TSRL inc
THERAPEUTIC SYSTEMS RESEARCH LABORATORIES

March 29, 2007

Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Materials Licensing Branch;

Attached are two sets of the renewal application forms for license 21-26771-01 held by TSRL, Inc. Included in the renewal are the following sections:

- Radioactive Material usage
- Purpose of Use
- Individual Responsible for Radiation Safety Program and Their Training Experience
- Training for Individuals Working in or frequenting Restricted Areas
- Facilities and Equipment
- Radiation Safety Program
- Waste Management
- Attachment # 1 – Training of Personnel
- Attachment # 2 – TSRL, Inc. Facility Schematics

If there are any questions regarding this renewal application please contact me, Dr. John Hilfinger, Radiation Safety Officer at TSRL, Inc. I can be reached at (734) 663-4233 ext. 225.

Sincerely,

John M. Hilfinger, PhD

RECEIVED MAR 3 0 2007

540 Avis Drive, Suite A • Ann Arbor, Michigan 48108 • 734 663-4233 tel • 734 663-3607 fax • www.tsrlinc.com

NRC FORM 313 (10-2005) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL 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, 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

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 21-26771-01

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

TSRL, Inc.
540 Avis Drive, Suite A
Ann Arbor, MI 48108

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

540 Avis Drive, Suite A
Ann Arbor, MI 48108

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

John M. Hilfinger

TELEPHONE NUMBER

(734) 663-4233

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 7C 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 CONTANED 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 C RIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURIS DICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE: John Hilfinger / Vice President

SIGNATURE

DATE: 03/29/07

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		

APPROVED BY DATE

5. RADIOACTIVE MATERIAL -

There have been no changes to the radioactive material usage from the original application.

Byproduct, Source and/or Special Nuclear Material	Chemical and/or Physical Form	Maximum Possession limit	Use
A. Hydrogen-3	Any	10 millicuries	*In vitro* studies; studies in small lab animals
B. Carbon-14	Any	10 millicuries	*In vitro* studies; studies in small lab animals
C. Sulfur - 35	Any	10 millicuries	*In vitro* studies;
D. Phosphorus - 32	Any	10 millicuries	*In vitro* studies;

6. PURPOSE OF USE

There have been no changes to the purpose of use of the radioactive material from the original application.

The purpose of use is for research and development including animal studies and *in vitro* studies. TSRL is a pharmaceutical research and development firm specializing in oral drug delivery and formulation. Our experiments with radioactive material center on determining transport of a variety of drugs in animal and *in vitro* model systems. In addition, TSRL is pursuing molecular biological research on a number of intestinal transport systems.

Animal Studies - The majority of the animal studies are intestinal perfusion or arterial perfusion studies in small rodents (rats and mice). These are acute studies, and the animals are sacrificed at the end of the procedure.

In vitro studies - The *in vitro* studies use small amounts of radioactive material as a traceable marker compound in HPLC analysis or in molecular biological analysis (gel electrophoresis, *in vitro* transport studies).

7. INDIVIDUAL RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

Dr. Hilfinger will remain as the RSO for the TSRL facility.

Dr. John Hilfinger will remain as the Radiation Safety Officer in charge of the Radiation Safety Program. Dr. Hilfinger received a BS in Chemistry from the State University of New York at Syracuse in 1977. As a part of his undergraduate training, he completed the following course work related to the theory, handling and use of radioactive material:

1. Intro to Probability and Statistics

2. Physics for Science Students I and II
3. Calculus III/IV
4. Introduction to Ordinary Differential Equations
5. Physical Chemistry (Lecture and Laboratory)
6. Quantitative Analysis (Lecture and Laboratory)
7. Instrumental Methods Analysis
8. Spectrophometric Identification of Organic Compounds
9. Nuclear and Radiation Chemistry

Dr. Hilfinger received his doctorate in Biochemistry from the University of Michigan Medical School in 1984 and worked as a postdoctoral researcher from 1985 to 1990 in Biochemistry at the University of Michigan and from 1990 to 1993 as a research investigator in Internal Medicine at the University of Michigan Medical School. In addition to completing the Radiation Safety Course offered by the University of Michigan, Dr. Hilfinger has experience with the handling of radioactive material in his graduate and postdoctoral work. This experience includes:

- extensive research laboratory usage of ^{14}C, ^{3}H, ^{32}P, and ^{35}S
- familiarity with waste handling procedures (segregation of waste, waste manifest records, record keeping) at the University of Michigan
- Completion of Radiation Safety Course at the University of Michigan.

Since 1997, Dr. Hilfinger has served as the Radiation Safety Officer at TSRL.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

There have been some personnel changes at the facility since the original material license application. The following staff members at TSRL either work in and/or frequent the restricted areas:

- Paul Kijek
- Jae Seung Kim, PhD
- Phil Kish, PhD.
- Summer LaViolette
- Stefanie Mitchell
- Andrew Palmer
- Beth Quintas
- Wei Shen
- Jai Zhang

A summary of their training is given in Attachment 1. TSRL also holds annual radiation safety classes.

9. FACILITIES AND EQUIPMENT

The TSRL facility has undergone some minor changes in its design. A description of the facility and schematic diagrams are provided.

