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REGION 1

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Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Rd.
King of Prussia, PA 19406-1415

November 15, 2004

Dear Sir or Madam,

Enclosed please find two copies of our application for Material License renewal. If you have any questions, please call me at 804-254-8421.

Best regards,

Richard L. Tacey
Radiation Safety Officer

45-25314-01
03033656
X

NRC FORM 313

(4-2004)

10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 10/31/2005

Estimated burden per response to comply with this mandatory collection request: 7 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 F52), 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 MATERIAL 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, MISSISSIPPI, 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, 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
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

03033656
X

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 45-25314-01

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

PPD, Inc.
2240 Dabney Road
Richmond, VA 23230

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

2240 Dabney Road
Richmond, VA 23230

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Mr. Richard L. Tacey

TELEPHONE NUMBER

(804) 359-1900

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

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

Robert Nicholson, Vice President Bio-Analytical Labs, PPD, Inc.

SIGNATURE



DATE

15 Nov 2004

FOR NRC USE ONLY

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

135991

Attachments to cover sheet for renewal of license No. 45-25314-01

All the following information is detailed as per Appendix C, "Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313" as published in NUREG – 1556, Volume 7.

ITEM No. 5

Radioactive Material

By Product Element	Chemical Form	Maximum amount that licensee may possess at any one time under this license
Hydrogen – 3 (Tritium)	Liquid (bound)	3.7 GBq (100 milliCuries)
Iodine – 125	Liquid (bound)	740 MBq (20 milliCuries)
Carbon – 14	Liquid	370 MBq (10 milliCuries)

A review of Appendix G of NUREG – 1556, Volume 7 indicates no financial assurance obligation for this facility.

ITEM No. 6

Purpose for which Licensed Material will be used

All isotopes are employed individually in a variety of immunoassay protocols at this facility. All processes are conducted 'invitro'. Examples of written protocols can be provided if necessary.

ITEM No. 7

Individuals responsible for Radiation Safety Program

RSO

Richard L. Tacey, Director of Immunochemistry
Training and Experience:

Type*of Training	Where Trained	Length of Training	On the Job	Formal
A,B,C,D	Lowell Univ.	2 weeks, June 1978	No	Yes
A,B,C	American Univ.	4 months, 1974	No	Yes
A	Hazleton Labs. America, Inc.	18 years, 1973-81 & 1984-94	Yes	No
A	Boston Univ.	2 years, 1971-73	Yes	No

*Type definition:

- A. Principles and Practices of Radiation Protection
- B. Radioactivity Measurement Standardization, Monitoring Techniques and Instruments
- C. Mathematics and Calculations Basic to Use & Measurement of Radioactivity
- D. Biological Effects of Radiation

In July 1994 Mr. Tacey joined PPD, Inc. (formerly Pharmaco LSR) in Richmond, Virginia and established the Immunoassay Chemistry Group. It was at that time the initial application for an NRC Materials License was requested and granted by the Regulatory Agency. Mr. Tacey is currently the Director of Immunoassay Chemistry at PPD, Inc.

Authorized Users (AUs)

Warren Harman, Manager – Research and Development

“Jake” Harman manages the R&D group for PPD’s immunochemistry department where he oversees the development and implementation of analytical methodologies. He ensures that the staff is compliant with contractual, regulatory, and company guidelines as well as radiation safety procedures. Jake serves as Richard Tacey’s back-up for the position of Radiation Safety Officer at PPD, Richmond, Virginia. Mr. Harman attended the University of Florida, and holds a B.S. degree in Neuroscience-Biochemistry, awarded in May of 1986. His work experience includes, quantitative RIA using both tritium (10 milli-Curies) and iodine-125 (5.0milli-Curies).

Authorized Users (AUs) Continued

Jim Gorman, Manager – Sample Analysis

Since 1984 Jim Gorman has worked in private, government, and university laboratories that have used radioisotopes. Over this period of time, he has been trained on the use of numerous isotopes. Currently he oversees the sample analysis group within the Immunochemistry Department at PPD. Mr. Gorman received a B.A. in Biology and English from Cornell University, Ithaca, New York in 1982. Mr. Gorman participates in the annual radiation safety training provided to all users at PPD, Inc. His background in isotope usage includes the isotopes Iodine-125, Hydrogen-3 and Carbon-14

Kristen Hallwachs, Associate Group Leader

Kristen Hallwachs has a B.S. degree from William and Mary and has been working with radioactive isotopes in a laboratory setting since 1992. Kristen has received isotope user and radiation safety training yearly since 1995. Kristen has an extensive experience with the iodinated tracers and tritiated tracers in radioimmunoassay protocols.

