

TSRL, Inc.

540 Avis Drive • Suite A • Ann Arbor, MI 48108 • (734) 663-4233 • FAX (734) 663-3607

Facsimile Cover Sheet

To: James Mullauer
Company: N.R.C.
Phone:
Fax: 630-829-9873

From: John Hilfinger
TSRL, Inc
Date: July 20, 2007

**Pages including this
cover page: 31 pages**



July 20, 2007

James Mullauer
Nuclear Regulatory Commission
Fax: 630-829-9873

Dear Mr. Mullauer;

Attached is the renewal application forms and descriptions 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,

A handwritten signature in black ink, appearing to read 'John M. Hilfinger', is written over a vertical line. The signature is fluid and cursive.

John M. Hilfinger, PhD

APPENDIX C

Item No.	Suggested Response	Yes	Description Attached
5.	<p>RADIOACTIVE MATERIAL</p> <p>Unsealed and/or Sealed Sources</p> <ul style="list-style-type: none"> • For unsealed materials: <ul style="list-style-type: none"> - Provide element name with mass number, chemical and/or physical form, and maximum requested possession limit. - For potentially volatile materials (e.g., I-125, I-131, H-3), specify whether the material will be free (volatile) or bound (non-volatile) and the requested possession limit for each form. • For sealed materials: <ul style="list-style-type: none"> - Identify each Radionuclide (element name and mass number) that will be used in each source. - Provide the manufacturer's (distributor's) name and model number for each sealed source and device requested. - Confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by NRC or an Agreement State. - Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State. • Provide an Emergency Plan (if required). <p>Financial Assurance and Recordkeeping for Decommissioning</p> <p>No response is needed from most applicants. If F/A or a DFP is required, submit the required documents as described in Regulatory Guide 3.66.</p>	<p>*</p> <p>*</p> <p>N/A</p>	<p><input checked="" type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/> N/A</p>
6.	<p>PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED</p> <p>List the specific use or purpose of each radioisotope.</p>	<p>*</p>	<p><input checked="" type="checkbox"/></p>

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Item No.	Suggested Response	Yes	Description Attached
7.	<p>INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE</p> <p>RSO</p> <p>Provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience.</p> <p>AUs</p> <p>Provide the name of each proposed AU, with the types and quantities of licensed material to be used. Also provide information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials.</p>	<p>*</p> <p>*</p>	<p>☒</p> <p>☒</p>
8.	<p>TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (Occupationally Exposed Individuals and Ancillary Personnel)</p> <p>Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.</p>	<p>*</p>	<p>☒</p>

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Item No.	Suggested Response	Yes	Description Attached
9.	<p>FACILITIES AND EQUIPMENT</p> <p>Describe the facilities and equipment to be made available at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage, preparation and measurement of radioactive materials. Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted.</p>	*	☒
10.	<p>RADIATION SAFETY PROGRAM</p> <p>Audit Program</p> <p>The applicant is not required to, and should not, submit its audit program to the NRC for review during the licensing phase.</p>	N/A	N/A

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Item No.	Suggested Response	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p>Radiation Monitoring Instruments</p> <p>Describe the instrumentation that will be used to perform required surveys and state that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary."</p> <p style="text-align: center;">OR</p> <p>Describe the instrumentation that will be used to perform required surveys and state that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. Additionally, we will implement the model survey meter calibration program published in Appendix M to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary."</p> <p>Material Receipt and Accountability</p> <p>Develop and maintain procedures for ensuring material accountability,</p> <p style="text-align: center;">AND</p> <p>State that: "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license."</p>	<p style="text-align: center;">*</p> <p style="text-align: center;">*</p>	<p style="text-align: center;"><input checked="" type="checkbox"/></p> <p style="text-align: center;">[]</p> <p style="text-align: center;"><input checked="" type="checkbox"/></p>