The TSRL facility is located at 540 Avis Drive, Suite A, Ann Arbor MI 48108. A layout of the laboratory area is included in Attachment 2. The laboratory areas designated for use of radioactive material within the facility are also indicated on Attachment 2. There is approximately 3000 sq. feet of laboratory space at TSRL in 4 separate laboratories, Lab 1, Lab 2, Analytical lab, and Surgery. Each of the labs has a designated laboratory space for use of radioactive materials.

Lab 1	Radioactive materials use in this laboratory consists of low level tracer work normally associated with biological and pharmaceutical science. This room also houses the scintillation counter.
Lab 2	Radioactive materials use in this laboratory consists of low level tracer work normally associated with biological and pharmaceutical science. A biosafety cabinet for tissue culture is also located in this room.
Analytical Lab	Radioactive materials use in this laboratory consists of low level tracer work normally associated with biological and pharmaceutical science.
Surgery	A large portion of the work with radioactive materials is performed in the surgery room. The TSRL Animal Use facility is responsible for providing animal care in accordance with applicable federal and state regulations. Animal studies involving the use of radioactive material are a significant portion of radiation policy. Short-term (acute) studies represent the overwhelming majority of the type of radionuclide use in animals.

Short-term animal studies are conducted in the surgery laboratory in accordance with RSO or TSRL management approval. Less common long term animal studies involving the use of radionuclides are also conducted in the surgery laboratory and the adjacent animal housing area.

The radiation detection instrumentation present at TSRL consists of:

- 1 x Wallac Trilux 1450 Microbeta Liquid Scintillation and Luminescence Counter.
- 1 x Portable survey meter – Radiation Alert Inspector – S.E. International, Inc. The Portable radiation survey instrument is calibrated at least annually or following repairs that affect an instrument calibration. The

calibration of the instruments is contracted out to the original manufacturer or a qualified calibration /repair facility. All certificates of calibrations are maintained on file.

10.0 RADIATION SAFETY PROGRAM

There are no changes to the radiation safety program from the original license.

11.0 WASTE MANAGEMENT

There are no changes to the waste management program from the original license.

Attachment #1 – Training of Personnel at TSRL

Pages 5 through 14 contain a summary of the radiation safety training for the following TSRL, Inc. personnel

- Paul Kijek
- Jae Seung Kim, PhD
- Phil Kish, PhD.
- Summer LaViolette
- Stefanie Mitchell
- Andrew Palmer
- Beth Quintas
- Wei Shen
- Jai Zhang

RSS-101A 6/95 **STATEMENT OF RADIATION TRAINING AND EXPERIENCE**

(Please Print or Type)

Name: Kijek (LAST) Paul (FIRST) (MIDDLE) Sex: M

Job Title: Assoc. Research Scientist Birth date: 4/15/71 Work Phone: 734 663-4233 ext 245

Please complete this form to the best of your knowledge.

- Received general radiation training at Janssen Pharmaceutica (07/99)
- Received general radiation training at Caymen Chemical Company (08/00)
- Received general radiation training at TSRL, Inc. (04/06)
- Used C-14 and PEG -4000 in assaying samples at TSRL, Inc. (2003-present)

Paul V Kijek — Signature

03/28/07 — Date

RSS-101A 6/95

STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: Kim (LAST) Jae Seung (FIRST MIDDLE) Soc. Sec. #: ___ Sex: M

Job Title: Research Scientist Birthdate: 5/22/56 Work Phone: 734 663-4233 ext 247

Please complete this form to the best of your knowledge. Check the appropriate response and elaborate on "YES" answers in space provided.

YES NO HAVE YOU:

(X) ( ) Attended the University of Michigan - Radiation Safety Orientation Course required by the Nuclear Regulatory Commission (10 CFR 19.12). Attended: 1990

(X) ( ) Had formal training or college level courses in the radiological areas listed below. If yes, list course title, instructional location, and approximate date or duration in space provided.

(X) ( ) • Physics of Radiation: Seoul National University, one year class

(X) ( ) • Radiation - Physical Chemistry: Seoul National University, one year class

(X) ( ) • Statistics of Radioactivity: Seoul National University, one year class

(X) ( ) Attended seminars, conferences, or training sessions relative to radiation, radioactive material, or radiological safety: Radiation Safety Training at TSRL, Inc. 4/06

(X) ( ) Handled radioactive materials or operated radiation-producing devices (x-ray, etc.). Indicate radioisotope(s) or equipment used, activity handled (uCi or mCi), location and purpose of use: C-14(10 uCi), H-3(10 uCi) and I-125 (10 uCi) - for research(1year) - drug absorption analysis, on-the-job training at College of Pharmacy, University of Michigan,

also C-14 & H3, contract & research work at TSRL, Inc. (7 years)

Jae Seung Kim — Signature

03/28/07 — Date

RSS-101A 6/95

STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: Kish (LAST) Phillip (FIRST) Edwin (MIDDLE) Soc. Sec. #: ___ Sex: M

Job Title: Research Scientist Birthdate: 5/22/56 Work Phone: 734 663-4233 ext 247

Please complete this form to the best of your knowledge. Check the appropriate response and elaborate on "YES" answers in space provided.

YES NO HAVE YOU:

(X) ( ) Attended the University of Michigan - Radiation Safety Orientation Course required by the Nuclear Regulatory Commission (10 CFR 19.12). Date attended: 7/22/88

(X) ( ) Had formal training or college level courses in the radiological areas listed below. If yes, list course title, instructional location, and approximate date or duration in space provided.