Chris Wilson, Research Scientist

Christopher Wilson has been employed in the Immunochemistry department since 1995 and is responsible for the development and validation of more than thirty radioimmunoassay methods. Mr. Wilson received a B.S. degree in Genetics at the University of Liverpool, UK in 1986. He has worked with all radioactive materials that are part of the PPD's Materials License. He has received radiation safety training annually.

Item No. 8

Training for Individuals Working in areas of Isotope Usage

All personnel assigned to the Immunoassay Chemistry Department have been instructed in basic radiation safety. Annual training is provided to the entire staff. During this training an effort is made to address new regulatory changes that would impact this particular licensee.

New members of staff are instructed in the very basics of radiation safety, this training covers about four hours and is usually provided by an outside resource. Internal instruction covers written procedures for specific analysis to be performed, these are practiced prior to use with any radiochemicals. Such a rehearsal will preclude unforeseen

Item No. 8 Continued

situations that could lead to a radiochemical spill that otherwise could have been avoided. All individuals on staff have prior experience with good laboratory practices relative to isotope applications. Training is provided by an outside consultant who has an extensive background in radiation protection issues and management of Materials License as issued by the Nuclear Regulatory Commission. Details of qualifications and prior experience are available if necessary.

An outline of the most recent annual training provided to all staff members follows:

1. Nuclear Regulatory Commission Materials License
 - a. Isotopes of Use
 - b. Conditions of License
2. General Laboratory Safety
 - a. "The Key to Contamination Control" 25 minute tape
 - b. Discussion
3. Sources of Radiation- External and Internal
4. Units of Radioactivity
 - a. some conversions (old units of radioactivity versus new units)
 - b. units that will appear on shipping receipts – details
5. Title 10 Part 19 Overview – NRC Form 3
6. Title 10 Part 20 – Package Receipt, Surveys, Use of Film Badges/TLDs,
Posting of Laboratory, Security of Licensed Material
7. Radioactive Waste Management
 - a. mixed waste – define
 - b. 'DIS' – decay in storage, half life issue
 - c. problems with a. and b.
8. Regulatory Guides
 - a. Guide 8.13 "Instruction Concerning Prenatal Radiation Exposure"
 - b. Summary of new regulations that apply to materials license
9. Radioactive Material Spill Guidelines
10. Overview – Questions – Test!

Selected groups are provided with an abbreviated training in the above topics. For example receiving and shipping staff are instructed extensively on the Package Receipt Procedure, the details therein detail actions to be taken should a package of radiolabeled material be damaged upon arrival, etc. PPD staff, whose responsibility is to audit

Item No. 8 Continued

analyses that are governed by contract or by other regulatory agencies also receive instruction in some phases of radiation protection. These topics include actions to be taken in case of a radiochemical spill, protective clothing to be worn while in the radioimmunoassay laboratory and their general conduct while making observations so as not to interfere with the investigator. Personnel responsible for cleaning are advised of areas within the isotope applications laboratory to avoid and details as to the radioactive labeling that is visible on some of the refrigerators and cabinets.

PPD, Inc. maintains comprehensive training records for all individuals that are considered permanent members of staff.