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Item No.	Suggested Response	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p>Occupational Dose</p> <p>State that: "we have done a prospective evaluation and determined 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 Part 20," or "we will monitor individuals in accordance with the criteria in the section entitled 'Radiation Safety Program - Occupational Dose' in NUREG - 1556, Vol. 7, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Academic, Research and Development and Other Licenses of Limited Scope,'" dated December 1999."</p> <p>Public Dose</p> <p>No response is required from the applicant in a license application.</p> <p>Safe Use of Radionuclides and Emergency Procedures</p> <p>Develop and maintain procedures for safe use and emergencies. State that such procedures have been developed.</p> <p>If an emergency response plan is needed, submit it as a separate part of the application.</p>	<p>*</p> <p>N/A</p> <p>*</p> <p>[]</p>	<p><input checked="" type="checkbox"/></p> <p>N/A</p> <p><input checked="" type="checkbox"/></p> <p>[] N/A</p>

APPENDIX C

Item No.	Suggested Response	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p>Survey</p> <p>State that: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions."</p>	<p>*</p> <p>[]</p>	<p><input checked="" type="checkbox"/></p>

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Item No.	Suggested Response	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p style="text-align: center;">OR</p> <p>State that: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions. As an alternative, we will implement the model leak test program published in Appendix R to NUREG - 1556, Vol. 7, "Consolidated Guidance about Materials Licenses: 'Program-Specific Guidance About Academic, Research and Development, and Other Licensees of Limited Scope,' dated December 1999."</p> <p>Transportation</p> <p>No response is needed from applicants during the licensing phase.</p>	<p>[]</p> <p>N/A</p>	<p>N/A</p>

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Item No.	Suggested Response	Yes	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont'd)</p> <p>Minimization of Contamination</p> <p>The applicant does not need to provide a response to this item under the following condition. NRC will consider that the above criteria have been met if the applicant's responses meet the criteria in the following sections: "Radioactive Material - Unsealed and/or Sealed Sources," "Facilities and Equipment," "Radiation Safety Program - Safe use of Radioisotopes and Emergency Procedures," "Radiation Safety Program - Surveys," and "Radiation Safety Program - Waste Management."</p>	N/A	N/A
11.	<p>WASTE MANAGEMENT</p> <p>State that: "We will use the model waste procedures published in Appendix T to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999."</p> <p style="text-align: center;">OR</p> <p>"We will use the (specify either (1) Decay-In-Storage, (2) Disposal of Liquids Into Sanitary Sewerage) model waste procedures that are published in Appendix T to NUREG- 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999."</p>	<p>*</p> <p><input type="checkbox"/></p> <p><input checked="" type="checkbox"/></p>	<p><input type="checkbox"/></p> <p><input checked="" type="checkbox"/></p>

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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	Sealed or Unsealed free or bound	Use
A. Hydrogen-3	Any	10 millicuries	Unsealed / bound	<i>In vitro</i> studies; studies in small lab animals
B. Carbon-14	Any	10 millicuries	Unsealed / bound	<i>In vitro</i> studies; studies in small lab animals
C. Sulfur - 35	Any	10 millicuries	Unsealed / bound	<i>In vitro</i> studies;
D. Phosphorus - 32	Any	10 millicuries	Unsealed / bound	<i>In vitro</i> studies;

No sealed sources of material are used at TSRL, Inc.

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

RSO

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:

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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. Spectrophotometric 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 , ^3H , ^{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.

A U

Dr. Hilfinger and Dr. Phillip Kish are the Authorized Users at TSRL, Inc.

Dr. Hilfinger's qualifications are listed above.

Dr. Kish received his BS in Biology from the University of Michigan at Ann Arbor in 1978. Dr. Kish received his doctorate in Toxicology from Union University, Albany Medical College of Albany, NY in 1985.

Dr. Kish completed the following coursework related to the theory, handling and use of radioactive material, as a part of his collegiate and post-doctoral training:

1. Calculus
2. Quantitative Analysis
3. Intro. To Probability & Statistics
4. Principles/Practices of Radiation Protection
5. Biological Effects of Radiation
6. Radioactivity Measurements, Monitoring and Radiation Instrumentation Use
7. Completion of Radiation Safety Course at University of Michigan in 1988

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Dr. Kish has extensive postdoctoral research laboratory experience in radioactive material usage. This experience includes:

- 3H-amino acids (10mCi), 36-Cl (5mCi), 86Rb (1mCi)
- 22Na (0.25 mCi) for transporter uptake assays
- 32P (10mCi) for protein and lipid phosphorlation
- DNA probes
- 125I and 131I (0.5 mCi) iodinated protein binding assays

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, the instructor is the RSO (qualifications listed under #7).