(X) ( ) • Principles/Practices of Radiation Protection: Albany Medical College 1984, one semester class

(X) ( ) • Biological Effects of Radiation: Albany Medical College 1984, one semester class

(X) ( ) • Radioactivity Measurements, Monitoring, or Radiation Instrumentation Use: Albany Medical College 1984, one semester class

(X) ( ) • Mathematics/Calculations Basic to the Use and Measurements of Radioactivity: Albany Medical College 1984, one semester class

(X) ( ) • Atomic/Nuclear Structure, Radiochemistry, Nuclear Engineering, Nuclear Physics, etc.: Albany Medical College 1984, one semester class

( ) (X) Attended seminars, conferences, or training sessions relative to radiation, radioactive material, or radiological safety:

(X) ( ) Handled radioactive materials or operated radiation-producing devices (x-ray, etc.). Indicate radioisotope(s) or equipment used, activity handled (uCi or mCi), location and purpose of use: 3H-amino acids (10 mCi), 36-Cl (5 mCi), 86Rb (1 mCi), 22Na (0.25 mCi), for transporter uptake assays 32P (10 mCi) for protein and lipid phosphorylation, DNA probes 125I and 131I (0.5 mCi) iodinated protein binding assays

Signature 03/15/07 Date

RSS-101A 6/95

STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: LaViolette (LAST) Summer (FIRST) Camille (MIDDLE) Soc. Sec. #: ___ Sex: F

Job Title: Research Tech Birthdate: 07-19-82 Work Phone: 734 663-4233 ext 241

Please complete this form to the best of your knowledge. Check the appropriate response and elaborate on "YES" answers in space provided.

YES NO HAVE YOU:

( ) (X) Attended the Ashland University - Radiation Safety Orientation Course required by the Nuclear Regulatory Commission (10 CFR 19.12). Date attended: _____

( ) (X) Had formal training or college level courses in the radiological areas listed below. If yes, list course title, instructional location, and approximate date or duration in space provided.

( ) (X) • Principles/Practices of Radiation Protection: __

( ) (X) • Biological Effects of Radiation: ____

( ) (X) • Radioactivity Measurements, Monitoring, or Radiation Instrumentation Use: _____

( ) (X) • Mathematics/Calculations Basic to the Use and Measurements of Radioactivity: ____

( ) (X) • Atomic/Nuclear Structure, Radiochemistry, Nuclear Engineering, Nuclear Physics, etc.: _____

(X) ( ) Attended seminars, conferences, or training sessions relative to radiation, radioactive material, or radiological safety: TSRL, Inc. Radiation Safety Training

( ) (X) Handled radioactive materials or operated radiation-producing devices (x-ray, etc.). Indicate radioisotope(s) or equipment used, activity handled (uCi or mCi), location and purpose of use: _

Summer LaViolette — Signature

03-27-2007 — Date

RSS-101A 6/95

STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: Mitchell (LAST) Stefanie (FIRST) (MIDDLE) Soc. Sec. #: _____ Sex: F

Job Title: Associate Research Scientist Birthdate: 7/9/74 Work Phone: 734 663-4233 ext 243

Please complete this form to the best of your knowledge. Check the appropriate response and elaborate on "YES" answers in space provided.

YES NO HAVE YOU:

( ) (X) Had formal training or college level courses in the radiological areas listed below. If yes, list course title, instructional location, and approximate date or duration in space provided.

( ) ( ) • Principles/Practices of Radiation Protection: _____

( ) ( ) • Biological Effects of Radiation: _____

( ) ( ) • Radioactivity Measurements, Monitoring, or Radiation Instrumentation Use: _____

( ) ( ) • Mathematics/Calculations Basic to the Use and Measurements of Radioactivity: _____

( ) ( ) • Atomic/Nuclear Structure, Radiochemistry, Nuclear Engineering, Nuclear Physics, etc.: _____

(X) ( ) Attended seminars, conferences, or training sessions relative to radiation, radioactive material, or radiological safety: Radiation Safety Training Provided by TSRL, Inc. on an Annual Basis.

(X) ( ) Handled radioactive materials or operated radiation-producing devices (x-ray, etc.). Indicate radioisotope(s) or equipment used, activity handled (uCi or mCi), location and purpose of use: ^{14}C- PEG 4000 for Perfusion Studies at TSRL, Inc.

Stefanie Mitchell
Signature

03/28/07
Date

RSS-101A 6/95

STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: Palmer (LAST) Andrew (FIRST) Thomas (MIDDLE) Soc. Sec. #: ___ Sex: M

Job Title: Assistant Chemist Birthdate: 10/19/1982 Work Phone: 734 663-4233 ext 241

Please complete this form to the best of your knowledge. Check the appropriate response and elaborate on "YES" answers in space provided.

YES NO HAVE YOU:

( ) (X) Attended the Hope College Radiation Safety Orientation Course required by the Nuclear Regulatory Commission (10 CFR 19.12). Date attended: ___

(X) ( ) Had formal training or college level courses in the radiological areas listed below. If yes, list course title, instructional location, and approximate date or duration in space provided.