ITEM No. 9

Facilities and Equipment

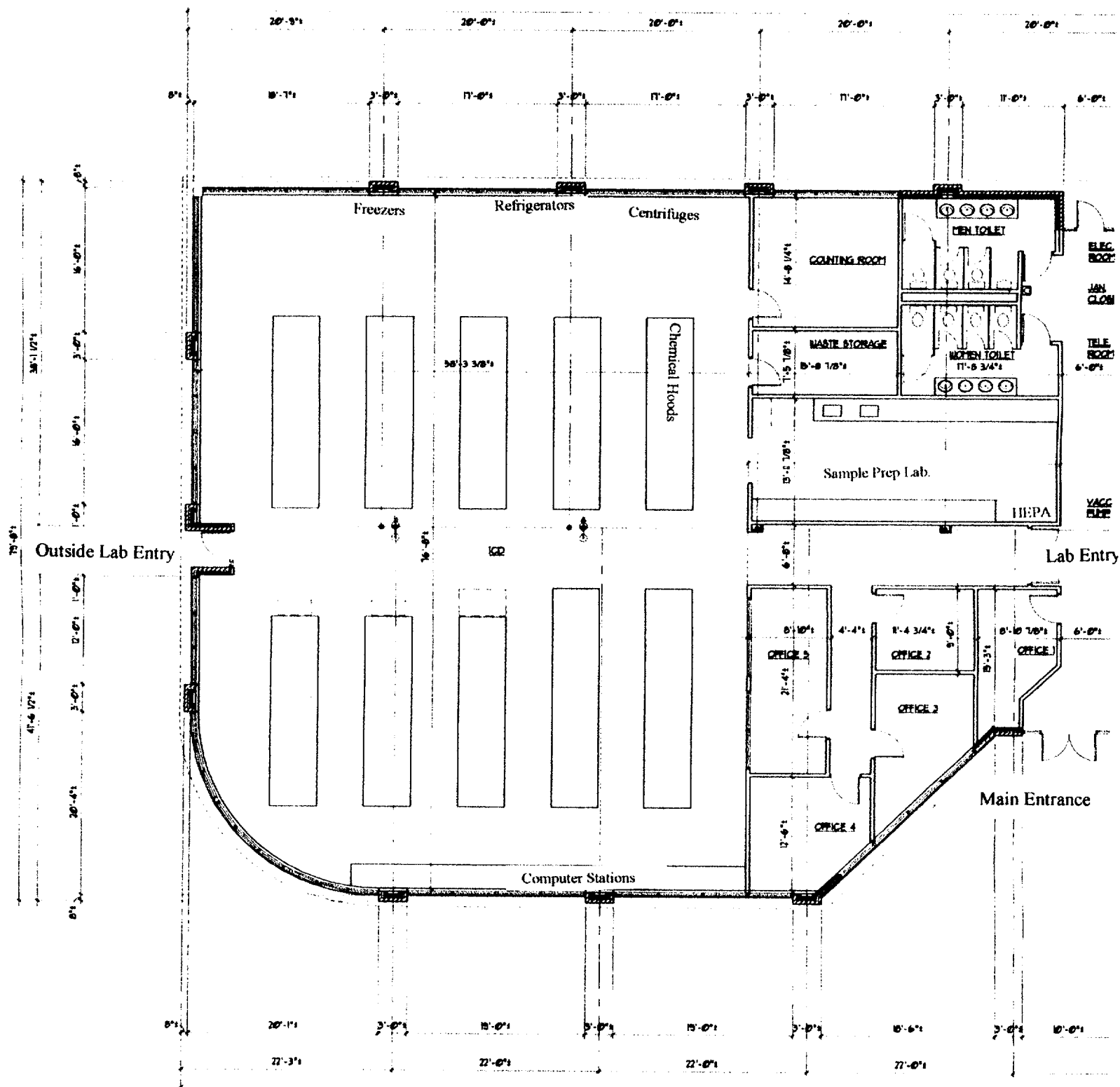
The isotopes requested in Item 5 of this application are used solely in the area drawing that is attached as Figure 1 "PPD Inc. Immunoassay Chemistry Laboratory". This lab has 3900 square feet of floor area in the main section where samples are processed. Off of the main floor are three areas, one is the counting room, one is a small room for radioactive waste storage and last a sample preparation room with a HEPA filtered hood (indicated on the attached Figure 1). The HEPA hood is checked annually and is certified by the vendor who conducts the inspection. All access points to the facility are indicated in the enclosed drawing. Entry is controlled by an electronic lock system, trade name Sonitrol, which is equipped with a sound sensing device for after hours security.

The laboratory is equipped with any number of refrigerators, freezers, and centrifuges. These are all stationed on the outside walls of the laboratory. Five of the benches that are on the side with the computer stations are all used as work stations for processing samples. Benches located on the opposite side of the facility contain high pressure liquid chromatographs (HPLCs), etc. The bench located nearest the counting room has two chemical hoods for routine chemical dilutions and preparation of solutions that require ventilation.

The laboratory is equipped with all the necessary items for the safe handling of radioactive materials. Items include: radioactive waste containers, trays of various designs, automatic pipettes with disposable tips of various sizes, disposable syringes, latex gloves, plastic backed absorbent paper, laboratory coats, and radioactive labels and placards. Due to the small levels of radioactive material used on a day to day basis, no shielding or remote handling equipment is employed. All radioactive materials that are part of inventory are kept in suitable containers in locked cabinets or freezer-refrigerators used specifically for this purpose. All radiolabeled materials are secured after normal working hours.