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 areas and receiving 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.

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- 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.

10.0 RADIATION SAFETY PROGRAM

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

Radiation Monitoring Instruments

"We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary."

The radiation detection instrumentation present at TSRL consists of:

- 1 x Wallace 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.

Material Receipt and Accountability

TSRL - Renewal of Laboratory and industrial use of small quantities of byproduct material license - # 21-26771-01.

“Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license.”

Occupational Dose

“We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year , a radiation dose in excess of 10% of the allowable limits in 10CFR Part 20.”

Safe Use of Radionuclides and Emergency procedures

TSRL, Inc. has developed and is maintaining safe use and emergency procedures.

Survey

“We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG – 1556, Vol. 7, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,’ dated December 1999.”

11.0 WASTE MANAGEMENT

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

“We will use the Disposal of Liquids Into Sanitary Sewerage model waste procedure that is published in Appendix T to NUREG – 1556, Vol. 7, ‘Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,’ dated December 1999.”

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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

TSRL - Renewal of Laboratory and industrial use of small quantities of byproduct material license - # 21-26771-01.

RSS-101A 6/95

STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: Kim Jae Seung Soc. Sec. #: Sex: M

Job Title: Research Scientist Birthdate: 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)

Handwritten signature: Jae Seung Kim

Handwritten date: 03/28/07

Signature

Date

TSRL - Renewal of Laboratory and industrial use of small quantities of byproduct material license - # 21-26771-01.

R33-101A 6/95

STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: Kish Phillip Bdwin Soc. Sec. #: _____ Sex: M
LAST FIRST MIDDLE

Job Title: Research Scientist Birthdate: 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

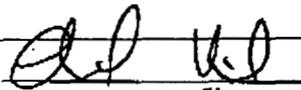
(X) () • Radioactivity Measurements, Monitoring, or Radiation Instrumentation Use: Albany Medical College 1984, one semester class

(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

TSRL - Renewal of Laboratory and industrial use of small quantities of byproduct material license - # 21-26771-01.

ASS-101A 6/95

STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: LaViolette Summer Camille Soc. Sec. #: Sex: F
Job Title: Research Tech Birthdate: 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...
() (X) Had formal training or college level courses in the radiological areas...
() (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:
() (X) Handled radioactive materials or operated radiation-producing devices (x-ray, etc.).

Signature: Summer LaViolette Date: 03-27-2007

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STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: Mitchell Stefanie A. T. Soc. Sec. #: Sex: F
LAST FIRST MIDDLE

Job Title: Associate Research Scientist Birthdate: Work Phone: 734 663-4233 ext 234

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.
(X) () Principles/Practices of Radiation Protection: North Central College, 1992-1996
(X) () Biological Effects of Radiation: North Central College 1992-1996
(X) () Radioactivity Measurements, Monitoring, or Radiation Instrumentation Use: North Central College, 1992-1996
(X) () Mathematics/Calculations Basic to the Use and Measurements of Radioactivity: North Central College, 1992-1996
(X) () Atomic/Nuclear Structure, Radiochemistry, Nuclear Engineering, Nuclear Physics, etc.: North Central College, 1992-1996
(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: Scintillation Counter for measuring H3 and C14

Handwritten signature of Stefanie Mitchell

Signature

06/05/07

Date

TSRL - Renewal of Laboratory and industrial use of small quantities of byproduct material license - # 21-26771-01.

R58-101A 6/95

STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: Palmer Andrew Thomas Soc. Sec. #: Sex: M

Job Title: Assistant Chemist Birthdate: 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: Andrew Thomas Date: 03/26/07

TSRL - Renewal of Laboratory and industrial use of small quantities of byproduct material license - # 21-26771-01.