(X) ( ) • Principles/Practices of Radiation Protection: Hope College, 2002, one semester class

( ) (X) • Biological Effects of Radiation:

(X) ( ) • Radioactivity Measurements, Monitoring, or Radiation Instrumentation Use: Hope College 2002, one semester class

(X) ( ) • Mathematics/Calculations Basic to the Use and Measurements of Radioactivity: Hope College 2002, one semester class

(X) ( ) • Atomic/Nuclear Structure, Radiochemistry, Nuclear Engineering, Nuclear Physics, etc.: Hope College 2002-2005, four (4) one semester classes

( ) (X) Attended seminars, conferences, or training sessions relative to radiation, radioactive material, or radiological safety:

___

( ) (X) Handled radioactive materials or operated radiation-producing devices (x-ray, etc.). Indicate radioisotope(s) or equipment used, activity handled (uCi or mCi), location and purpose of use:

Signature 03/26/07 Date

RSS-101A 6/95

STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: Quintus (LAST) Elizabeth (FIRST) Susan (MIDDLE) Soc. Sec. #: 279869376 Sex: F

Job Title: _____ Birthdate: 05/17/1983 Work Phone: 734-663-4233 ext. 232

Please complete this form to the best of your knowledge. Check the appropriate response and elaborate on "YES" answers in space provided.

YES NO HAVE YOU:

( ) (X) Attended the Eastern Michigan University - Radiation Safety Orientation Course required by the Nuclear Regulatory Commission (10 CFR 19.12). Date attended: _____

( ) (X) Had formal training or college level courses in the radiological areas listed below. If yes, list course title, instructional location, and approximate date or duration in space provided.

( ) (X) • Principles/Practices of Radiation Protection

( ) (X) • Biological Effects of Radiation:

( ) (X) • Radioactivity Measurements, Monitoring, or Radiation Instrumentation Use:

( ) (X) • Mathematics/Calculations Basic to the Use and Measurements of Radioactivity:

( ) (X) • Atomic/Nuclear Structure, Radiochemistry, Nuclear Engineering, Nuclear Physics, etc.:

(X) ( ) Attended seminars, conferences, or training sessions relative to radiation, radioactive material, or radiological safety: TSRL,Inc. Radiation Safety Training

( ) (X) Handled radioactive materials or operated radiation-producing devices (x-ray, etc.). Indicate radioisotope(s) or equipment used, activity handled (uCi or mCi), location and purpose of use:

_____

_____ 03/27/07

Signature Date

RSS-101A 6/95

STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: Shen (LAST) Wei (FIRST) Soc. Sec. #: 354883590 Sex: M

Job Title: Research Scientist Birthdate: 03/07/70
Work Phone: 734 663-4233 ext 238

Please complete this form to the best of your knowledge. Check the appropriate response and elaborate on "YES" answers in space provided.

YES NO HAVE YOU:

( ) (X) Attended the University of Michigan - Radiation Safety Orientation Course required by the Nuclear Regulatory Commission (10 CFR 19.12). Date attended: _____

(X) ( ) Had formal training or college level courses in the radiological areas listed below. If yes, list course title, instructional location, and approximate date or duration in space provided.

(X) ( ) • Principles/Practices of Radiation Protection: University of Memphis, 1 Semester non credit trainingclass

(X) ( ) • Biological Effects of Radiation: School of Medicine, Case West Reserve University

( ) (X) • Radioactivity Measurements, Monitoring, or Radiation Instrumentation Use:

( ) (X) • Mathematics/Calculations Basic to the Use and Measurements of Radioactivity:

( ) (X) • Atomic/Nuclear Structure, Radiochemistry, Nuclear Engineering, Nuclear Physics, etc.: Albany Medical College 1984, one semester class

(X) ( ) Attended seminars, conferences, or training sessions relative to radiation, radioactive material, or radiological safety: ACS Memphis regional Biomedical Engineering (Electron Spin Resonance) Conference

( ) (X) Handled radioactive materials or operated radiation-producing devices (x-ray, etc.). Indicate radioisotope(s) or equipment used, activity handled (uCi or mCi), location and purpose of use: _

Signature 03/15/07 Date

RSS-101A 6/95

STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: Zhang (LAST) Jie (FIRST) (MIDDLE) Soc. Sec. #: Sex: F

Job Title: Lab technician Birthdate: 08/10/77 Work Phone: 734 663-4233 ext 232

Please complete this form to the best of your knowledge. Check the appropriate response and elaborate on "YES" answers in space provided.

YES NO HAVE YOU:

( ) (X) Attended the University of Michigan - Radiation Safety Orientation Course required by the Nuclear Regulatory Commission (10 CFR 19.12).

( ) (X) Had formal training or college level courses in the radiological areas listed below. If yes, list course title, instructional location, and approximate date or duration in space provided.