Figure 1

PPD Inc. Immunoassay Chemistry Laboratory



BUILDING "A" FLOOR PLAN

SCALE: 1/8" = 1'-0"

ITEM No. 10

Radiation Monitoring Instruments

1. A Tricarb 2900TR Liquid Scintillation Analyzer, Packard Instrument Manufacture, serial number 431023. This unit is employed in the assay of samples from the immunoassay protocols as well as wipe tests taken of bench tops for contamination surveys.
2. Cobra II Gamma Counter, Model 5010 Serial # 421608, Packard Instrument Manufacture, used in assay of I-125.

Both instruments are under a service maintenance agreement with Perkin Elmer, the parent company of Packard Instruments. These instruments meet the radiation monitoring specifications published in Appendix M to NUREG – 1556, Volume 7, “Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,” dated December 1999. We reserve the right to upgrade all survey instruments as necessary.

Two Eberline Model 120 survey meters (GM type) are also part of this facility’s inventory. Pan-cake probes are used to examine incoming radioactive shipments and support monthly surveys of the laboratory space. These units are returned annually to the manufacture for calibration and diagnostics.

Thermo-Eberline
Eberline Instrument Corp.
312 Miami Street
West Columbia, South Carolina 29169
(803) 822-8843 or 1-800-234-4212

Material Receipt and Accountability

Both “Radioactive Materials Package Receipt and Opening” and a “Radioactive Materials Inventory” procedure have been developed for this facility. These documents reflect current regulatory guidance. In support of the six month inventory, package receipts are generated for each radioactive item received and a corresponding use log is established for same. These documents are reconciled at the end of each six month time frame to establish the level of each isotope within the facility. All cited documentation is on file for Regulatory review. No sealed source possession is authorized under the current materials license.

ITEM No. 10 Continued

Occupational Dose

In the initial submission for a material license this facility committed to monitoring program for individuals working and frequenting the areas where isotope applications would be conducted. The program began in 1994 and was terminated in October of 1998. During this time frame no occupation dose was recorded. This extensive evaluation demonstrated that under current use levels no unmonitored individual would receive a dose in excess of 10% of the allowable limits as set forth in 10CFR Part 20. The documentation to support this finding was reviewed in the most recent NRC inspection of this facility dated December 18, 2002, (NRC INSPECTION REPORT NO. 45-25314-01/02-01, Docket No. 030-33656, Region II).

Safe Use of Radionuclides and Emergency Procedures

As part of the initial training as well as annual updates that are conducted, the safe use of radioisotopes in a laboratory setting is always a topic for review. Great emphasis is placed on the conduct of individuals in the event of a spill of radioactive material and the course of action that must be followed. ALARA considerations are a major focus of the instruction process. 'General laboratory conduct for the safe use of radioisotopes' is posted in the laboratory area.

Surveys

A detailed procedure for "Radiation Surveys" exists for this facility. Monthly radiation survey of the radioisotope use area is conducted using wipe tests over an area of 100 square centimeters. The generated wipes are counted using liquid scintillation counting techniques. Surveys of this facility meet the requirements as stated in Appendix Q to NUREG - 1556, Volume 7 dated December 1999. Documentation is maintained for Regulatory review.

Waste Management

At present this facility makes use of a radioactive waste broker for the disposal of generated waste from the radio-immunoassay program. All waste is managed as per the direction of Radiation Services Organization, Inc. located at 5204 Minnick Road, Laurel, Maryland, 20707.

Contact: Mr. David Wellner
RSO, Inc.
5204 Minnick Road
Laurel, MD 20707
301-953-2482

ITEM No.11 Continued

In support of the radioactive waste program, training has been provided to all staff personnel on the model waste procedures published in Appendix T to NUREG -1556, Volume 7, dated December 1999. 'Radioactive Waste Management' procedure is in place to define responsibilities for the segregation and processing of information necessary to the transfer of radioactive-waste to the identified broker.

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

11/15/98, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Review 45-25314-01
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

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

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

Your action has been assigned Mail Control Number 135981.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

Sincerely,
Licensing Assistance Team Leader

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

: (FOR LFMS USE)
: INFORMATION FROM LTS
: -----
:
: Program Code: 03620
: Status Code: 2
: Fee Category: 3M
: Exp. Date: 20041130
: Fee Comments: _____
: Decom Fin Assur Req'd: N
: ::::::::::::::::::::::::::::::::::::::

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: PPD DEVELOPMENT, INC.
Received Date: 20041116
Docket No: 3033656
Control No.: 135991
License No.: 45-25314-01
Action Type: Renewal

2. FEE ATTACHED

Amount: _____
Check No.: _____

3. COMMENTS

Signed M. A. Perkins
Date 11/16/04

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

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment _____
Renewal _____
License _____

3. OTHER _____

Signed _____
Date _____