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STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

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

Job Title: Birthdate: 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:

Signature Date 07/27/07

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RSS-101A 6/95

STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: Shen Wei Soc. Sec. #: [REDACTED] Sex: M
LAST FIRSTJob Title: Research Scientist Birthdate: [REDACTED]
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 training class
- ~~(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]
Signature

07/15/07
Date

TSRL - Renewal of Laboratory and industrial use of small quantities of byproduct material license - # 21-26771-01.

RSS-101A 695

STATEMENT OF TRAINING AND EXPERIENCE

(Please Print or Type)

Name: Zhang Jie Soc. Sec. #: Sex: F

Job Title: Lab technician Birthdate: 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:

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

Handwritten signature

Signature

03/15/07

Date

TSRL - Renewal of Laboratory and industrial use of small quantities of byproduct material license - # 21-26771-01.

Attachment # 2 - TSRL Facility Schematics

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

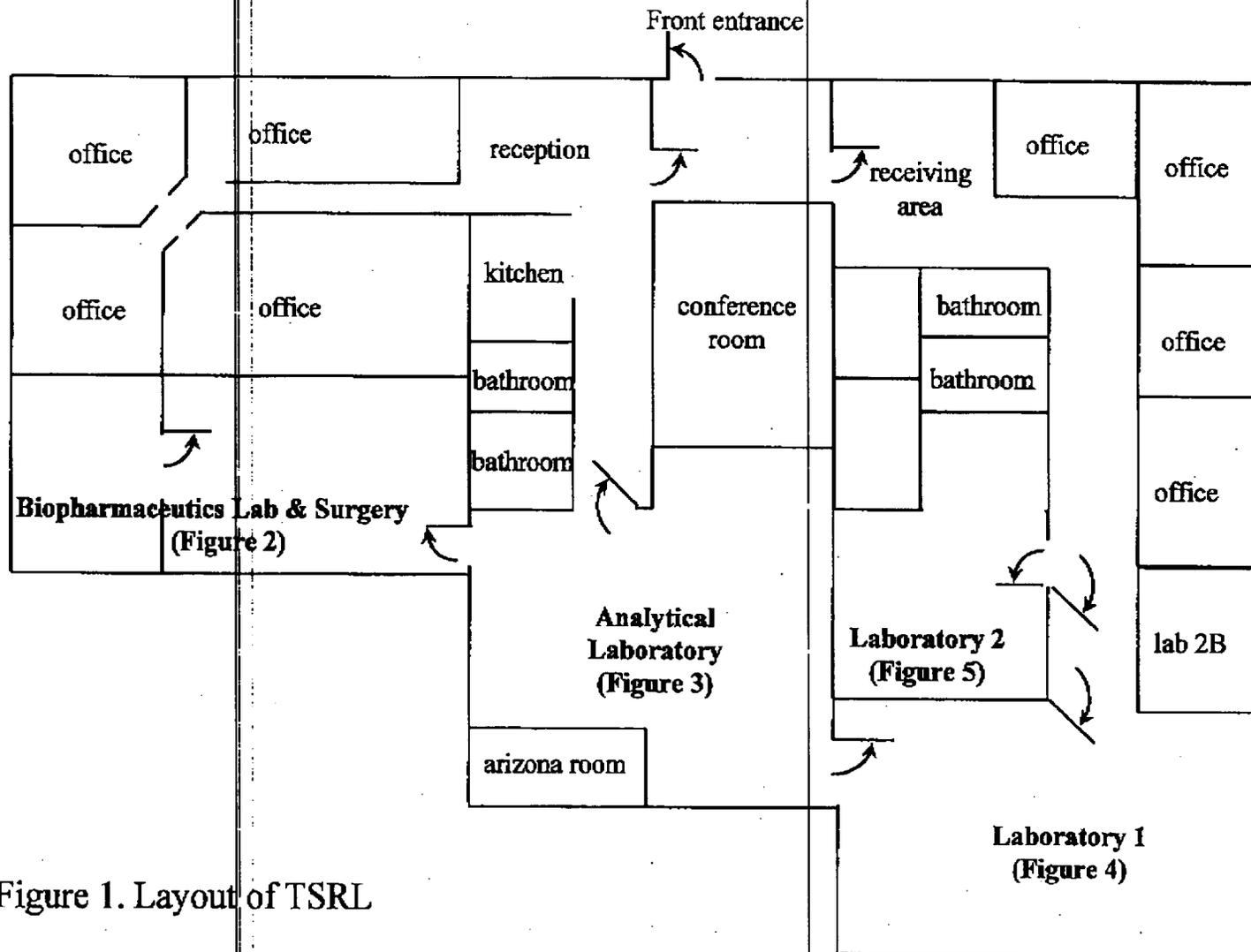


Figure 1. Layout of TSRL

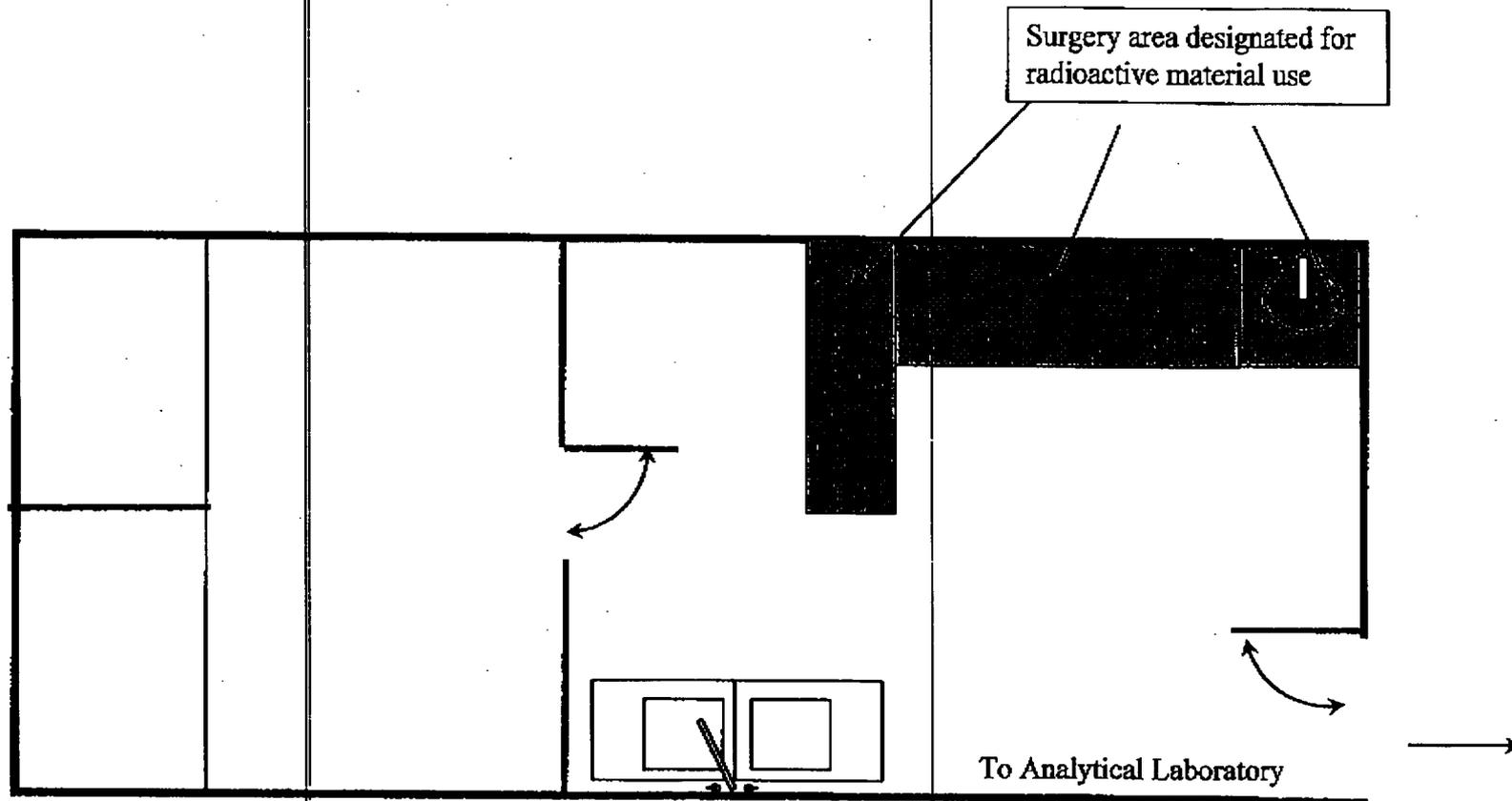


Figure 2. Biopharmaceutics Laboratory & Surgery.

