-924-9000 • www.biodex.com

CIRCLED ITEMS ARE ON HAND

Attachment 10.2

THML PET Imaging Center - Daily Radiation Survey Record

Month:_____, 20___ Survey Instrument:_____ Cal Date:_____

DATE	MONITORING LOCATIONS (reported in mR/hr)													TECH INIT.
	A Inj. Chair	B Inj. Floor	C Unused	D Hot Lab	E H. Lab Floor	F H. Lab Lblock	G PET Scan	H Pt. Waitng	I Rest Room	J Hall Sink	K Contrl Room	L Hall way	Bkgrnd	
TRIGGER →	**0.05**	**0.05**		**1.20**	**1.20**	**0.50**	**1.00**	**0.05**	**0.05**	**0.05**	**0.05**	**0.05**	**mR/hr**	
1														
2														
3														
4														
5														
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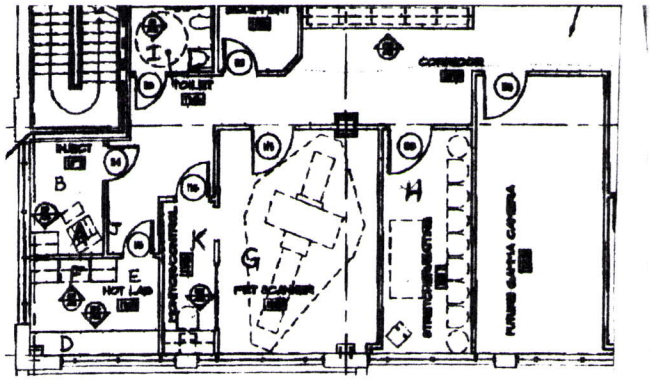
Note: Notify manager and RSO if any trigger levels are exceed.

Monthly Review by the RSO:

_____

Date:_____



DAT 11/04

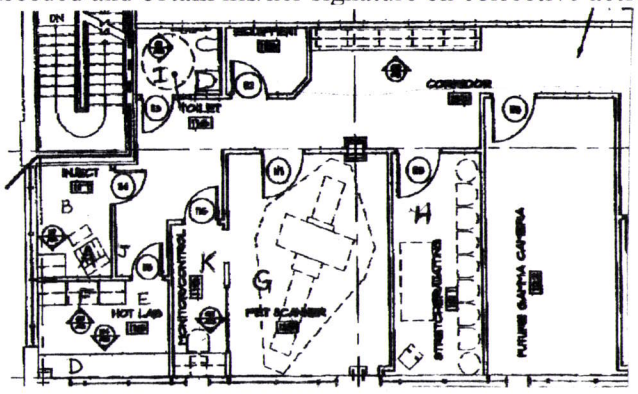
THML PET IMAGING CENTER WEEKLY WIPE TEST RECORD

Date	Bkgrnd Count	Tech.	A. Patient Injection Chair	B. Injection room Floor	C. Unused	D. Hot Lab	E. Hot Lab Floor	F. Hot Lab Counter L-Block	G. PET Scan Room Floor	H. Patient Waiting Floor	I. Rest Room & Floor	J. Hall Sink	K. PET Control Room	L. Dept. Corridor	Survey Meter Battery Check

Notes: 1. **Trigger Levels**: If the wipe indicates contamination levels >200 dpm, decontaminate area until subsequent wipes indicate <200 dpm. Record contamination levels and corrective actions. **Notify the RSR immediately** when trigger levels are exceeded and obtain his/her signature on corrective actions report.

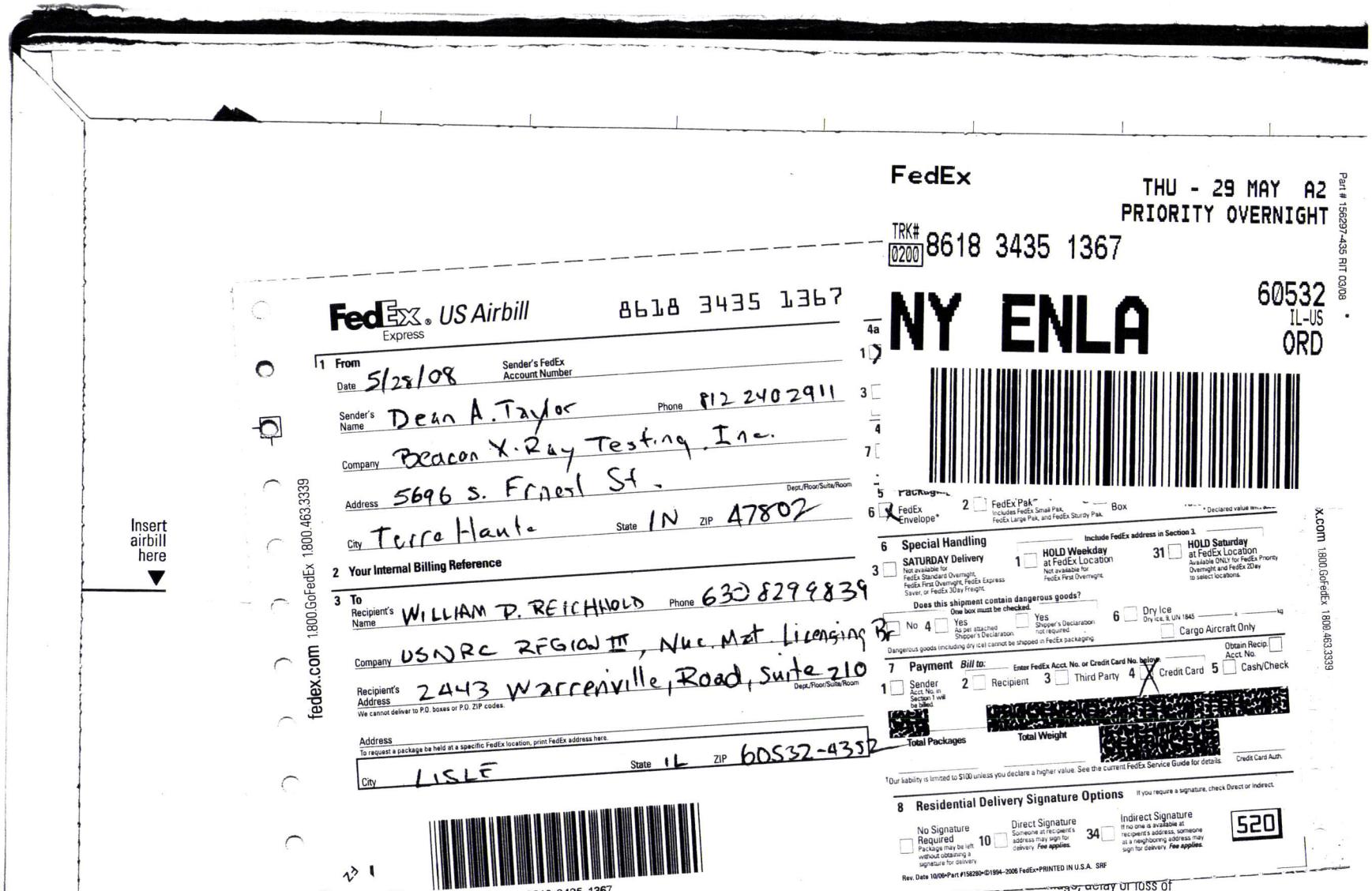
2. **Instrument used**: Capintec CAPRAC Well Counter, Serial Number:_____

RSO Review:_____ Date:_____



DAT 09/04

Attachment 10.2



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Total Packages Total Weight Credit Card Auth.

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