(X) ( ) Attended seminars, conferences, or training sessions relative to radiation, radioactive material, or radiological safety:

Attended training relative to radiation at TSRL

(X) ( ) Handled radioactive materials or operated radiation-producing devices (x-ray, etc.). Indicate radioisotope(s) or equipment used, activity handled (uCi or mCi), location and purpose of use:

^{3}H and ^{14}C, measurement of partition coefficient of zanamivir and methotrexate, Liquid scintillation counter, TSRL

Signature 03/15/07 Date

Attachment # 2 - TSRL Facility Schematics

Figure 1. Entire Facility – page 16
Figure 2. Biopharmaceutics Lab – Page 17
Figure 3. Analytical Laboratory – Page 18
Figure 4. Laboratory 1 – Page 19
Figure 5. Laboratory 2 – Page 20

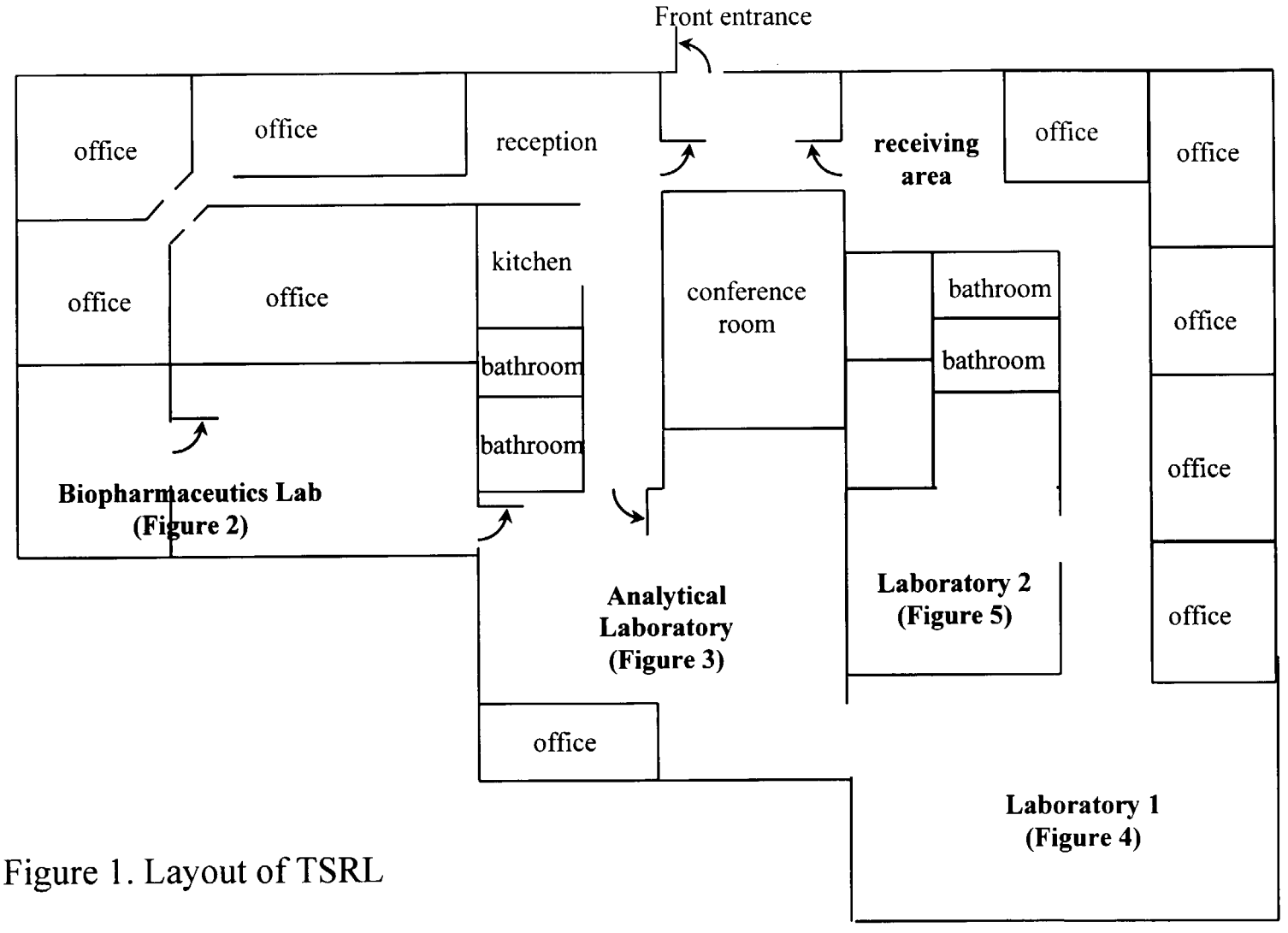

Figure 1. Layout of TSRL

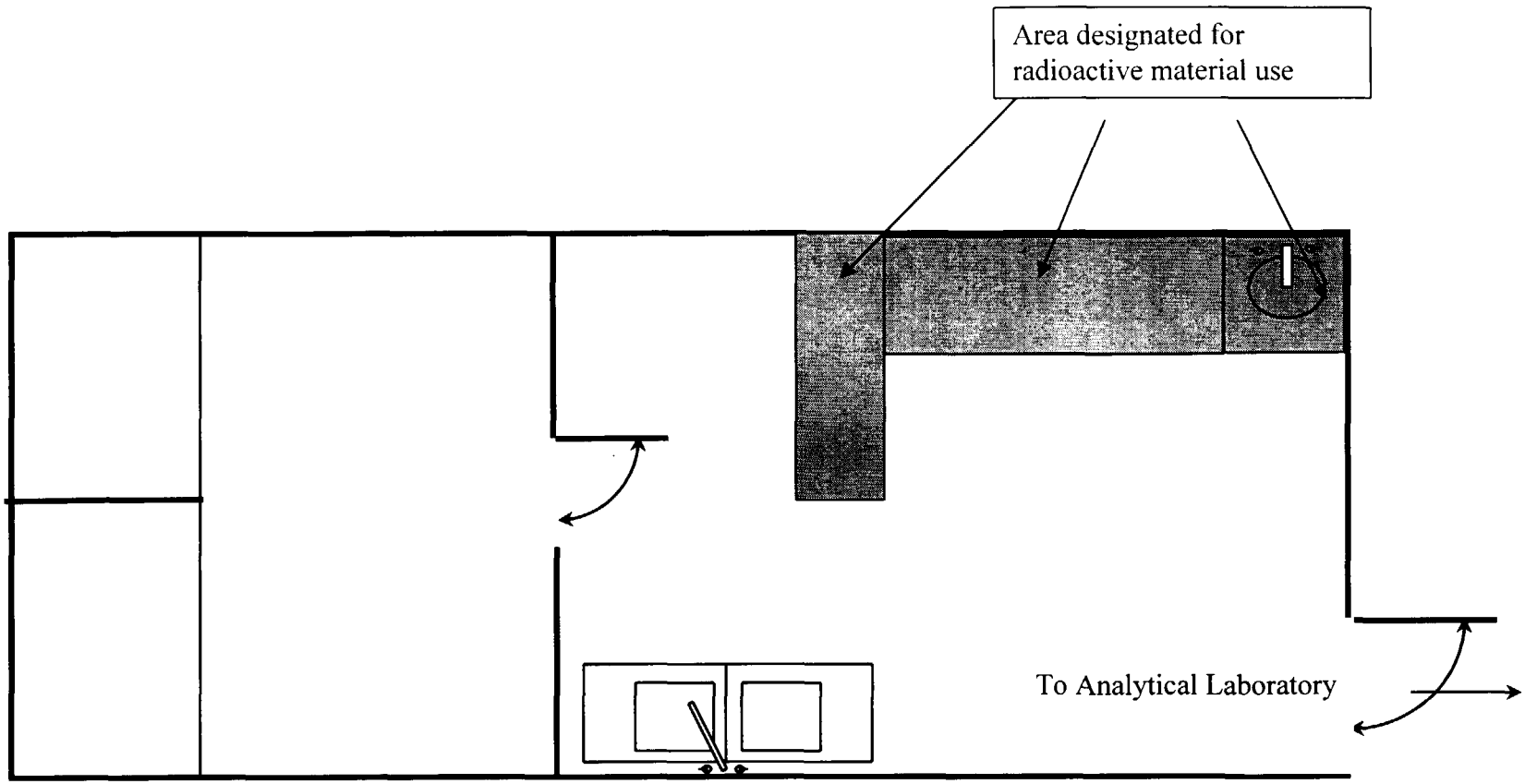

Figure 2. Biopharmaceutics Laboratory.