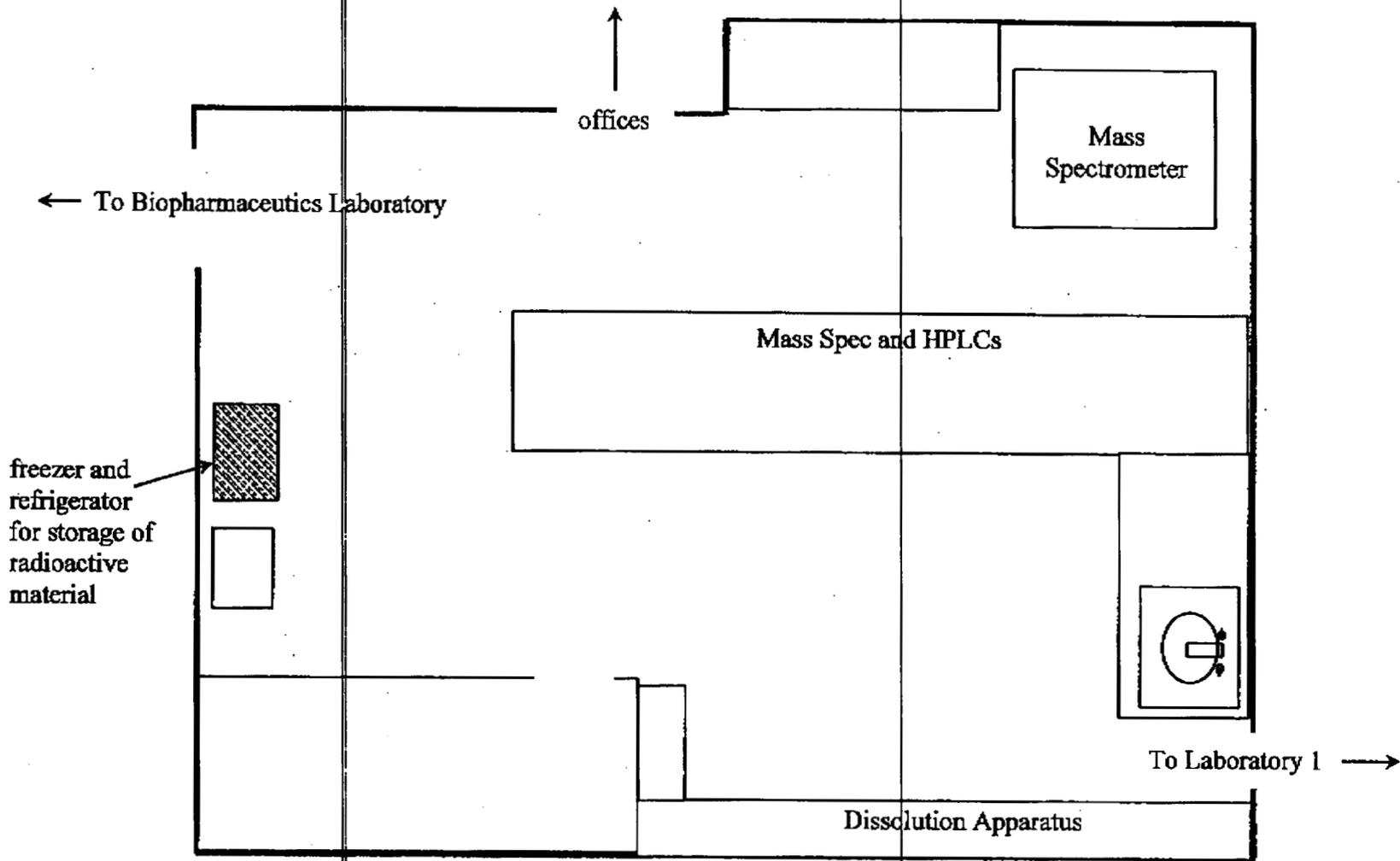


Figure 3. Schematic of the Analytical Lab