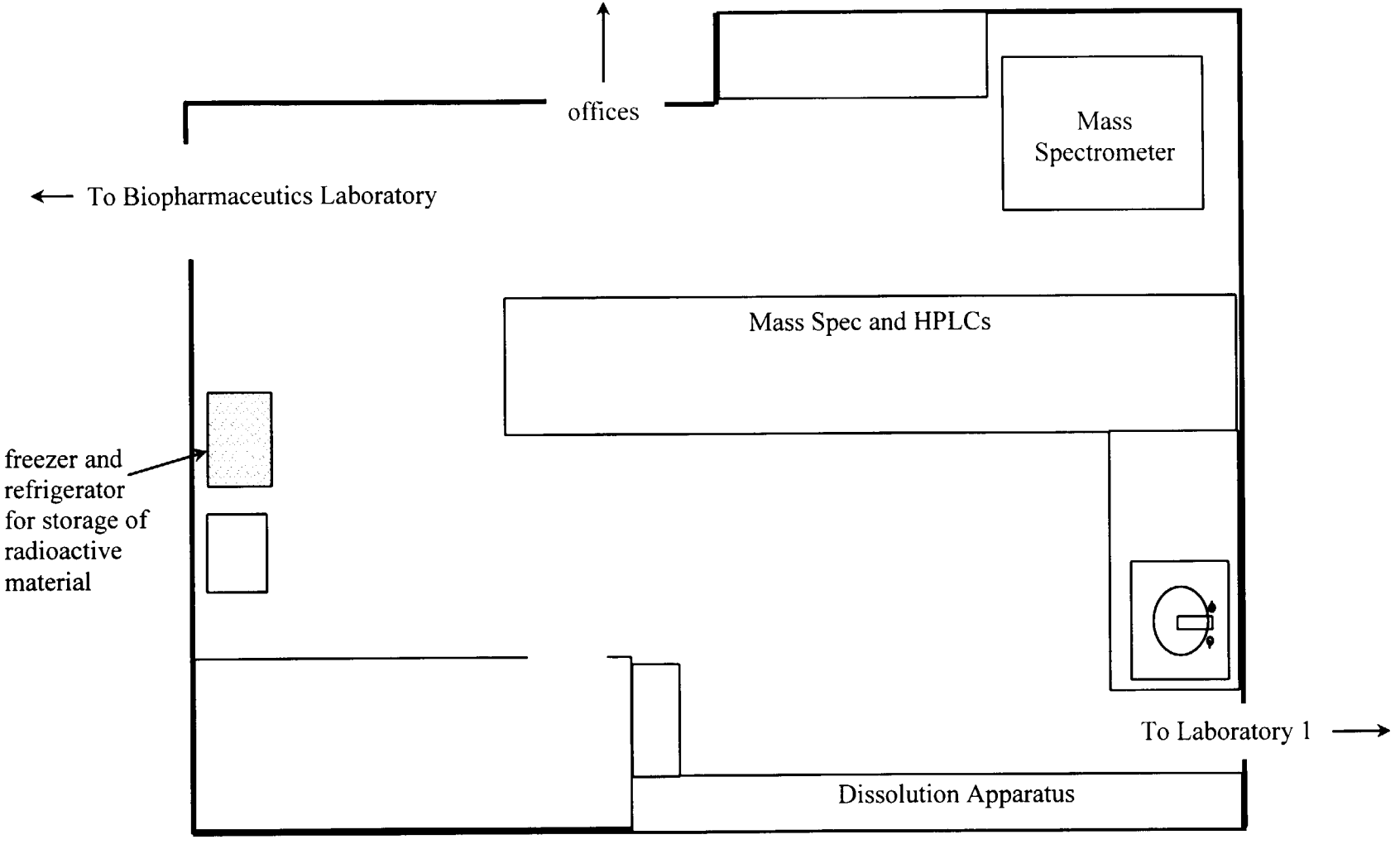

Figure 3. Schematic of the Analytical Lab

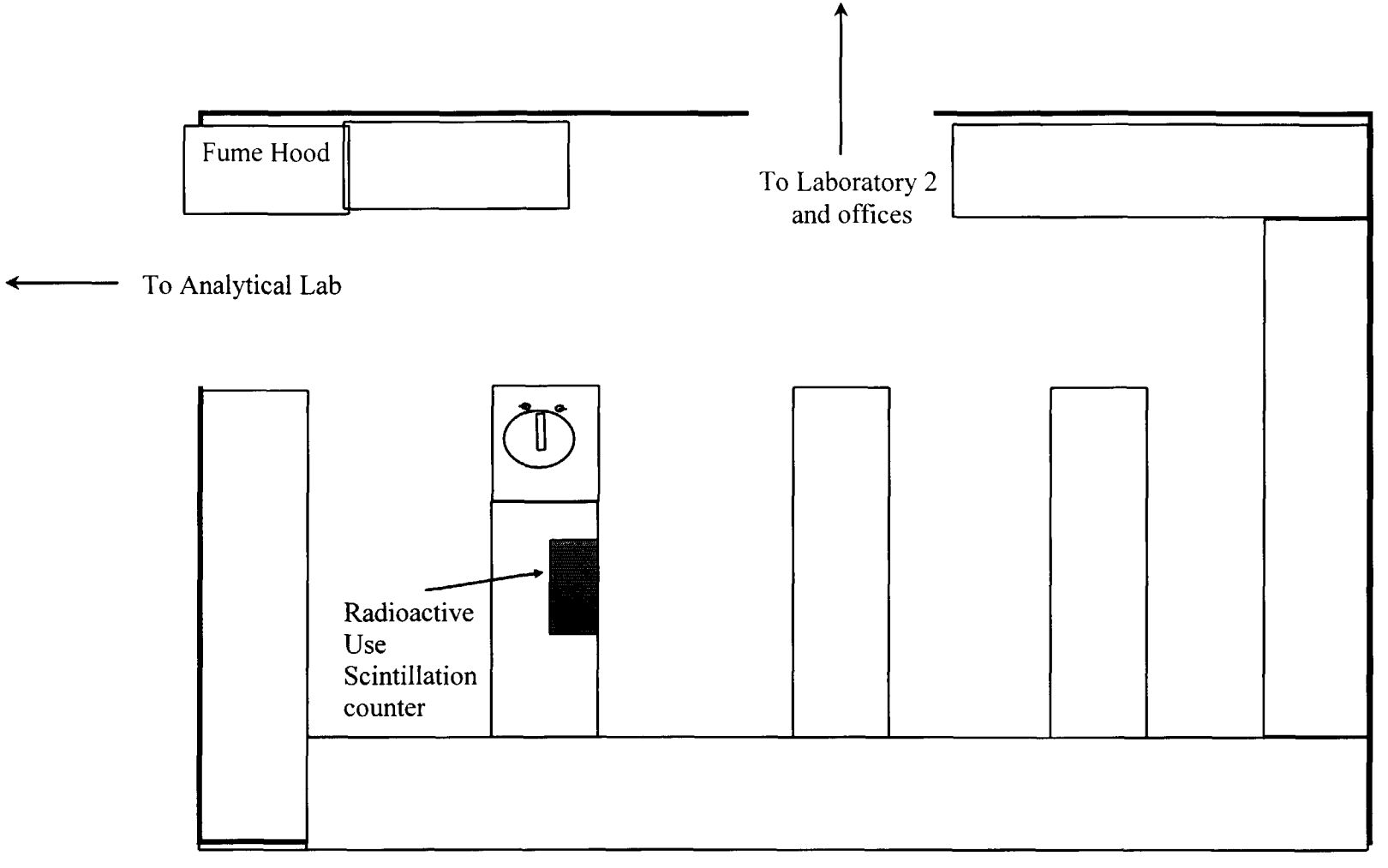

Figure 4. Schematic of Laboratory 1

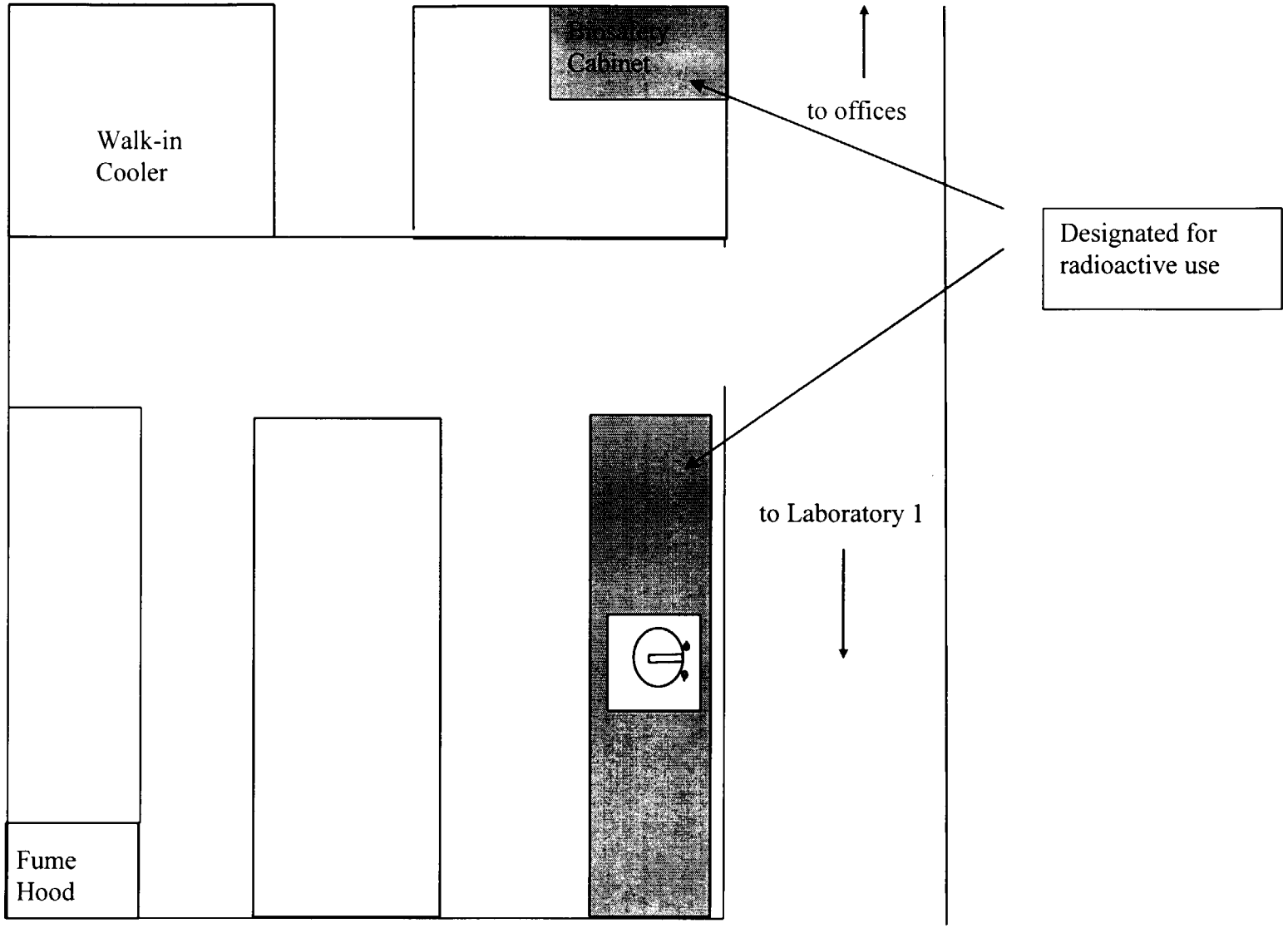

Figure 5. Schematic of Laboratory 2.

l services provided by
HL Express are subject to
HL Terms and Conditions
Carriage as published at
ww.dhl-usa.com and on
e DHL Waybill*.
HL liability shall not exceed
$100.00. Shipment Value
otection may be arranged
on request. If this shipment
volves an ultimate stop in a
untry other than the country
departure, the Warsaw
onvention may be applicable.

ubject to change without notice.

FROM

127599987

TSRL INCORPORATED
CHERYL PAYNE
540 AVIS DR STE A

ANN ARBOR MI 48108

774-617-4777

TO

2443 Warrenville Rd. Suite 310

Lisle IL 60532

Payment

Bill to:

Receiver ☐ 3rdParty ☐

☐ Paid in Advance

1 800 Call-DHL

Origin | Waybill Number 18897056146

Next Day 10:30 ▸
Next Day 12:00 ▸
Next Day 3:00 ▸

Billing Reference (will appear on invoice) 15599

# of Pkgs	Weight (LBS)	Packaging One box must be checked
1	0.5 lbs	☒ Express Envelope ☐ Express Pack ☐ Other Packaging

Special Instructions

☐ SAT ☐ HAA

☐ LAB ☐

2nd Day ▸

18897 056146

18897 056146

001 (03/04) S-11 PACKAGE LABEL

18897056146

DRAV LT SBH

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Place Waybill in this pouch or peel and stick in this area.