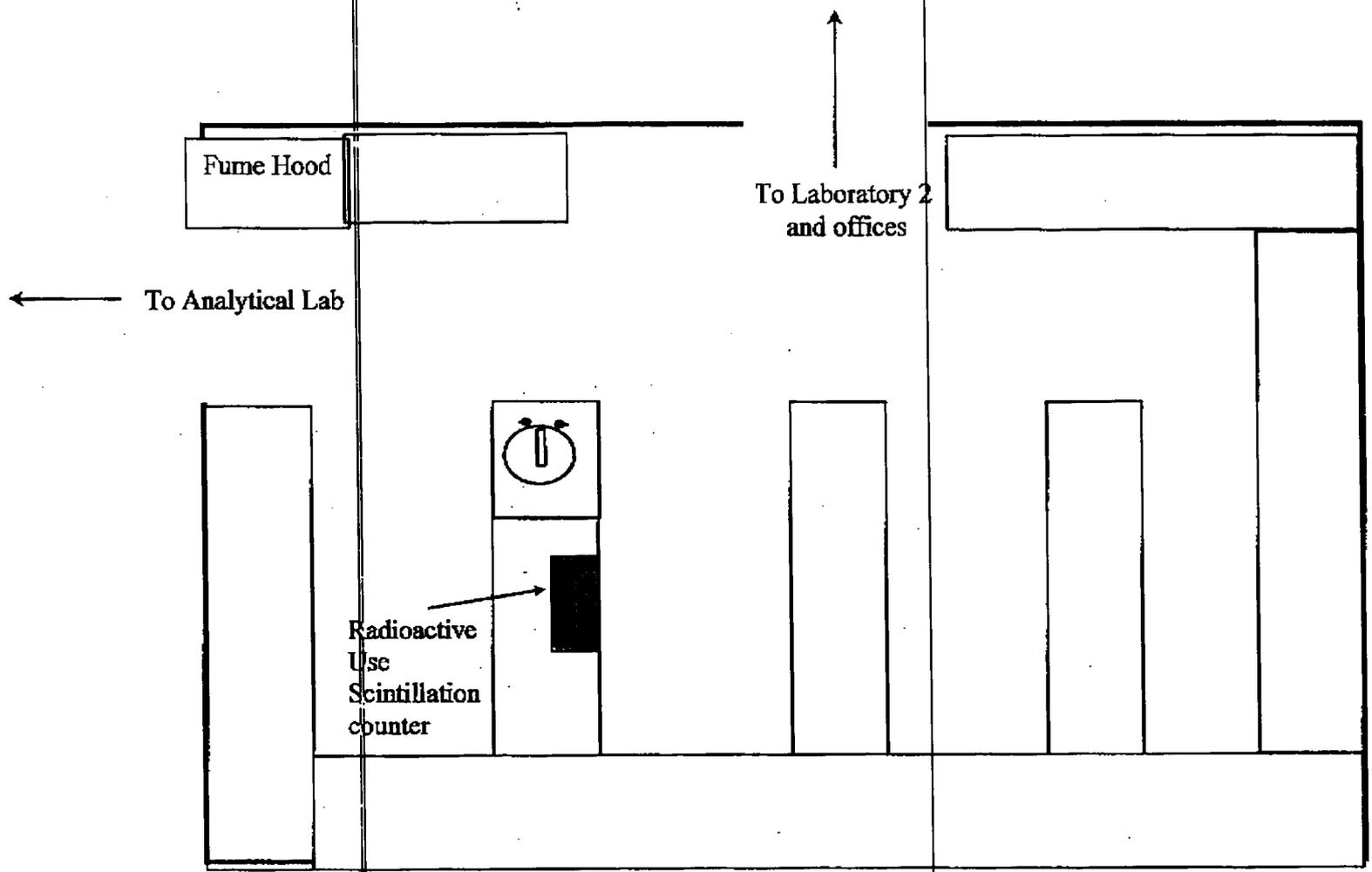


Figure 4. Schematic of Laboratory 1

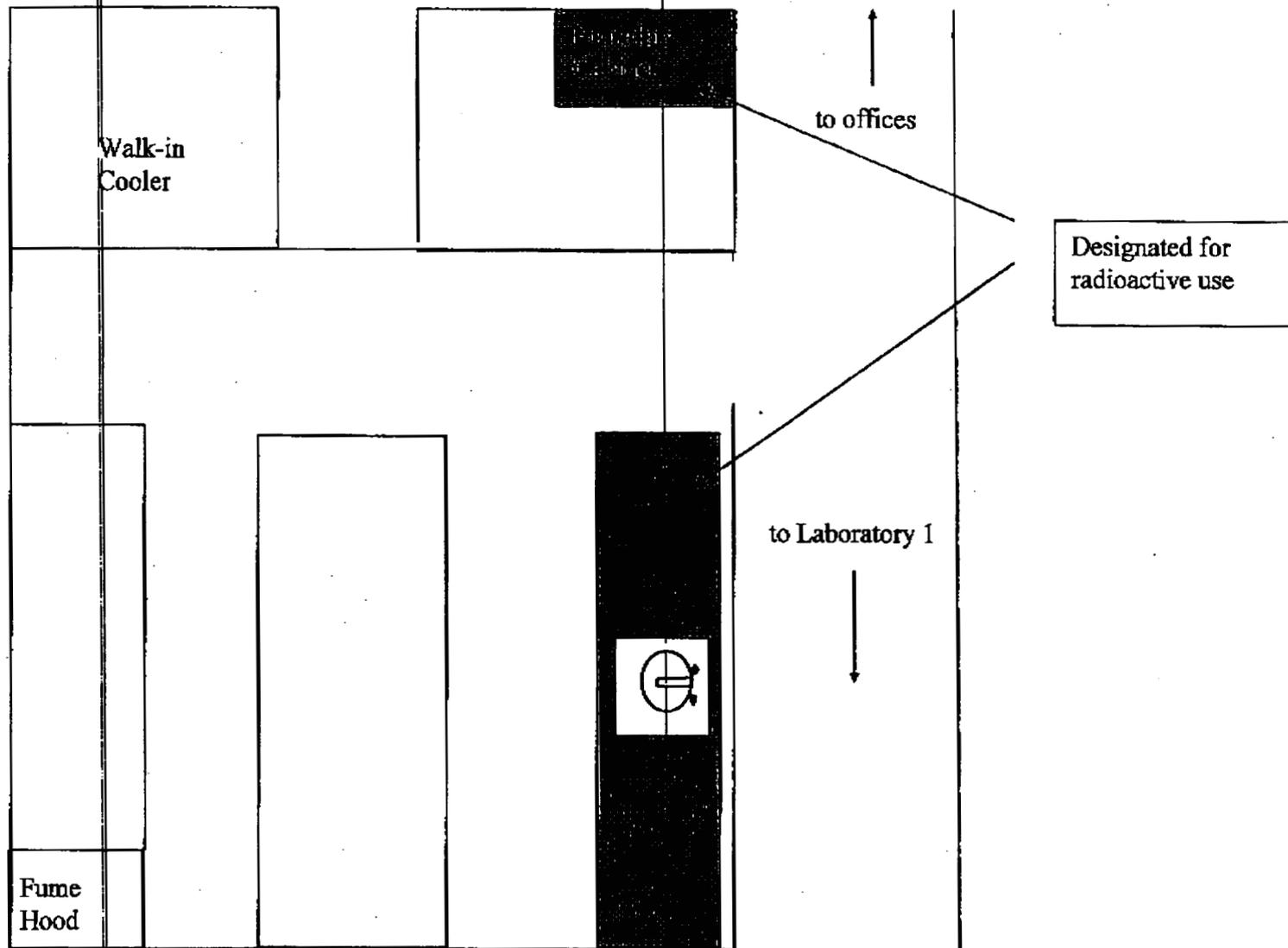


Figure 5. Schematic of Laboratory 2.